

RECORD REFERENCES & ABBREVIATIONS

Oral Arg. Tr. – Transcript of Oral Argument before the Commission

ALJ Oral Arg. Tr. – Transcript of Oral argument before the ALJ

Opin. – The Commission’s Opinion

Dissent – Commissioner Ohlhausen’s Dissent

ALJID – Initial Decision of the Administrative Law Judge

ALJFF – The Administrative Law Judge’s Findings of Fact

CCX – Complaint Counsel’s Exhibit

RX – Respondent’s Exhibit

JX – Joint Exhibit

Tr. – Transcript of Testimony before the Administrative Law Judge

Dep. – Transcript of Deposition

CCB – Complaint Counsel’s Post-Trial Brief

CCRB – Complaint Counsel’s Post-Trial Reply Brief

CCFF – Complaint Counsel’s Proposed Findings of Fact

CCRRFF – Complaint Counsel’s Reply to Respondent’s Proposed Findings of Fact

RPB – Respondent’s Pre-Trial Brief

RB – Respondent’s Post-Trial Brief

RRB – Respondent’s Reply to Complaint Counsel’s Post-Trial Brief

RFF – Respondent’s Proposed Findings of Fact

RRCCFF – Respondent’s Reply to Complaint Counsel’s Proposed Findings of Fact

“ECM Plastic” – A plastic properly manufactured through heat molding to contain ECM’s proprietary additive equally dispersed through the plastic, which additive causes plastics to biodegrade

“Biodegradable Claim” - ECM’s claim that ECM Plastic is biodegradable and/or that tests prove that ECM Plastic is biodegradable

“Rate Claim” - ECM’s claim that ECM Plastic is biodegradable in 9 months to 5 years and/or that tests prove that ECM Plastic is biodegradable in 9 months to 5 years

“One Year Rule” – Statement in the Green Guide, 16 CFR § 260.8(c), stating that “[i]t is deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal.”

“End-Use Consumer” – A member of the general public exposed to ECM claims in the marketplace

“Plastic Company Purchaser” – Those companies to which ECM solicits business, sells its product, or sold its product

TABLE OF CONTENTS

INTRODUCTION 7

STANDARD FOR GRANTING A STAY..... 10

THE STAY STANDARD IS SATISFIED ON THIS RECORD 10

 A. ECM is Likely to Succeed on Appeal..... 12

 1. ECM’s Unqualified “Biodegradable” Claim Is Protected by the First Amendment..... 13

 2. The Commission Violates ECM’s Due Process Rights by Failing to Provide ECM with
 Notice of the Charges 26

 B. Absent a Stay, ECM will Suffer Irreparable Financial and Constitutional Harm 29

 1. Absent a Stay, ECM Will Suffer Irreparable Financial Injury..... 29

 2. Absent a Stay, ECM Will Suffer Irreparable Harm to its First Amendment Rights..... 31

 C. Staying the Order Presents no Risk of Harm or Injury to Consumers and a Stay is in the
 Public Interest..... 35

CONCLUSION..... 37

TABLE OF AUTHORITIES

CASES

44 Liquormart v. Rhode Island, 517 U.S. 484 (1996) 16, 20

Am. Fed. Of Gov’t Emps., AFL-CIO, Local 3090 v. Fed. Labor Relations Auth., 777 F.2d 751
(1985) 24

Am. Meat Inst. v. U.S. Dep’t of Agriculture, 760 F.3d 18 (2014)..... 34

Ark. Dep’t of Human Servs. v. Sebelius, 818 F. Supp. 2d 107 (D.D.C. 2011) 26

Bates v. State Bar of Ariz., 433 U.S. 350 (1977) 34

Califano v. Sanders, 430 U.S. 99 (1977) 30

Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y., 447 U.S. 556 (1980)..... 16

Cinderella Career & Finishing Schools, Inc. v. F.T.C., 425 F.2d 583 (D.C. Cir. 1970) 20

Council of Alt. Political Parties v. Hooks, 121 F.3d 876 (3d Cir. 1997)..... 35

Ctr. for Individual Freedom v. Madigan, 697 F.3d 464 (2012)..... 26

Elrod v. Burns, 427 U.S. 347 (1976) 30

F.T.C. v. Church & Dwight Co., Inc., 75 F. Supp. 2d 81 (D.D.C. 2010) 28

FCC v. Fox Television Stations, 132 S.Ct.2307 (2012)..... 26

Fontroy v. Beard, 2007 WL 1810690 (E.D. Pa. June 21, 2007)..... 35

Gates & Fox Co. v. OSHRC, 790 F.2d 154 (D.C. Cir. 1986)..... 26

Gen. Elec. Co. v. U.S. EPA, 53 F.3d 1324 (D.C. Cir. 1995)..... 26, 27

Herschaft v. City of N.Y., 2002 WL 1204780 (E.D.N.Y. Feb. 15, 2002) 30

Holder v. Humanitarian Law Project, 561 U.S. 1 (2010) 26

In re R.M.J., 455 U.S. 191 (1982)..... 17

In the Matter of Jerk, LLC, 2015 WL 3413323 (F.T.C. May 6, 2015)..... 34

In the Matter of N.C. Bd. of Dental Exam’rs, 2012 WL 588756 (Feb. 10, 2012) 9, 28

In the Matter of Novartis Corp., 128 F.T.C. 233, 235 (1999) 9, 11

Morall v. Drug Enforcement Admin., 412 F.3d 165 (D.C. Cir. 2005)..... 21

N. Tex. Specialty Physicians, 141 F.T.C. 10 (2006) passim

Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999)..... 17, 34

Retail Digital Network, LLC v. Appelsmith, 945 F. Supp. 2d 1119 (C.D. Cal. 2013) 16

Standard Oil Co. v. F.T.C., 475 F. Supp. 1261 (N.D. Ind. 1979)..... 27

Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002)..... 17

Ungar v. Sarafite, 376 U.S. 575 (1964)..... 26

United States v. Chrysler Corp., 158 F.3d 1350 (D.C. Cir. 1998)..... 26

Whitaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002)..... 16, 17

Wisc. Right To Life, Inc. v. Barland, 751 F.3d 804 (7th Cir. 2014)..... 26

REGULATIONS

16 C.F.R. § 260.8(c)..... 7, 25, 27

16 C.F.R. § 3.56(c)..... 10

INTRODUCTION

On October 12, 2015, the Commission issued its Final Decision and Order (“Decision”) in the above-referenced matter. That Decision is unprecedented in at least eight material respects:

1. The FTC overruled the ALJ’s Initial Decision as it pertains to the core “biodegradability” claim, wherein the ALJ held biodegradability for plastics infused with the ECM additive substantiated by competent and reliable scientific evidence; in overruling the ALJ, the Commission failed to cite and assess key findings and conclusions in the Initial Decision, departing from those findings and conclusions without reasoned explanation.

2. For the first time in FTC history, outside of a rulemaking proceeding and in contravention of the One Year Rule set in its “Green Guides,” 16 C.F.R. § 260.8(c), the FTC determined that unqualified “biodegradable” claims could only be made if a product were proven to break down completely into elements in nature within five years after customary disposal (“Five Year Rule”) (an arbitrary cut-off for which there is no scientific means to prove attainable for any substance in light of the inherent and widely varying nature of disposal environments).

3. For the first time in FTC history, FTC based its deceptive advertising standard for a term in advertising on what it perceived an undefined percentage of consumers¹ (a “minority”) thought the term “biodegradability” meant.

4. For the first time in FTC history, FTC prohibited use of an unqualified term (“biodegradable”) in advertising unless it satisfied a definition in accord with what it perceived to be a publicly held minority view, a definition that is contrary to the scientifically accepted meaning of the term; in science, the term “biodegradability” refers to proof of intrinsic

¹ Commissioner Ohlhausen stated in Dissent that the majority of the Commission defines a “significant minority” of reasonable consumers as between 11% and 20%. *See* Dissent at 11 n. 55. The actual percentage is unstated in the Commission’s majority opinion.

biodegradability, not to proof of complete break down within an arbitrary number of years, here five. Degree and rate of break down are inherently variable from disposal locus to disposal locus due to variance in moisture, humidity, temperature, relative presence of degrading biota, etc., thus making it scientifically impossible to predict in advance of disposal any rate or period of time within which an intrinsically biodegradable thing (like a banana, an apple core, an orange, a piece of paper, a piece of wood, or an ECM additive infused plastic) will break down in nature. Consequently, because it is scientifically impossible to predict when an intrinsically biodegradable thing will break down in nature in advance of disposal, the FTC's new standard can never be satisfied and thus effectively bans the term "biodegradable," making it legally verboten).

5. For the first time in FTC history, FTC substantially relied for the creation of its new standard, the Five Year Rule, on a methodologically unsound, unreliable, and untested survey, Dr. Frederick's Google Consumer Surveys (which lacked screening questions, lacked blinding, lacked a defined survey population, and lacked any sound means to ensure reliable results, among other glaring defects).²

6. For the first time in FTC history, FTC contradicted uncontroverted expert testimony of record on general acceptance of gas evolution testing to determine intrinsic biodegradability, indeed even testimony and evidence given by the FTC's own experts, without provision of any sound scientific bases for its deviation therefrom and without any generally accepted scientific alternative to the testing rejected.

² Moreover, Google Consumer Surveys had *never* been used in any prior legal proceeding to establish consumer impression, including any state, federal, or administrative action. No credible evidence was introduced showing that such methods were generally recognized as reliable or competent to prove consumer impression in legal proceedings.

7. For the first time in FTC history, the “fencing-in” relief ordered restrained scientifically supported and truthful speech concerning biodegradability without reasoned explanation.

8. For the first time in FTC history, FTC effectively amended an industry guidance through adjudication without notice to, or comment from, the affected industry and has through this decision imposed on all industry regulatees an impracticable and scientifically invalid standard as a condition precedent for use of the unqualified term “biodegradable” in advertising.

The complexity of this case and difficult legal questions, as evidenced by the differing opinions of the ALJ, the majority of the Commission, and Commissioner Ohlhausen make a stay appropriate. *See N. Tex. Specialty Physicians*, 141 F.T.C. 10, at *2 (2006) The numerous unprecedented actions will be evaluated by the United States Court of Appeals as this matter proceeds to judicial review. Because so many material aspects of the Decision are unprecedented, it behooves the Commission to impose a stay to preserve the status quo ante while the United States Court of Appeals determines whether the novel actions comply with the First Amendment, the Federal Trade Commission Act, and the Administrative Procedure Act. As explained below, the Decision imposes a prior restraint on truthful speech in violation of constitutional limits on agency power, and it exceeds FTC statutory and procedural limits.

The unprecedented aspects of the Decision not only raise substantial constitutional, statutory, and administrative law issues, they also {

} The Final Order imposes limits on

truthful scientific speech concerning ECM's product in a manner that renders ECM incapable of representing to the public the accurate scientific record. On that same scientific record, the ALJ held that ECM's product efficacious, substantiated by "competent and reliable scientific evidence." ALJID at 284.

Nowhere in the record is there proof of a palpable risk of harm to consumer health or safety created or caused by the advertising at issue in this matter. Indeed, the ALJ found that there was no evidence of injury or harm to end-consumers, which factual finding is uncontroverted. *See* ALJID at 300–01 nn. 58–59, attached as Exh. A. The { } to ECM caused by the Decision, when balanced against the absence of provable risk to consumer health or safety, and the public's interest in judicial finality at the Circuit level, tilt the equitable balance strongly in favor of imposition of a stay of the Decision pending appeal.

STANDARD FOR GRANTING A STAY

"Pursuant to Rule 3.56(c) of the Commission's Rules of Practice, an application for a stay is evaluated on four factors: (1) the likelihood of the applicant's success on appeal; (2) whether the applicant will suffer irreparable harm if a stay is not granted; (3) the degree of injury to other parties if a stay is granted; and (4) whether the stay is in the public interest." *In the Matter of N.C. Bd. of Dental Exam'rs*, 2012 WL 588756, at *1 (F.T.C. Feb. 10, 2012) (citing 16 C.F.R. § 3.56(c)).

THE STAY STANDARD IS SATISFIED ON THIS RECORD

Under agency law, a stay is appropriately granted when the law has been applied to a complex factual record (here involving several novel elements, not least of which is a previously untested and untried Google consumer survey), which complexity and novelty could have resulted in an alternative outcome. *In the Matter of Novartis Corp.*, 128 F.T.C. 233, 235 (1999);

North Texas, 141 F.T.C. 10 at *2. Under this method of evaluating the likelihood of success on the merits, a stay is appropriate in this case.

There is an inherent conflict of interest present when the very same decision makers who have ruled against a party on the merits are asked to determine whether there is a likelihood of that party's success on appeal. Whether a just, independent assessment is ever possible in such a circumstance is open to question. Nevertheless, based solely on the law, ECM is likely to succeed on appeal based on the controlling constitutional, statutory, and administrative law here in issue because, *inter alia*, the Final Order violates ECM's First Amendment right to claim a verified fact, that its additive accelerates biodegradation of plastic products (when in fact the scientific record in this case proves that very point), and because the Commission's Five Year Rule is arbitrary, capricious, and contrary to the generally accepted scientific definition of the term "biodegradability." The Commission's position concerning the science of biodegradation and biodegradation testing is inconsistent with Complaint Counsel's own expert testimony, including an expert from the EPA who embraced the very "accelerated" gas evolution testing that so amply supported the ALJ's finding of ECM's product efficacy.

ECM will suffer irreparable harm absent a stay. The Decision limits the constitutional freedom to communicate the essential functionality of ECM's product (its ability to accelerate biodegradation of plastics), and also portends {

t

} A stay is therefore equitable and essential to maintain the status quo ante pending judicial review.

The public interest weighs in favor of a stay because the Decision violates ECM's rights under the Constitution, the FTC's enabling statute, and the Administrative Procedure Act, and because there is no evidence of record that anyone who was allegedly misled by ECM's unqualified biodegradable claim actually suffered any harm or injury. Moreover, by establishing the new Five Year Rule, the Decision has an *in terrorem* effect or chilling effect on the entire biodegradable plastics industry, inducing self-censorship and also eliminating the sale of products that are demonstrably beneficial to the environment.

A. ECM is Likely to Succeed on Appeal

“[A]rguable difficulties arising from the application of the law to a complex factual record can support a finding that a stay applicant has made a substantial showing on the merits.” *Novartis*, 128 F.T.C. at 235. A complex factual record exists where the Commission must “evaluate numerous scientific studies of consumer behavior...” *North Texas*, 141 F.T.C. 10 at *2. A respondent sufficiently shows a likelihood of success on appeal where the Commission's application of a complex factual record to the law is vulnerable to alternative reasonable applications. *Id.*; *Novartis*, 128 F.T.C. at 235. The ALJ's decision is in stark contrast to the Commission's Decision. In the realm of consumer deception adjudications, the Commission has never before so dramatically departed from an ALJ ruling on a core claim, particularly a decision as robust and well-developed with record support as the ALJ's Initial Decision in this case. The ALJ noted 1,539 findings of fact, many of which directly contradict substantial portions of the Decision, but were never addressed by the Commission (or even cited in the Decision).

1. ECM's Unqualified "Biodegradable" Claim Is Protected by the First Amendment

Based on Dr. Barlaz's testimony and statistical analyses (Barlaz being recognized as one of the foremost authorities on biodegradation in the world), the ALJ found that ECM's additive causes the underlying plastic material to biodegrade anaerobically. ALJID at 284 ("Dr. Barlaz persuasively and credibly testified that competent and reliable scientific evidence shows that plastics manufactured with the ECM Additive are anaerobically biodegradable."). Dr. Barlaz proved through his statistical analysis that ECM's product caused the underlying *plastic* to biodegrade, and not just the additive. ALJFF ¶¶ 1020, 1041–42; ALJID at 263–67 ("Dr. Barlaz explained convincingly that where the methane produced from the test vessel is not attributable to the inoculum, and not attributable to the ECM Additive, then the biodegradation must come from the plastic substrate itself."). He did so by showing that the carbon collected in the gas evolution studies (sourced from methane) far exceeded any plausible amount of carbon that could conceivably be attributable to the ECM additive alone and that which could have also come from the inoculum. ALJFF ¶¶ 1020–41. His calculations were conservative as he estimated the total amount of carbon that could conceivably be produced by the ECM additive at the weight values introduced in the finished plastics. ALJFF ¶¶ 1021–22. He still found, even at those conservative values (far more conservative than Dr. McCarthy's estimation of the ECM additive), that the ECM additive caused the *plastic* (and not just the additive) to biodegrade. ALJFF ¶ 1017. ECM also introduced evidence that microbes necessarily consumed the plastic because the ECM additive was bonded and infused throughout the plastic substrate through heat molding. ALJFF ¶¶ 870–74, 891–92, 910, 913, 917–19, 934–39. Importantly, none of

Complaint Counsel's experts submitted a rebuttal to Dr. Barlaz's critical testimony and, so, the Decision has no basis in fact upon which to reject Dr. Barlaz's well-reasoned expert opinion.

The ALJ fully credited Dr. Barlaz's testimony. ALJFF ¶¶ 1006–42; ALJID at 263–67. He likewise issued credibility findings in addition to factual findings which discredited FTC's expert testimony. *See, e.g.*, ALJID at 227 (“Dr. McCarthy has been inconsistent with respect to the definition of biodegradable”), 269 (“While Dr. McCarthy posits these four criticisms of ERL's testing in his report, he did not convincingly explain those points in his testimony at trial”), 275 (“Weighing the criticisms offered by Complaint Counsel's expert, Dr. McCarthy, against the more credible and persuasive evidence offered by Respondent's experts...”), 279 (“Weighing the criticisms offered by Complaint Counsel's experts against the more credible and persuasive evidence offered by Respondent's experts...”), 281 (same), 283 (same), 284 (“Having weighed the evidence, considering the totality of the expert witness testimony, and placing substantial weight on the better supported and more credible testimony of Respondent's experts...”), 284 (“Based on the greater weight of the more credible and persuasive evidence, Complaint Counsel did not meet its burden...”). The Decision misinterpreted or, more often, entirely ignored the ALJ's findings. On the record before the agency, the ECM product was proven to accelerate biodegradation of plastics. ALJID at 284–85.

The Commission's deviation from the scientific findings and conclusions in the Initial Decision is itself void of any foundation in credible expert testimony, peer-reviewed science, or record evidence. *Opin.* at 48. The Commission cited no evidence for the following false statement in the Decision: “ECM presents no calculations to establish the statistical significance of methane generated from the plastic itself.” *Opin.* at 48–49. To the contrary, Dr. Barlaz performed those very calculations and testified concerning them at length; the ALJ's findings

recited that evidence and testimony, and he adopted conclusions based thereupon. ALJFF ¶¶ 1091, 1094, 1109, 1125, 1127, 1130, 1132, 1146, 1148, 1161, 1180, 1195, 1213, 1214, 1279, 1280, 1282, 1284, 1298, 1299, 1301, 1303, 1325, 1327, 1352, 1374, 1375, 1378, 1380, 1401, 1441, 1442; ALJID at 263–67. Indeed, Dr. Barlaz’s testimony and opinions were not addressed by any of Complaint Counsel’s experts, who had not even reviewed Dr. Barlaz’s calculations. *See Tolaymat*, Tr. 316–17, attached as Exh. B; *McCarthy*, Tr. 359–480, attached as Exh. C; *Michel*, Tr. 2966, attached as Exh. D.

Dr. Barlaz testified that his statistical analyses established that “there are many tests [involving plastics infused with the ECM additive] where there’s good scientific evidence that the material . . . underwent anaerobic [biodegradation].” ALJFF ¶ 1042 (referring to the plastic substrate rather than the additive). Dr. Barlaz used t-statistics as the basis for his determination that the amount of biodegradation observed in the test vessels was statistically relevant. But he then examined the amount of biodegradation in a separate mathematical analysis to determine whether the value of biodegradation observed was attributed to the additive alone, the additive and the inoculum alone, or the plastic itself. ALJFF ¶¶ 1014–35. He did that by calculating the maximum amount of methane that could conceivably have been produced by the additive alone. *See, e.g.*, ALJFF ¶ 1020. He repeatedly found in positive test after positive test that the biodegradation was indeed attributable to the plastic, not the additive and not the inoculum. *See, e.g.*, ALJFF ¶¶ 1092 (“the amount of methane recorded from the test sample . . . was nearly twenty times the biodegradation that could have been sourced from the ECM Additive alone”); *see also* ALJFF ¶¶ 1095, 1110, 1133, 1149, 1162, 1283, 1302, 1311, 1328, 1353, 1379, 1402, 1403. All of the experts agreed that methane production is proof of anaerobic biodegradation. ALJID at 240–43. All of the experts agreed that gas evolution testing is therefore designed to

test and record biodegradation of test articles. ALJFF ¶¶ 743–90. Methane is a compound composed of one carbon and two hydrogen atoms. So the methane produced from biodegradation means that a carbon atom has been drawn from the plastic amended with the ECM Additive (where that carbon is not attributable to the inoculum). The ECM Additive can only source so many carbon atoms, after which scientists can reliably say that the excess methane must come from the plastic (which also donates carbon atoms during biodegradation). ALJID at 241. Dr. Barlaz calculated the maximum amount of carbon atoms that could have been sourced by the ECM Additive alone in the vast majority of independent tests of ECM Additive infused plastics. ALJFF ¶¶ 1092, 1110, 1128, 1133, 1149, 1162, 1181, 1182, 1196, 1215, 1216, 1238, 1302, 1311, 1328, 1353, 1379, 1402, 1403. He determined that the ECM Additive could produce a maximum of 933 mL of methane gas per gram of the additive. ALJFF ¶ 1022. The ALJ’s findings of fact clearly explained that calculation: “Dr. Barlaz explained that where the methane is associated and produced from the test vessel is not attributable to the inoculum, and not attributable to the ECM Additive, then the biodegradation must come from the plastic substrate itself.” *See* ALJFF ¶ 1036; *see also* ALJFF ¶¶ 1006–1042. None of Complaint Counsel’s experts performed any comparable testing of the additive or even reviewed Dr. Barlaz’s statistics. None testified in rebuttal to Barlaz. The ALJ’s decision concerning Dr. Barlaz’s crucial testimony—evidence that *proved* the ECM additive’s efficacy—was entirely omitted from the Decision.

The Commission lacks expertise in t-tests or biodegradation analyses and its attempt to construe them, without relying on any expert testimony³ or peer reviewed science, grossly distorts the record and misconstrues the way in which Dr. Barlaz’s statistical analyses proceeded.

³ None of Complaint Counsel’s experts even reviewed or attempted to discredit Dr. Barlaz’s credible statistical analyses.

Opin. at 48 (failing to cite to Complaint Counsel expert testimony); ALJID at 263–66 (explaining Dr. Barlaz’s statistical analyses in detail and concluding that the “**tests in evidence showed net methane yields greater than the amount of biodegradation that could have possibly been sourced from the ECM Additive alone**”) (emphasis added). The t-tests when combined with Dr. Barlaz’s additional calculations prove that the ECM Additive causes plastic to biodegrade in anaerobic conditions. ALJID at 284. The testing demonstrated that ECM’s product substantially accelerates biodegradation of plastics when tested alongside traditional plastics. *Id.*

Because the evidence shows that ECM’s Additive accelerates plastics biodegradation,⁴ the First Amendment entitles ECM to convey that benefit to consumers in truthful and non-misleading ways, which involve use of representations that are forbidden by the Decision, to wit, information concerning accelerated gas evolution testing, intrinsic biodegradability, and the inability to predict with reasonable certainty the time within which complete biodegradation is achievable for any plastic (as well as for any piece of wood, banana, orange, apple core, paper, or other intrinsically biodegradable substance). *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 556, 566 (1980). “[C]omplete speech bans are particularly dangerous because they foreclose alternative means of disseminating certain information.” *Retail Digital Network, LLC v. Appelsmith*, 945 F. Supp. 2d 1119, 1124 (C.D. Cal. 2013) (citing *44 Liquormart v. Rhode Island*, 517 U.S. 484, 501–04 (1996)). That is why “more disclosure rather than less is the preferred approach, so long as the commercial speech is not inherently misleading.” *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 14 (D.D.C. 2002). Claims are not inherently misleading merely because they lack “significant scientific agreement.” *Pearson v. Shalala*, 164

⁴ At the very least, the complexity of the scientific question of whether the ECM Additive causes plastics to biodegrade renders a stay appropriate. *North Texas*, 141 F.T.C. 10 at *2.

F.3d 650, 655 (D.C. Cir. 1999); *see also Whitaker*, 248 F. Supp. 2d at 11 (“any complete ban of a claim would be approved only under narrow circumstances, *i.e.*, when there was almost no qualitative evidence in support of the claim *and* where the government provided empirical evidence proving that the public would still be deceived even if the claim was qualified by a disclaimer.”). The Commission bears the First Amendment burden of proving that complete suppression of ECM’s biodegradable claim is “a *necessary* as opposed to *merely convenient* means of achieving its interests.” *Whitaker*, 248 F. Supp. 2d at 15 (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002)); *see also In re R.M.J.*, 455 U.S. 191, 203 (1982)) (holding that the government “may not place an absolute prohibition on certain types of potentially misleading information ... if the information also may be presented in a way that is not deceptive”). Here, the Commission failed to present evidence that the biodegradable claim, “if accompanied by a disclaimer, would be deceptive or unlawful.” *Id.* at 9. Instead, the Commission completely barred ECM from making a truthful claim that its Additive causes plastic to become intrinsically biodegradable. The Commission neither evaluated nor provided a reasonable disclaimer to cure any potential misleadingness. The difficult legal question of whether the biodegradable claim is entitled to protection under the First Amendment shows that ECM has a substantial likelihood of success on the merits. *North Texas*, 141 F.T.C. 10 at *2. Given the record evidence, the “biodegradable” claims sought by ECM are truthful and, at worst, only potentially misleading. Potentially misleading speech is entitled to constitutional protection; it may not be banned but must be allowed with reasonable qualifications.

To the extent that communication has the potential to mislead consumers, the Commission is obligated to allow ECM to make the claim accompanied by a reasonable disclaimer. *See Pearson*, 164 F.3d 650. However, the Decision completely bans use of the word

“biodegradable.” To use the unqualified term “biodegradable,” ECM must have data from tests that “simulate the physical conditions found in landfills” demonstrating that “the entire item will completely decompose into elements found in nature within five (5) years after customary disposal.” Order at 2–3. That is an impossible standard to meet. Complaint Counsel’s own expert, the EPA’s Dr. Thabet Tolaymat, testified that even the most biodegradable substances, which he characterized as “rapidly degrading wastes” like “food waste and sewage sludge,” may take seven to fourteen years to fully biodegrade in a landfill. *See* CCX 893 (Tolaymat, Rep. at 16), attached as Exh. J. So, under the Decision’s terms, there is nothing that could be labeled “biodegradable” without a qualifier.

The FTC’s proposed standards for qualifiers are also impossible for ECM (or any advertiser) to meet. The first option for a qualifier is for ECM to state “Biodegradable. This product will decompose into elements found in nature in [time to complete decomposition.]” Order at 3. However, there is no generally accepted scientific method (no competent and reliable scientific method) by which ECM or any company can reliably determine the time a biodegradable substance will take to achieve complete decomposition. Indeed, the Commission failed to rebut ECM’s argument on appeal “that Complaint Counsel have not identified a test methodology that would provide scientific evidence sufficient to support claims that ECM Plastics biodegrade fully in a landfill within a specified period of time.” *Opin.* at 44. The Commission skirted that issue by stating that ECM’s argument “misses the point.” *Id.* But the real point is that Paragraph I(A)(ii)(a)(1) of the Order is indisputably impossible to meet, as no test can demonstrate how long it will take an ECM Plastic or any intrinsically biodegradable substance to completely decompose into elements found nature under precise landfill

“simulations”—not when the Commission in its Decision concurrently prohibits extrapolation theories and accelerated testing.

The only other method by which ECM can make a qualified biodegradable is through Paragraph I(A)(i)(ii)(a)(2) of the Order. That standard requires ECM to qualify its biodegradable claim by disclosing “the rate and extent of decomposition into elements found in nature.” Order at 3. The ALJ made clear, and the Commission failed to rebut, that “the evidence at trial shows that no one test can support a rate of biodegradation of plastics in a landfills ...” ALJID at 239. Not a one. The ALJ further explained that it is not possible to project rates when applied to a landfill environments because “[a] landfill, by its nature, is different from a controlled laboratory reactor; a landfill cannot be standardized or homogenized.” ALJID at 240. The ALJ explained in detail:

It would be scientifically impractical to design a perfect closed-system test that would be representative of all the potential microenvironments in an MSW landfill. Further it is not practical to try to simulate the landfill ecosystem at that time scale in a laboratory. Because landfills are heterogeneous, one has to be cautions in projecting rates that one gets from lab environments, which tends to be homogenous.

ALJID at 240; *see also* ALJID at 312 (“it has been found, as a matter of fact, that there is presently no single test that can substantiate the precise rate of biodegradation of plastics in a landfill”). When pressed, FTC’s experts were unable to provide a test (or combination of tests) that would permit rate calculations. ALJID at 239–40. The Commission’s opinion and order ignores those detailed ALJ findings. *See, e.g.*, Opin. at 64. The Commission instead states that “any protocol (or combination of protocols) substantiating such claims must simulate the physical conditions found in the type of disposal facility or method stated in the representation, or if not qualified by disposal facility or method, the conditions found in landfills.” *Id.* That is impossible because, as the ALJ explained, there is no way to test for biodegradation rates in

actual landfills because landfills are heterogeneous and laboratory tests are, necessarily, homogenous. ECM cannot know the conditions of the landfill into which a specific piece of ECM Plastic will find its resting place (nor will the environment in that part of the landfill remain static rather than dynamic), and those overall environmental conditions will largely dictate “the rate and extent of decomposition.” Because no test can simulate the “physical conditions found in a landfill,” as those conditions vary landfill to landfill, locus within a landfill to locus within a landfill, and minute to minute, ECM cannot make the qualified biodegradable claim under paragraph I(A)(ii)(a)(2) of the Order, and, thus, both unqualified and qualified biodegradable claims are effectively forbidden ECM and the entire industry. Therefore the qualifiers purportedly available to ECM through Paragraph I(A)(ii)(a) of the Order are illusory. The Order thus completely bars biodegradable claims, whether qualified or not, in violation of the First Amendment. *See 44 Liquormart*, 517 U.S. at 502 (“The special dangers that attend complete bans on truthful, nonmisleading commercial speech cannot be explained away by appeals to the ‘commonsense distinctions’ that exist between commercial and noncommercial speech”).

The Commission blithely passes over that constitutional issue by ignoring the ALJ’s detailed findings on the scientific definition of “biodegradable.” *See* Opin. at 14 (stating that the focus of the Commission’s inquiry is unrelated to the scientific definition of biodegradation); ALJFF ¶¶ 633–696; ALJID at 224–234 (concluding that “[c]onsistent with the greater weight of the credible scientific evidence ... biodegradation is defined as the biological process by which microorganisms such as bacteria and fungi use the carbon found in organic material as a food source”); *see Cinderella Career & Finishing Schools, Inc. v. F.T.C.*, 425 F.2d 583, 589 (D.C. Cir. 1970) (explaining that “[t]he Commission may not ‘ignor[e] ... the findings of the [ALJ]’);

see also Morall v. Drug Enforcement Admin., 412 F.3d 165, 177 (D.C. Cir. 2005) (“The agency’s departures from the ALJ’s findings are vulnerable if they fail to reflect attentive consideration to the ALJ’s decision.”) (citations omitted). Instead, the Commission principally relies on Dr. Frederick’s Google Consumer Survey, and considers three additional surveys, to conclude “that attaching a ‘biodegradable’ label to a plastic product leads reasonable consumers to believe that the product will biodegrade within five years.” *Opin.* at 18. That “evaluat[ion of] numerous scientific studies of consumer behavior” is sufficient alone to demonstrate that ECM has a substantial likelihood of success on the merits. *North Texas*, 2006 WL 6679063 at *2. Further, the Commission’s use of a “significant minority” in this case is novel in that, for the first time, it relies “solely on the significant minority exception to find an ad interpretation reasonable.” *Dissent* at 9. Under the First Amendment, the Commission may not make it impossible to use a scientifically verifiable term in commerce on the argument that a minority of consumers misunderstand it. The remedy for potential misleadingness is disclosure, not suppression, yet the Decision here falls on the constitutionally prohibited side of suppression.

The record made clear that Dr. Frederick’s survey (upon which the Commission’s “minority” consumer perception argument is principally based) was invalid and unreliable. *Dissent* at 3–6; ALJFF ¶¶ 353–454; ALJID at 189–202. The ALJ analyzed Dr. Frederick’s survey in great detail, in over 100 specific findings of fact, concluding that Dr. Frederick’s survey “failed to comport with generally accepted standards for survey research, as well as the legal standards used by the Commission, and is insufficiently reliable or valid to draw any material conclusions.” ALJFF ¶¶ 353–454; ALJID at 200–02. Commissioner Ohlhausen similarly found that “Dr. Frederick’s GCS survey is flawed in methodology and application.” *Dissent* at 3–6. The ALJ’s and Commissioner Ohlhausen’s respective opinions are evidence that

the Commission is applying a complex factual record to the law over which there is considerable disagreement, meaning that ECM has made the requisite showing of a likelihood of success on the merits. If Complaint Counsel failed to meet their burden of showing that an unqualified biodegradable claim implies to consumers biodegradation within one or five years, as the ALJ and Commissioner Ohlhausen have found, ECM has an undoubted First Amendment right to claim that its Additive causes plastic to biodegrade.

Second, even assuming Dr. Frederick's surveys were accurate and reliable (a supposition contrary to the overwhelming weight of record evidence), the Commission's Decision hinges on the scientifically incorrect and misguided beliefs it presumes to be held by a "significant minority" of consumers. As Commissioner Ohlhausen explained, the "FTC has never used extrinsic evidence of a 'significant minority' as a stand-alone basis to determine that a claim interpretation is reasonable." *See* Dissent at 9–10. And for good reason. The "significant minority" theory necessarily suggests that for the *majority* of consumers the claim was not deceptive. Thus, in most applications, the ECM claim was evidently understood as intended and was truthful and non-misleading. The claim is therefore, at worst, only *potentially* misleading to a select few consumers in the minority. That is a distinction without a material difference needed for decision, because undoubtedly a minority of consumers will misunderstand the plain and intended meaning of virtually every material term used in advertising. *See* Dissent at 8 (citing the *FTC Policy Statement on Deception* and explaining that "some people, because of ignorance or incomprehension, may be misled by even a scrupulously honest claim"); *see also* Dissent at 8 n. 43 (citing work by prominent consumer behavior experts for the proposition that "at least some consumers will misunderstand some aspect of any communication"). That a minority holds a view contrary to science cannot be the test for deception lest every

advertisement by definition would be illegal on grounds of deception. The majority of consumers understood that biodegradation rates or extents are unpredictable because they are dependent on many factors including the type of product and ambient environmental conditions. ALJID at 217. For the vast majority, the language conveyed by ECM is apparently unlikely to mislead. And because the claim is merely “potentially” misleading as opposed to inherently misleading, the First Amendment protections substantially limit the Commission’s ability to restrain prospective “biodegradable” claims through its cease-and-desist and fencing-in orders.

Moreover, this case presents the unique circumstance in which a product found efficacious by the ALJ on a substantial scientific record is deemed deceptive on its principal basis of biodegradability, not because it fails to work as promised but because a minority of consumers fail to understand how it works. That turns the law of deception on its head and makes truth in advertising dependent not on what the evidence establishes to be true but on what the Commission politically deigns to be the perception of a minority. Indeed, here the Commission’s basis for decision is particularly arbitrary and capricious because the minority perception said to exist for the term biodegradability conflicts with the scientific definition of that term.

In arriving at its newfound “Five Year Rule” (a wholly arbitrary cut-off which begs the obvious question, why not Ten Years? Why not Twenty Years? Why not Thirty?), the Commission found that “at least an [undefined] significant minority of reasonable consumers would interpret ECM’s unqualified representation that ECM Plastics are ‘biodegradable’ to convey the claim that ECM Plastics fully biodegrade in landfills within a reasonably short period of time, *i.e.*, five years.” Opin. at 33. That “Five Year Rule,” interpreting “biodegradable” to imply complete decomposition within five years after customary disposal, directly contradicts

the FTC's Green Guides. 16 C.F.R. § 260.8(c) ("It is deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal."). So, FTC amended the Green Guides, which were formed only after proper notice and comment rulemaking, in violation of the APA. Only adjudications—and not industry guidance—can be overruled through adjudications. *See Am. Fed. Of Gov't Emps., AFL-CIO, Local 3090 v. Fed. Labor Relations Auth.*, 777 F.2d 751, 761 (1985) (Scalia, J., concurring) (explaining that the APA "clearly provides that a rule can only be repealed by rulemaking" and not adjudication). And upon what objective measure is five years per se reasonable, but five years and one second not? Moreover, nothing disappears within five years in a landfill, even materials that experts accept to be fully and rapidly biodegradable (such as paper and wood, bananas and oranges). ALJID at 245–46.

That "five year" consumer belief is thus contrary to scientific fact and, thus, scientifically unreasonable. Yet the Commission deemed the Five Year Rule "reasonable" simply because it presumed a "significant minority" of consumers believed it so. The "substantial minority" is never defined in the Decision but is, apparently, some presumed percentage of those surveyed. Opin. at 33. By comparison, a recent poll performed by National Science Foundation in 2014 concerning the "State of Science" in America reported that twenty six percent (26%) of Americans believe that the sun orbits the Earth as opposed to the Earth orbiting the sun.⁵ The flaw in the "significant minority" approach is that it deems the unscientific and objectively false truthful commercial speech and condemns the scientific and objectively true as false. Were the FTC's Decision applied to the NSF example, this Commission would hold advertisements for

⁵*See* Science and Engineering Indicators 2014, National Science Foundation (2014), at 7-23, *available at* <http://www.nsf.gov/statistics/seind14/content/chapter-7/chapter-7.pdf> (last visited Nov. 3, 2015).

orbital models of the solar system deceptive despite the fact that they accurately depict the earth orbiting the sun, due to the fact that a substantial minority of consumers erroneously perceive the opposite to be true. Thus, the Commission decision distorts the information marketplace and propounds falsehood in lieu of truth. If a consumer cannot comprehend the true nature and timespan of a biodegradable substance, are they then going to understand the Commission's proposed disclaimers which would report only the percentage of biodegradation recorded in simulated gas evolution testing? The Commission has failed to satisfy its First Amendment burden to prove that all potential claim qualifications deceive, let alone prove that the rather straightforward claim qualifications suggested by ECM—concerning the inherent uncertainty of rates of biodegradation—deceive.

The well-supported deficiencies identified by Commissioner Ohlhausen, which are backed by record evidence, raise substantial legal questions concerning the authority of the Federal Trade Commission in this case, including the constitutional issues identified herein. The Commission may not rewrite scientific definitions and preclude truthful scientific speech solely to protect a “minority” of consumers who have a flawed and unreasonable understanding of the science.

2. The Commission Violates ECM's Due Process Rights by Failing to Provide ECM with Notice of the Charges

The Commission's holding that ECM's unqualified biodegradable claim implied biodegradation within five years after customary disposal violated ECM's due process rights. Opin. at 13–14. The Due Process Clause prohibits administrative enforcement actions based on regulatory positions that are imposed without fair notice. Moreover, where administrative action “interferes with the right of free speech or of association, a more stringent [Due Process] test

should apply.” *See, e.g., Holder v. Humanitarian Law Project*, 561 U.S. 1, 18-19 (2010). The Seventh Circuit recently explained that the doctrine:

[A]ddresses at least two connected but discrete due process concerns: first, that regulated parties should know what is required of them so they may act accordingly; second, precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way.

Ctr. for Individual Freedom v. Madigan, 697 F.3d 464, 478–79 (2012) (noting that, in cases where government action “abuts upon sensitive areas of basic First Amendment freedoms, rigorous adherence to those requirements is necessary to ensure that ambiguity does not chill protected speech”).

Fair notice is thus required to “guard against the arbitrary and discriminatory exercise of enforcement discretion.” *Wisc. Right To Life, Inc. v. Barland*, 751 F.3d 804, 835 (7th Cir. 2014) (citing *FCC v. Fox Television Stations*, 132 S.Ct. 2307, 2317 (2012)); *see also Ungar v. Sarafite*, 376 U.S. 575 (1964)) (“Notice of charges with such specificity so as to allow the accused to defend against those charges is an inherent ingredient of due process of law.”). The vagueness and fair notice doctrines have been applied to agency interpretations, including those asserted for litigation purposes. *See, e.g., Gates & Fox Co. v. OSHRC*, 790 F.2d 154, 156 (D.C. Cir. 1986); *Gen. Elec. Co. v. U.S. EPA*, 53 F.3d 1324, 1328-29 (D.C. Cir. 1995); *United States v. Chrysler Corp.*, 158 F.3d 1350 (D.C. Cir. 1998); *Ark. Dep’t of Human Servs. v. Sebelius*, 818 F. Supp. 2d 107, 121 (D.D.C. 2011).

The Green Guides provide that an unqualified biodegradable claim implies complete decomposition “within one year after customary disposal.” 16 C.F.R. § 260.8(c).⁶ Further, beginning with the Initial Prehearing Conference (“IPC”), Complaint Counsel argued that the unqualified biodegradable claim implied decomposition within *one year* after customary

⁶ As explained in oral argument, ECM also objects to the One Year Rule, which

disposal, never suggesting that ECM made an implied claim of “five years or less.” *See* IPC at 8:5–22 (“So if you’re talking about the language ‘in a reasonable period of time,’ ... consumers would understand that to mean a period of time of one year – about one year for an unqualified claim.”), attached as Exh. E. Before the ALJ, Complaint Counsel reiterated that they drew “the line at one year.” ALJ Oral Arg. Tr. 36:22–24, attached as Exh. F. Yet again, before the Commission, Complaint Counsel’s exchange with Commissioner Ohlhausen clearly adheres to a one year rule:

COMM’R OHLHAUSEN: So you tried the case on the idea that the implied claim that consumers took from the unqualified biodegradable claim was that it would degrade within a year. And as Commissioner Brill has pointed out, that’s how you also have it in the proposed order. But my understanding was, on appeal, you are arguing that it was actually an implied rate of one to five years. So what – where is the source of my confusion?

MS. JOHNSON: We’ve always held the position that ECM’s unqualified biodegradable claim conveyed complete decomposition in a landfill within one year and that a significant minority [of] consumers would be deceived by any unqualified biodegradable claim.

Tr. Oral Arg. 60:25–61:4, attached as Exh. G; *see also* Tr. Oral Arg. 63:1 (“[t]he position is one year”). ECM was never afforded a full and fair opportunity to rebut the Commission’s claim that the unqualified biodegradable claim implies complete decomposition within five years, as opposed to one year. The Commission’s attempt to change its prior position and the charge against ECM at the eleventh hour on appeal violates ECM’s due process rights. *See Standard Oil Co. v. F.T.C.*, 475 F. Supp. 1261, 1275 (N.D. Ind. 1979) (citations omitted) (“The essence of due process ... is the requirement of prior notice of the charges against a person and a fair opportunity to be heard ...”); *see also General Electric*, 53 F.3d at 1332 (explaining that

divergent interpretations from different divisions within the EPA constituted evidence that the agency had not provided fair notice).

B. Absent a Stay, ECM will Suffer Irreparable Financial and Constitutional Harm

“A party seeking a stay must show, with particularity, that the alleged injury is substantial and likely to occur absent a stay.” *North Carolina Board*, 2012 WL 588756 at *2.

1. Absent a Stay, ECM Will Suffer Irreparable Financial Injury

Irreparable injury exists where “economic harm[] threaten[s] the very existence of the movant’s business ...” *F.T.C. v. Church & Dwight Co., Inc.*, 75 F. Supp. 2d 81, 86 (D.D.C. 2010). ECM is a small company of six employees. ALJFF ¶ 154.

} See

Decl. of Robert Sinclair, attached as Exh. H; Decl. of Kenneth Sullivan, attached as Exh. I. {

} Exh. H at

¶¶ 11, 13. The FTC’s Decision harms broadly the entire biodegradable plastics industry, but directly, substantially, and immediately ECM. Absent a stay of the Order pending judicial review, {

} Exh. H at ¶¶ 11–12, 15–17. Thus, denial of a stay could likely deny ECM meaningful judicial review of the agency decision—something to which all parties are, of right, entitled to receive.

Since the FTC initiated proceedings against ECM in this matter,

} Exh. I at ¶¶ 4–5.

ECM {

} Exhibit I at ¶ 5. It has 6 employees,
 whereas before this matter ECM employed 7 individuals (local residents in or around the
 Painesville, Ohio community). *Id.* at ¶ 7. ECM operates in a highly competitive market. Exh. H
 at ¶ 12. One competitor’s loss is another’s gain. Moreover, ECM customers are manufacturing
 entities that {

}
 ECM {

.}

On that point, immediate implementation of the Commission Decision (without a stay) harms
 both ECM and the public interest. The record reflects no proof that actual consumers have ever
 been deceived by ECM’s “biodegradable” claim and reflects substantial scientific evidence of
 ECM product efficacy. The relatively short period of time necessary to achieve closure
 following judicial review is thus insignificant compared {

} Moreover, given the multiplicity of entirely
 unprecedented applications of law in the Decision that raise constitutional, statutory, and

administrative law issues, the public interest is best served by allowing an Article III court to review the merits of agency action with the status quo ante preserved, particularly in light of the use of authority deemed novel in this case by at least one Commissioner. *Califano v. Sanders*, 430 U.S. 99, 109 (1977) (“Constitutional questions obviously are unsuited for resolution in administrative hearing procedures and, therefore, access to the courts is essential to the decision of such questions.”).

2. Absent a Stay, ECM Will Suffer Irreparable Harm to its First Amendment Rights

“The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.” *Elrod v. Burns*, 427 U.S. 347, 373 (1976).

Where the movant alleges that First Amendment rights at risk, “irreparable harm is presumed ...” *Herschaft v. City of N.Y.*, 2002 WL 1204780, *6 (E.D.N.Y. Feb. 15, 2002).

The Order prohibits ECM from making an unqualified biodegradable claim unless ECM has competent and reliable scientific evidence that a product biodegrades in five years or less. Order at 3. Thus, even if ECM has competent and reliable scientific evidence that its Additive accelerates plastics biodegradation under the generally accepted scientific tests, as the ALJ found, the Decision prohibits ECM from conveying that truthful claim. ALJID at 284. Nearly all experts who testified (including the FTC’s own experts, Dr. Tolaymat and Dr. Michel) explained that accelerated testing was appropriate and generally accepted. ALJID at 242–43. FTC expert Dr. McCarthy similarly used accelerated gas evolution testing to support claims of biodegradability for his own patented bioplastic polymers. *Id.*

The Commission’s Decision erects a standard for unqualified biodegradable claims that is scientifically impossible to satisfy by prohibiting ECM from representing:

That any plastic product or package is degradable, or that any product, package, or service affects a plastic product or package's degradability, unless such representation is true, not misleading, and at the time it is made, respondent possess and relies upon competent and reliable scientific evidence that substantiates the representation; and [] the entire item will completely decompose into elements found in nature within five (5) years after customary disposal.

Order at 3.

There is no evidence that any item will ever biodegrade into elements within 5 years in a landfill, a point reinforced by Complaint Counsel and the Commission during oral argument, Tr. Oral Arg. 40:5–6, 59:4–7, and Complaint Counsel's own experts. Dr. Tolaymat, Complaint Counsel's EPA landfill expert, testified that “[e]ven the most biodegradable material would not completely biodegrade in a landfill within 5 years even under optimum conditions for biodegradability.” ALJFF ¶ 699(b). Dr. Tolaymat explained in his report that even the most biodegradable substances, characterized as “rapidly degrading wastes” like “food waste and sewage sludge” may take seven to fourteen years to fully biodegrade in a landfill. *See* CCX 893 (Tolaymat, Rep. at 16), attached as Exh. J. The Commission Decision rejects two well-supported, generally accepted scientific principles that have been used and supported by nearly every expert in the case: accelerated testing and extrapolation.

The Decision requires conditions that “simulate” the landfill environment—qualities that were unproven and uncharacterized during the hearing because landfills are heterogeneous, having highly variable environments even within each landfill and, indeed, at each loci within a landfill. ALJID 223–24. There is no generally accepted scientific standard in existence to support the Commission's demand for testing that simulates a landfill environment beyond the gas evolution testing already in the record, but the Decision rejects gas evolution testing. Order at 2; *but see* ALJID at 278 (“scientists agree that it is perfectly acceptable to extrapolate whether

a material is biodegradable, including in a landfill, from accelerated lab test data”). By so doing, the Commission commands proof under testing methodologies that do not exist or are not accepted as scientific or generally accepted. The Decision then prohibits representations about a product’s intrinsic biodegradability as proven during the gas evolution test. Order at 2, ¶ 1; *but see* ALJID at 263, 277–78 (“The ASTM D5511 test method is a competent and reliable scientific method for assessing intrinsic biodegradability ... Complaint Counsel’s insistence that [ECM’s] substantiation fails because ECM’s tests do not show that the plastic ‘completely’ biodegraded ignores the scientific evidence that biodegradation is a process and not a clearly defined endpoint”).

The Decision limits claims concerning biodegradability only to the specific percentage recorded during the “simulated” test. Order at 2; *but see* ALJID at 278. Thus, the Decision precludes precisely that kind of extrapolation to a final conclusion which was used by its own expert, Dr. McCarthy, in his patents for biodegradable polymers, in the scientific literature on plastics biodegradation, and in the testimony of nearly every scientific expert of record, including the FTC’s experts Tolaymat and Michel. Order at ¶ 3; *but see* ALJID at 278.

Consider a “rapidly degrading” waste tested in an environment of that sort—something unquestionably “fully biodegradable.” With a lifespan between 7–14 years in a landfill, that product might degrade just three percent (3%) during a 180-day gas evolution test, or about seven percent (7%) during a full year of “simulated” testing. The Commission Decision would only permit a claim that the product degraded “7% over 365 days in gas evolution testing.” Order at ¶ I(A)(ii)(2). If anything, that claim grossly misleads by suggesting that a product (which is inherently biodegradable) would not otherwise continue to biodegrade outside of the test laboratory. Moreover, experts repeatedly testified that long-term gas evolution testing was

difficult, and the Commission appears to reject (erroneously) the idea that the inoculum could be refreshed during tests. ALJFF ¶¶ 724–28. In sum, under the Decision, no scientific method exists to prove that a product is “biodegradable,” and, so, no claim for “biodegradable” can be made in the market. That is arbitrary, capricious, unconstitutional, and directly in conflict with basic scientific principles—proving that the FTC lacks “expertise,” and thus deserves no deference on appeal, in factual areas related to complex scientific evidence.

The Decision thus has the effect of banning truthful speech while instituting a standard that is impossible for ECM or any other company to meet. The Decision also compels the use of misleading qualifications concerning “rates” of biodegradation (which are unknowable and unprovable) and precludes truthful statements concerning extrapolation from gas evolution data and “intrinsic biodegradability.” Even the most biodegradable waste products (e.g., food waste) will only biodegrade a small percentage in a gas evolution test that the near universal testimony of the experts in this case confirms to “simulate” the environment of landfills. ALJFF ¶¶ 631, 674, 702(a), 702(b) (Dr. Barlaz explained that food wastes take almost five years to biodegrade under *accelerated* conditions). If a company could only report the fraction of biodegradation recorded in those tests, the claim conveyed to consumers would mislead by suggesting (quite erroneously) that the material is not completely biodegradable when in fact it is. ALJFF ¶¶ 640, 729, 935. Complaint Counsel’s own witnesses testified that inherent or intrinsic biodegradability is thus the only major concern. ALJFF ¶¶ 652, 673, 693, 694. After all, a product that biodegrades 44% in gas evolution testing is “fully biodegradable” according to Complaint Counsel’s expert Dr. Michel. ALJFF ¶ 685.

The Order therefore causes ECM to suffer irreparable harm because it deprives ECM of its First Amendment freedom to convey truthful scientific information to consumers, and the

FTC has not met its constitutional burden to show that claim qualifications would not suffice to alleviate any potential for misleadingness alleged to have occurred in a minority of consumers. The Commission has advanced no tenable or supported reason to reject proposed disclaimers, including those that would provide consumers with helpful information concerning the process of biodegradation. The Supreme Court has been particularly skeptical of Government speech-restrictions that rest on the paternalistic assumption that consumers are better off when denied accurate information. *See, e.g., Bates v. State Bar of Ariz.*, 433 U.S. 350, 375 (1977) (“we view as dubious any justification that is based on the benefits of public ignorance”); *44 Liquormart*, 517 U.S. at 503 (“The First Amendment directs us to be especially skeptical of regulations [of non-misleading scientific information] that seek to keep people in the dark for what the government perceives to be their own good”). More information is always preferable than less information in the commercial speech context. *See Bates*, 433 U.S. at 376 (“the preferred remedy is more disclosure, rather than less”); *Pearson*, 164 F.3d at 657 (collecting cases). Indeed, it is unconstitutional to suppress truthful speech on the supposition that consumers are likely to misunderstand the truth. *See Am. Meat Inst. v. U.S. Dep’t of Agriculture*, 760 F.3d 18, 42–43 (D.C. Cir. 2014) (collecting cases and concluding that “[t]he clear trajectory of the Supreme Court’s jurisprudence is toward greater protection for commercial speech, not less”).

C. Staying the Order Presents no Risk of Harm or Injury to Consumers and a Stay is in the Public Interest

“Because [ECM’s] adversary is Complaint Counsel, responsible for representing the public interest in effective law enforcement, the Commission considers the Rule’s third and fourth prongs together, inquiring into the likely harm from issuing a stay to other and the public interest.” *In the Matter of Jerk, LLC*, 2015 WL 3413323, at *5 (F.T.C. May 6, 2015). Absent an actual showing of harm to the public, “the public interest runs in favor of protecting the First

Amendment rights implicated in this case.” *Fontroy v. Beard*, 2007 WL 1810690, at *5 (E.D. Pa. June 21, 2007). Further “[n]either the government nor the public generally can claim an interest in the enforcement of an unconstitutional law.” *Council of Alt. Political Parties v. Hooks*, 121 F.3d 876, 883–84 (3d Cir. 1997). Thus, if ECM is successful on appeal, a stay will have avoided constitutional injury not just to ECM, but also to industry regulatees who must accept the Decision as the Commission’s latest and most authoritative statement on the topic.

Judicial review therefore furthers all interests, including those of the FTC, the public, and the regulated class. This is a substantial case that raises important questions based on unprecedented FTC actions and the application of complex scientific principles under FTC doctrine. The decision could influence the manner and means by which companies conduct business throughout an entire industry and could adversely impact the availability of biodegradable plastics thus increasing ambient environmental pollution. The decision may serve as precedent in future advertising matters. Judicial review will impart finality and predictability for all parties involved.

Further, the ALJ found that no evidence of consumer injury or harm was present in this case—factual findings that were uncontroverted in the record. ALJID at 300–01 at nn. 58–59. Complaint Counsel presented no evidence showing that a single end-use consumer actually paid more for an ECM amended plastic than a comparable plastic without the ECM additive. *Id.* The record contains no evidence that end-use consumers actually purchased (i.e., paid money for) an ECM product. *Id.* As the ALJ explained:

Complaint Counsel did not present evidence that any end-use consumers (as opposed to commercial enterprises) purchased any ECM Plastic based, in whole or in part, on any claim made by ECM. There is no record evidence that any such end-use consumers “purchased” the grocery bags, shopping bags, restaurant bags, disposable dinnerware, packaging materials, or shipping

materials that comprise many of the product which, based on the customer deposition testimony, are manufactured using ECM Additive.

ALJID at 300 at n.58 (internal citations omitted).

The record contains no evidence that ECM *purchasers* were actually deceived by ECM's unqualified biodegradable claim. No valid survey in the record targeted ECM's purchasers. Opin. at 15–31. No evidence suggested that a direct ECM customer purchased the ECM technology based solely on ECM's so-called implied rate claim (which was allegedly perceived by just a minority of end-use consumers). The uncontroverted record evidence shows that ECM's customers are plastics manufacturers that make calculated decisions to use ECM's technology. ALJID at 172–73. The record has no evidence of any “impulse” purchases. Often ECM's customers take months or years to open an ECM account. *See* Sinclair, Tr. 767, attached as Exh. K. A simple internet search reveals the complete proceedings before the FTC.

Finally, ECM President Robert Sinclair explains in the accompanying sworn declaration (and in his sworn testimony) that ECM has long since discontinued its rate claims, particularly the “9 month to 5 years” claim. Exh. H at ¶ 10. ECM has pledged to permanently discontinue such claims, and to ensure that prospective advertising accurately reflects the supported and generally accepted science. *Id.* at ¶¶ 9–10.

Put simply, the risk of additional or ongoing harm to consumers is indefinite, ill defined, and low, if at all, but the risk of irreparable harm to ECM is immediate and great. A stay is therefore warranted.

CONCLUSION

ECM respectfully requests that the Commission stay the Final Order pending ECM's appeal to the United States Court of Appeals. Granting the requested stay benefits all parties, including the public and industry regulatees, by preserving the status quo ante until an Article III

CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of Respondent ECM BioFilms' Application to Stay the Final Order Pending Judicial Review, and that on this November 9, 2015, I caused the foregoing to be served **electronically** to the following:

Donald Clark
600 Pennsylvania Ave., NW
Suite 172
Washington, DC 20580

I hereby certify that this is a true and correct copy of Respondent ECM BioFilms' Application to Stay the Final Order Pending Judicial Review, and that on this November 9, 2015, I caused the foregoing to be served electronically to the following:

Jonathan Emord
Emord & Associates, P.C.
jemord@emord.com
Respondent

Peter Arhangelsky
Emord & Associates, P.C.
parhangelsky@emord.com
Respondent

Katherine Johnson
Complaint Counsel
Federal Trade Commission
kjohnson@ftc.gov
Complaint

Elissa Jillson
Complaint Counsel
Federal Trade Commission
ejillson@ftc.gov
Complaint

Jonathan Cohen
Federal Trade Commission, Bureau of Consumer Protection, Enforcement Division
jcohen@ftc.gov
Complaint

Arturo DeCastro
Attorney

Federal Trade Commission
adecastro@ftc.gov
Complaint

Eric Awerbuch

Attorney

EXHIBIT A

PUBLIC

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES**

DOCKET NO. 9358

In the Matter of

**ECM BIOFILMS, INC.,
a corporation, also d/b/a
Enviroplastics International,**

Respondent.

INITIAL DECISION

**D. Michael Chappell
Chief Administrative Law Judge**

Date: January 28, 2015

TABLE OF CONTENTS

I.	INTRODUCTION	i
A.	SUMMARY OF THE COMPLAINT AND ANSWER.....	1
B.	PROCEDURAL HISTORY	3
C.	EVIDENCE	4
D.	SUMMARY OF INITIAL DECISION	5
II.	FINDINGS OF FACT	8
A.	WITNESSES	8
1.	Complaint Counsel’s Fact Witnesses	8
2.	Complaint Counsel’s Customer Deposition Testimony	8
3.	Respondent’s Fact Witnesses	15
a.	Mr. Robert Sinclair	15
b.	Mr. Kenneth Sullivan.....	15
c.	Dr. Timothy Barber	16
d.	Mr. Thomas Poth	16
e.	Mr. Alan Johnson.....	17
4.	Complaint Counsel’s Expert Witnesses.....	17
a.	Dr. Thabet Tolaymat.....	17
b.	Dr. Stephen McCarthy	18
c.	Dr. Shane Frederick	18
d.	Dr. Frederick Michel	19
5.	Respondent’s Expert Witnesses.....	20
a.	Dr. Ranajit Sahu.....	20
b.	Dr. Morton Barlaz.....	21
c.	Dr. Ryan Burnette.....	22
d.	Dr. David Stewart	22
B.	BACKGROUND ON ECM AND ECM’S PRODUCT AND SALES	23
1.	Respondent ECM BioFilms, Inc. and the ECM Additive	23
2.	ECM Supply Chain.....	24
3.	Plastics	25
4.	ECM Plastics	26
C.	ECM’S CLAIMS	27
1.	Background.....	27
2.	ECM’s Marketing and Sales Process.....	29
3.	“Biodegradable” and “Biodegradable in a Landfill”	31
4.	Complete Biodegradation in a Landfill Within “9 Months to 5 Years” and “In Some Period Greater Than a Year”	33
5.	“Tests Prove” ECM’s Claims	37
6.	“Passing Down” of ECM’s Claims.....	40
D.	SURVEY EVIDENCE	45

1.	Expert Qualifications and Findings	45
2.	Survey Evidence Generally	46
3.	The Google Survey	49
a.	Generally.....	49
b.	Dr. Frederick’s choice to use a Google Consumer Survey.....	51
c.	Questioning methodology.....	51
d.	Disinterest bias.....	53
e.	Coding methodology	54
f.	Representativeness of sample	56
g.	Conclusions as to the Google survey.....	58
h.	Relevant survey questions and results	59
4.	The APCO Survey	62
5.	The Synovate Survey.....	65
6.	The Stewart Survey.....	68
a.	Methodology.....	68
b.	Relevant questions and responses.....	72
c.	Summary and conclusions	73
d.	Manufacturers Pilot Survey	74
E.	SUBSTANTIATION	75
1.	Landfill Conditions.....	75
a.	Temperature.....	75
b.	Oxygen.....	76
c.	Moisture.....	76
d.	Biodegradation in a landfill	78
e.	Anaerobic biodegradation.....	79
f.	Methane	80
g.	Degradation times in landfills.....	80
2.	Scientific Evidence on the Definitions of Biodegradability	81
a.	Dr. McCarthy’s definition of “biodegradability”	81
b.	Scientific definitions of “biodegradability”	86
3.	ECM Plastics Will Not Fully Biodegrade in 9 Months to 5 Years in a Landfill.....	88
4.	Competent and Reliable Scientific Methods to Prove Biodegradability	90
a.	General standards.....	90
b.	Landfill environment	90
c.	Extrapolation and the rate of biodegradation.....	90
d.	Accelerated testing.....	91
e.	Temperature	92
f.	Weight loss tests	93
g.	Gas evolution tests.....	93
h.	BMP tests.....	94
i.	The ASTM D5511 test.....	95

i.	Landfill environment	97
ii.	Temperature	97
iii.	Duration	97
j.	Limitations of closed-system testing	98
l.	Testing proposed by Dr. Tolaymat	100
i.	Lysimeter testing	100
ii.	<i>In situ</i> testing.....	101
m.	Testing proposed by Dr. McCarthy	102
i.	Radiolabeling testing	102
ii.	Sixty percent conversion to methane and carbon dioxide within 18 months	104
n.	The priming effect	105
5.	How the ECM Additive Works	106
6.	Types of Microbes that Biodegrade Plastics	114
7.	Dr. Barlaz’s Analysis of Gas Evolution Data from ECM Tests	118
8.	Testing Performed on the ECM Additive.....	121
a.	Anaerobic testing by Eden Research Laboratories	121
i.	RX 248, ERL No. 092511B.....	124
ii.	RX 839, ERL No. 070312C.....	125
iii.	RX 403, ERL Fellows.....	127
iv.	RX 402, ERL FP International	129
v.	CCX 548, ERL FP International.....	130
vi.	CCX 546, ERL FP International.....	131
vii.	CCX 534, ERL MicroTek.....	133
viii.	CCX 547, ERL EcoLab	134
b.	Anaerobic testing by Northeast Laboratories	136
i.	RX 836, NE Labs N1048340 (PPC Industries, Inc.)	139
ii.	RX 838, NE Labs 1149980 (MINIGRIPS).....	141
iii.	RX 398, NE Labs N0946510-01 (Masternet I)	144
iv.	RX 405, NE Labs 1048742-01 (Eco SmartPlastics I)	145
v.	RX 396, NE Labs 1048819 (Eco SmartPlastics II)	146
vi.	RX 395, NE Labs 1150851 (Sweet Tape Enterprise).....	147
vii.	RX 394, NE Labs 1150851 (Tycoplas Sdn. Bhd.)	148
viii.	RX 393, NE Labs 1253020 (National Tree Co.)	149
ix.	RX 392, NE Labs 1048036 (Transilwrap Co.)	151
x.	RX 399, NE Labs N0843980 (Bio-Tec Environmental, LLC).....	152
c.	Anaerobic testing by North Carolina State University	153
i.	CCX 952, NC State 2010 StarchTech BMP	154
d.	Other anaerobic gas evolution testing.....	155
i.	RX 265, OWS Microtech Research Inc. (Feb. 1999)	155
ii.	RX 268, OWS Covidien (May 2010)	156
iii.	CCX 164, Dr. Michel’s study	156

F. MATERIALITY	159
III. ANALYSIS	164
A. BURDEN OF PROOF	164
B. JURISDICTION	166
C. OVERVIEW	166
D. CLAIMS	169
1. General Legal Principles.....	169
2. ECM’s Customers and Supply Chain for ECM Plastics	172
3. ECM’S Claims.....	173
a. Claims that ECM Plastics are “biodegradable” and “biodegradable in a landfill” and that “tests prove” the claims	173
i. “Biodegradable in a landfill”	173
ii. Certificate of biodegradability.....	174
b. Challenged claims that ECM Plastic will fully biodegrade in a landfill in a “stated qualified timeframe” and that tests prove such claims.....	175
i. “9 Months to 5 Years”	175
ii. “Some period greater than a year”	178
c. Summary.....	179
4. Alleged Implied Claim of Biodegradation Rate of “Within OneYear”	180
a. Introduction.....	180
b. Extrinsic evidence.....	183
i. Common usage of words	183
ii. Survey evidence – arguments of the parties	184
iii. Expert qualifications	187
iv. Google survey	189
(a) Introduction.....	189
(b) Analysis of Google survey.....	191
(c) Summary and conclusion as to Google survey.....	200
v. APCO and Synovate surveys.....	202
(a) Pertinent survey questions and results	202
(b) Analysis of APCO and Synovate survey results.....	204
(c) Summary and conclusions as to APCO and Synovate surveys	207
vi. Convergent validity	208
vii. Dr. Stewart’s survey	213
(a) Introduction.....	213
(b) Complaint Counsel’s statistical analysis of Dr. Stewart’s data	214
(c) Dr. Stewart’s findings and conclusions	216
(d) Complaint Counsel’s objections to	

	Dr.Stewart’s survey	218
	(e) Summary and conclusions as to Dr. Stewart’s survey	219
	c. Totality of the evidence on Implied One Year Claim.....	220
E.	SUBSTANTIATION	223
	1. Overview.....	223
	2. Landfill Conditions.....	223
	3. Definition of Biodegradable	224
	a. The testimony of Complaint Counsel’s expert fails to prove the contention that “biodegradable” means complete decomposition within one year	226
	b. The greater weight of the scientific evidence shows that biodegradable means the process by which microorganisms decompose materials.....	230
	c. Summary.....	233
	4. Applicable Legal Standards.....	234
	5. Tests Showing Complete Biodegradation in a Landfill Within One Year Not Required	238
	6. Competent and Reliable Scientific Testing Methods to Prove Biodegradability	240
	a. Gas evolution reactor tests.....	240
	b. BMP testing	243
	c. Testing showing 60% conversion and C14 testing are not required.....	243
	d. Summary.....	245
	7. Whether Respondent’s “9 Months to 5 Years Claim” and Tests Prove “9 Months to 5 Years Claim” Are False or Unsubstantiated.....	245
	8. Whether Respondent’s Efficacy Claims Are False	246
	a. Evidence on how the ECM Additive works	246
	b. Evidence on the tests upon which Complaint Counsel relies	252
	9. Whether Respondent’s Establishment Claims Are False	262
	10. Whether Respondent Possessed Adequate Substantiation For Its Claims	262
	a. Tests relied upon by Respondent.....	263
	b. Complaint Counsel’s challenges to Respondent’s substantiation	267
	i. Challenged flaws in Respondent’s tests	267
	ii. Complete biodegradation of ECM Plastics in landfills	276
	(a) “Complete biodegradation”	276
	(b) Biodegradation in landfills	279
	(c) Priming effect	281
	c. Summary.....	284

11. Conclusion.....	284
F. MATERIALITY.....	285
1. Introduction.....	285
2. Analysis.....	288
G. MEANS AND INSTRUMENTALITIES LIABILITY.....	292
H. DUE PROCESS ARGUMENTS.....	294
1. Violation of Separation of Functions Doctrine.....	294
2. Discovery Objections.....	296
3. Unfair Surprise.....	297
I. REMEDY.....	298
1. Overview.....	298
2. The Proposed Order.....	302
a. Part I.A. restraints on future “unqualified” biodegradable claims.....	302
i. Arguments of the parties.....	303
ii. Analysis.....	304
b. Part I.B. restraints on future environmental benefit claims.....	308
c. Proposed Definition of competent and reliable scientific evidence.....	309
3. The Order.....	312
4. Conclusion.....	314
IV. SUMMARY OF CONCLUSIONS OF LAW.....	315
ORDER.....	320

I. INTRODUCTION

A. SUMMARY OF THE COMPLAINT AND ANSWER

The Administrative Complaint in this case (“Complaint”), issued by the Federal Trade Commission (“FTC” or “Commission”) on October 13, 2013 against Respondent ECM BioFilms, Inc. (“Respondent” or “ECM”), alleges that Respondent, a manufacturer and seller of a plastic additive known as “MasterBatch Pellets” (the “ECM Additive”), violated Section 5 of the Federal Trade Commission Act (“FTC Act”) by misrepresenting the biodegradability of plastics made with the ECM Additive (“ECM Plastics”). Specifically, paragraph 9 of the Complaint alleges that:

9. Through [various marketing and promotional materials], respondent has represented, expressly or by implication, that:
 - A. ECM Plastics are biodegradable, *i.e.*, will completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal;
 - B. ECM Plastics are biodegradable in a landfill;
 - C. ECM Plastics are biodegradable in a stated qualified timeframe; and
 - D. ECM Plastics have been shown to be biodegradable, biodegradable in a landfill, or biodegradable in a stated qualified timeframe under various scientific tests including, but not limited to, ASTM D5511.

Complaint ¶ 9A-D.

The Complaint further alleges:

10. In truth and in fact:
 - A. ECM Plastics will not completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal;
 - B. ECM Plastics will not completely break down and decompose into elements found in nature within a reasonably short period of time after disposal in a landfill;

- C. ECM Plastics will not completely break down and decompose into elements found in nature within respondent's stated qualified timeframe after customary disposal; and
- D. ECM Plastics have not been shown to completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal, after disposal in a landfill, or within respondent's stated qualified timeframe, under various scientific tests, including, but not limited to, ASTM D5511.

Complaint ¶ 10 A-D. As discussed more fully *infra*, FTC Complaint Counsel (“Complaint Counsel”) asserts that “a reasonably short period of time” for complete biodegradation is less than one year, and “customary disposal” is disposal in a municipal solid waste (“MSW”) landfill. In addition, as further addressed *infra*, the “stated qualified timeframe” for biodegradation challenged by Complaint Counsel is the period of 9 months to 5 years.

The Complaint charges that the representations set forth in Paragraph 9 of the Complaint, listed above, are false or misleading. Complaint ¶ 11. The Complaint further charges that these representations are false or misleading because, at the time they were made, Respondent did not possess and rely upon a reasonable basis that substantiated such representations. Complaint ¶¶ 12-13. Moreover, the Complaint alleges, Respondent distributed the false or misleading representations alleged in the Complaint, through its marketing and promotional materials, to its customers and distributors, and thereby provided those entities with the “means and instrumentalities” for the commission of deceptive acts and practices. Complaint ¶¶ 14-15.

The Notice Order issued with the Complaint seeks to prohibit Respondent, *inter alia*, from making any “unqualified” claim that ECM Plastics are “biodegradable” unless it can substantiate, with competent and reliable scientific evidence, that ECM Plastics will biodegrade completely, in a landfill, within one year. Notice Order, Part I.A.i. In addition, under the Notice Order, any “qualified” claim as to the rate and extent of biodegradation of ECM Plastics must also be substantiated by competent and reliable scientific evidence. Notice Order, Part I.A.ii.

Respondent filed its Answer and Affirmative Defenses to the Complaint on November

15, 2013. Respondent denies that it misrepresented the characteristics of its product, or that it lacks substantiation for its biodegradable claims. Answer ¶¶ 11-13. Specifically, Respondent maintains that it provides its customers, who Respondent alleges are highly sophisticated, with accurate and non-misleading information concerning the nature and characteristics of the ECM Additive. In addition, Respondent avers, competent and reliable scientific testing proves that ECM Plastics will fully biodegrade, including in landfills. Answer ¶ 9A-D. Respondent also challenges the definition of “biodegradable” employed by the FTC and by Complaint Counsel in this case, derived from the October 2012 Revised Guides For The Use Of Environmental Marketing Claims (“Green Guides”), which requires items claimed to be “biodegradable” to completely biodegrade in a landfill within one year. According to Respondent, this definition conflicts with the representations made by ECM and with the understanding of ECM’s customers and the scientific community; is unworkable; and is arbitrary and capricious. Answer ¶ 10A-D. Respondent further denies that it engaged in any deceptive trade practices, or provided others with the means and instrumentalities to do so. Answer ¶¶ 14-15.

Respondent further interposes a number of defenses, including that the Complaint does not serve the public interest; the Notice Order barring biodegradable claims, unless such item is demonstrated to completely biodegrade in a landfill within one year, if implemented, will violate the First Amendment to the United States Constitution by suppressing truthful speech; the alleged misrepresentations were not material to ECM’s customers; the Complaint constitutes arbitrary and capricious agency action; and these administrative proceedings violate the due process protections of the Constitution by failing to properly separate the FTC’s prosecutorial and adjudicative functions. Answer at 1-2, 13-16.

B. PROCEDURAL HISTORY

The administrative trial in the instant case began on August 5, 2014, and concluded on August 29, 2014. By Order dated September 4, 2014, the hearing record was closed. Over 1,760 exhibits were admitted into evidence, 29 witnesses testified, either live or by deposition, and there are 3,006 pages of trial transcript. The parties’ proposed findings of fact, replies to proposed findings of fact, post-trial briefs, and reply briefs total 1,782 pages.

Rule 3.51(a) of the Commission’s Rules of Practice states that “[t]he Administrative

Law Judge shall file an initial decision within 70 days after the filing of the last filed initial or reply proposed findings of fact, conclusions of law and order” 16 C.F.R. § 3.51(a). The parties filed concurrent post-trial briefs and proposed findings of fact on September 25, 2014. The parties filed replies to the other’s proposed findings and briefs on October 16, 2014. Pursuant to Commission Rule 3.41(b)(6), closing arguments were held on October 22, 2014.

Seventy days from the last filed reply proposed findings and conclusions and briefs was December 29, 2014, and, absent an order pursuant to Rule 3.51, the Initial Decision was to be filed on or before December 29, 2014. Based on the voluminous and complex record in this matter and other grounds, an Order was issued on December 19, 2014, finding good cause for extending the time period for filing the Initial Decision by 30 days. Accordingly, issuance of this Initial Decision by January 28, 2015 is in compliance with Commission Rule 3.51(a).

C. EVIDENCE

This Initial Decision is based on a consideration of the whole record relevant to the issues, including the exhibits properly admitted into evidence, deposition transcripts, and the transcripts of testimony at trial, and addresses the material issues of fact and law. The briefs and proposed findings of fact and conclusions of law, and the replies thereto, submitted by the parties, and all contentions and arguments therein were thoroughly reviewed and considered.

Proposed findings of fact submitted by the parties but not included in this Initial Decision were rejected, either because they were not supported by the evidence or because they were not dispositive or material to the determination of the allegations of the Complaint or the defenses thereto. Similarly, legal contentions and arguments of the parties that are not addressed in this Initial Decision were rejected, because they lacked support in fact or law, were not material, or were otherwise lacking in merit. Ruling upon a decision of the Interstate Commerce Commission, and interpreting language in the Administrative Procedure Act (“APA”) that is almost identical to language in FTC Rule 3.51(c)(1), the United States Supreme Court held that “[b]y the express terms of [that Act], the Commission is not required to make subordinate findings on every collateral contention advanced, but only upon those issues of fact, law, or discretion which are ‘material.’” *Minneapolis & St. Louis Ry. Co. v. United States*, 361 U.S. 173, 193-94 (1959). *Accord Stauffer Labs., Inc. v. FTC*, 343 F.2d 75, 82 (9th Cir.

1965). *See also Borek Motor Sales, Inc. v. NLRB*, 425 F.2d 677, 681 (7th Cir. 1970) (holding that it is adequate for the Board to indicate that it had considered each of the company’s exceptions, even if only some of the exceptions were discussed, and stating that “[m]ore than that is not demanded by the [APA] and would place a severe burden upon the agency”). Furthermore, the Commission has held that Administrative Law Judges are not required to discuss the testimony of each witness or all exhibits that are presented during the administrative adjudication. *In re Amrep Corp.*, No. 9018, 102 F.T.C. 1362, 1670, 1983 FTC LEXIS 17, at *566-67 (Nov. 2, 1983).

Under Commission Rule 3.51(c)(1), “[a]n initial decision shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable and probative evidence.” 16 C.F.R. § 3.51(c)(1); *see In re Chicago Bridge & Iron Co.*, No. 9300, 138 F.T.C. 1024, 1027 n.4, 2005 FTC LEXIS 215, at *3 n.4 (Jan. 6, 2005). Under the APA, an Administrative Law Judge may not issue an order “except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence.” 5 U.S.C. § 556(d). All findings of fact in this Initial Decision are supported by reliable, probative, and substantial evidence. Citations to specific numbered findings of fact in this Initial Decision are designated by “F.”¹

D. SUMMARY OF INITIAL DECISION

¹ References to the record are abbreviated as follows:

CCX – Complaint Counsel’s Exhibit
RX – Respondent’s Exhibit
JX – Joint Exhibit
Tr. – Transcript of testimony before the Administrative Law Judge
Dep. – Transcript of Deposition
CCB – Complaint Counsel’s Post-Trial Brief
CCRB – Complaint Counsel’s Post-Trial Reply Brief
CCFF – Complaint Counsel’s Proposed Findings of Fact
CCRRFF – Complaint Counsel’s Reply to Respondent’s Proposed Findings of Fact
RB – Respondent’s Post-Trial Brief
RRB – Respondent’s Reply Brief
RFF – Respondent’s Proposed Findings of Fact
RRCCFF – Respondent’s Reply to Complaint Counsel’s Proposed Findings of Fact

Complaint Counsel has demonstrated that until late 2013, Respondent's marketing and promotional materials included claims that plastics treated with the ECM Additive would fully biodegrade, in a landfill, within 9 months to 5 years, and that tests proved such claim. The evidence further shows that these claims were false and unsubstantiated because ECM Plastics will not, in fact, fully biodegrade in a period of 9 months to 5 years in a landfill, as represented, and tests do not prove the claimed biodegradation rate. In addition, the evidence demonstrates that these false and unsubstantiated claims were material to ECM's customers, as well as to downstream sellers and distributors of ECM Plastics. Accordingly, Respondent's claim that ECM Plastics would fully biodegrade, in a landfill, within 9 months to 5 years, and that tests proved such claim, were deceptive in violation of Section 5 of the FTC Act. Moreover, the evidence proves that Respondent passed these deceptive claims on to its customers and others, and is thereby liable for providing them with the means and instrumentalities to deceive others in the stream of commerce.

It is undisputed that Respondent claims that plastics treated with the ECM Additive are "biodegradable," including in a "landfill" (Respondent's "biodegradable" or "biodegradability" claims). The evidence shows that Respondent claimed that tests proved that ECM Plastics are biodegradable. However, Complaint Counsel has failed to prove that Respondent's biodegradability claims are deceptive. Complaint Counsel's theory, consistent with that of the Green Guides, is that Respondent's "unqualified" biodegradable claim (*i.e.*, Respondent's claim that ECM Plastics are "biodegradable," without qualification as to a time period for complete biodegradation after customary disposal) impliedly claims that ECM Plastics would completely break down into elements found in nature in a landfill within one year (the "Implied One Year Claim"), and that this implied claim is deceptive because ECM Plastics will not completely biodegrade in a landfill within one year. The evidence in this case fails to prove Complaint Counsel's theory. The Implied One Year Claim is inconsistent with the language and the overall net impression of the marketing materials at issue; is not proven by Complaint Counsel's proffered consumer survey evidence; and is refuted by high quality survey evidence introduced by Respondent. Because the evidence fails to demonstrate that a significant number of reasonable consumers would interpret Respondent's claim that ECM Plastics are "biodegradable" to be conveying the further, implied message that ECM Plastics will

biodegrade completely into elements found in nature, in a landfill, within one year, Complaint Counsel has not met its burden of proving the Implied One Year Claim. Therefore, Respondent's biodegradability claims cannot be deemed false or unsubstantiated on the theory that ECM Plastics do not completely biodegrade in a landfill within one year.

To the extent Complaint Counsel contends that Respondent's "unqualified" biodegradable claims are false or unsubstantiated, apart from any express or implied time period for complete biodegradation, Complaint Counsel has failed to meet its burden of proof on this issue. First, Complaint Counsel has failed to prove that the ECM Additive does not render plastics biodegradable. The term "biodegradable" is defined by qualified experts in the field to mean that an item degrades via biotic or biological agents, and does not require completion or impose a time restraint. Evaluated in accordance with this scientific definition, the evidence fails to show that Respondent's biodegradability claims are false. Second, Complaint Counsel has failed to prove that the many scientific tests presented by Respondent at trial showing that the ECM Additive renders conventional plastics biodegradable, including in a landfill environment, are inadequate to substantiate Respondent's biodegradability claims. Rather, the evidence shows that Respondent's testing constitutes competent and reliable scientific evidence demonstrating that ECM Plastics are biodegradable, including in a landfill. Thus, Complaint Counsel has failed to prove that Respondent's biodegradability claims are unsubstantiated or that Respondent falsely, or without adequate substantiation, claimed that tests prove that ECM Plastics are biodegradable.

Consistent with the findings in this case, summarized above, the Order issued with this Initial Decision prohibits Respondent from representing that any product or package will completely biodegrade within any time period, or that tests prove such representation, unless such representation is true, not misleading, and, at the time it is made, Respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. The Order will prohibit and prevent Respondent from making the deceptive claims found to have been made in this case, is reasonably related to the unlawful acts or practices found to exist, and is sufficiently clear and precise.

II. FINDINGS OF FACT

A. WITNESSES

1. Complaint Counsel's Fact Witnesses

1. Between February 18, 2014 and May 30, 2014, Complaint Counsel took sixteen fact depositions of testing laboratories and ECM customers all over the country, including Hawaii, California, New York, Ohio, and the District of Columbia. (*See* CCX 799-CCX 805; CCX 809-812; CCX 815; CCX 817; CCX 821-CCX 823).
2. Respondent was unrepresented, or had counsel appear telephonically, at 14 fact witness depositions. (*See* CCX 800; CCX 803; CCX 801; CCX 810; CCX 811; CCX 812; CCX 817; CCX 822; CCX 802; CCX 804; CCX 808; CCX 809; CCX 815; CCX 821).
3. Complaint Counsel did not call any fact witnesses at trial. (Tr. 259).

2. Complaint Counsel's Customer Deposition Testimony

3M Company

4. 3M Company ("3M") is a diverse multi-national manufacturer, headquartered in St. Paul, Minnesota, with \$30 billion in annual sales. 3M employs approximately 80,000 people worldwide. (CCX 821 (3M, Dep. at 12)).
5. Mr. Stephen Joseph is 3M's corporate designee. (CCX 821 (3M, Dep. at 9)).
6. 3M sells products for a variety of markets across a variety of different businesses in many different parts of the world. 3M has several businesses that serve markets such as the industrial and transportation industry. It also has consumer, office, and healthcare businesses, and safety, security and protection services. (CCX 821 (3M, Dep. at 11)).
7. 3M manufactures products that are made of plastics. 3M also manufactures various additives that can be used in conjunction with plastic processing. (CCX 821 (3M, Dep. at 11)).
8. 3M purchased the ECM Additive in February 2010. (CCX 821 (3M, Dep. at 95)).

ANS Plastics Corporation

9. ANS Plastics Corporation ("ANS") is located in New Brunswick, New Jersey. ANS employs 15 people and its annual sales revenue is approximately \$1.9 million. (CCX 822 (ANS, Dep. at 9-10)).

10. Mr. Ramy Samuel, one of the owners and the vice president of ANS, is ANS' corporate designee. (CCX 822 (ANS, Dep. at 7, 9)).
11. ANS manufactures plastic "t-shirt" style shopping bags. (CCX 822 (ANS, Dep. at 8)).
12. The purchasers of ANS manufactured bags are wholesalers, distributors and some end users. ANS considers its end users to be stores, such as restaurants, bagel shops, auto parts stores, supermarkets, pet stores, and pizza stores. (CCX 822 (ANS, Dep. at 8-9, 26)).
13. ANS purchased the ECM Additive in 2009. (CCX 822 (ANS, Dep. at 9)).

BER Plastics, Inc.

14. BER Plastics, Inc. ("BER"), located in Riverdale, New Jersey, manufactures a film that is made into textile packaging for the food industry and clothing industry, and for plastic pillow bags. BER is one of the biggest pillow film producers in the country. (CCX 800 (BER, Dep. at 11)).
15. BER-produced plastic film goes to converters. A converter will place an order with BER for a particular size, gauge, and thickness of material, and the converter then converts the film into a rolled stock of plastic bags, usually with printing on them. (CCX 800 (BER, Dep. at 11)).
16. BER's customers all make low density polyethylene bags with different applications. (CCX 800 (BER, Dep. at 19)).
17. BER employs approximately 22 employees that work in three shifts, 24 hours a day, six days a week. BER makes approximately \$10 million in annual revenue. (CCX 800 (BER, Dep. at 13-14, 15)).
18. Mr. Robert Ringley, who is the vice president of BER, is BER's corporate designee. (CCX 800 (BER, Dep. at 4, 7)).
19. BER uses the ECM Additive in the manufacture of low density polyethylene film for packaging, including packaging for the food industry and the clothing industry. (CCX 800 (BER, Dep. at 10)).
20. BER has 10 customers to which it sold films made with the ECM Additive. (CCX 800 (BER, Dep. at 10)).
21. BER does not generally know the end use of its plastic product. BER does not sell to any end user. (CCX 800 (BER, Dep. at 11)).
22. BER was an ECM Customer from January 2009 until January 2014. (CCX 800 (BER, Dep. at 12)).

D&W Fine Pack, LLC

23. D&W Fine Pack, LLC (“D&W”) is located in Fountain Inn, South Carolina. (CCX 801 (D&W, Dep. at 14)).
24. D&W’s corporate designees are Mr. Donald Kizer, supply chain manager for D&W, and Ms. Ashley Leiti, an employee since 2008 in the fields of marketing, product development, and sales. (CCX 801 (D&W, Dep. at 11); CCX 802 (D&W, Dep. at 14)).
25. D&W is a manufacturer of disposable products for the food service industry. D&W manufactures plastic cutlery, drinking straws, and foam trays. (CCX 801 (D&W, Dep. at 12)).
26. Prior to 2009, D&W was known as “Dispoz-o Products” (“Dispoz-o”). (CCX 801 (D&W, Dep. at 11–12)).
27. Dispoz-o began purchasing the ECM Additive in 2008. (CCX 801 (D&W, Dep. at 17)).
28. In 2008, Dispoz-o had approximately \$83 million in revenue, and 740 employees. (CCX 801 (D&W, Dep. at 15-16)).
29. In 2009, D&W had approximately \$120 million in revenue, and 1,540 employees. (CCX 801 (D&W, Dep. at 16-17)).
30. In August 2009, D&W stopped making the claim “biodegradable” regarding its “Enviroware” line of products containing the ECM Additive. (CCX 802 (D&W, Dep. at 62, 67-68, 135-137)).
31. All products sold by D&W are sold to distributors. In turn, the distributors sell to retail businesses, such as restaurants. The restaurants’ customers do not likely know that they are receiving D&W products. (CCX 802 (Leiti, Dep. at 160-161)).

Down to Earth Organic and Natural

32. Down to Earth Organic and Natural (“DTE”) is a chain of grocery stores, with five stores, four on the island of Oahu, Hawaii, and one on Maui, Hawaii. DTE has approximately 200 employees and annual sales revenue of approximately \$30 million. (CCX 803 (DTE, Dep. at 10-12)).
33. Mr. Frank Santana, the marketing director for DTE, testified on behalf of DTE. (CCX 803 (DTE, Dep. at 8)).
34. DTE promotes organic farming, by selling organic and natural products, and promotes an organic and natural lifestyle. (CCX 803 (DTE, Dep. at 12)).

35. DTE began searching for biodegradable grocery bags in 2008 and began communicating with a distributor of ECM products mid-2008. (CCX 803 (DTE, Dep. at 19-20)).
36. DTE bought their bags made with the ECM Additive from Island Plastic Bags, through Triple F, a distributor. (CCX 803 (DTE, Dep. at 46); CCX 307 at 2).

Eagle Film Extruders Inc.

37. Eagle Film Extruders, Inc. (“Eagle Film”), located in Grand Rapids, Michigan, started its business August 1, 2001. (CCX 804 (Eagle Film, Dep. at 64)).
38. Mr. George Collins, president of Eagle Film, who has been with the company since 2001, is Eagle Film’s corporate designee. (CCX 804 (Eagle Film, Dep. at 9)).
39. Eagle Film manufactures blown plastic film. The blown film is used for countless facets of industry. (CCX 804 (Eagle Film, Dep. at 10)).
40. Generically, Eagle Film sells coating films of varying degrees, including signage. Eagle Film serves customers in such industries as food, medical, pharmaceutical, and health and beauty. (CCX 804 (Eagle Film, Dep. at 10)).
41. In most instances, Eagle Film sells their blown film to a converter, who in turns sells the blown film to somebody else. A converter is typically someone who is going to print, laminate, die cut, or coat those types of services. (CCX 804 (Eagle Film, Dep. at 65-66)).
42. Eagle Film first purchased the ECM Additive around 2008, and has continued purchasing, as needed, into the first quarter of 2014. (CCX 804 (Eagle Film, Dep. at 11-12)).
43. From 2008 to present, Eagle Film’s sales revenue ranged from \$14 to \$18 million. From 2008 to the present, Eagle Film has sold 1.2 million pounds of blown film containing the ECM Additive, out of a total of approximately 67 million pounds of blown film sold. (CCX 804 (Eagle Film, Dep. at 12-13)).

Flexible Plastics, Inc.

44. Flexible Plastics, Inc. (“Flexible”) prints and manufactures plastic bags. All printing is done in-house. (CCX 809 (Flexible, Dep. at 8)).
45. Mr. David Sandry testified on behalf of Flexible. (CCX 809 (Flexible, Dep. at 4)).
46. Flexible has been operating since 1985. Flexible is located in South Central Minnesota. (CCX 809 (Flexible, Dep. at 61)).

47. Flexible purchases rolls of plastic from extruders. (CCX 809 (Flexible, Dep. at 9)).
48. Flexible sells all over the country. Half of Flexible's business is the manufacture of printed poly meat bags for the meat processing industry (including small town butchers and meat markets). (CCX 809 (Flexible, Dep. at 62, 66)).
49. Half of Flexible's business consists of garbage bags that are sold regionally in Minnesota, South Dakota, Iowa and Wisconsin to small cities, municipalities, or small trash haulers, who buy custom printed garbage bags for volume-based refuse collection. (CCX 809 (Flexible, Dep. at 62, 66)).
50. Flexible uses the ECM Additive for its plastic bags. Flexible first purchased the ECM Additive around October 2008, and still uses it. (CCX 809 (Flexible, Dep. at 9, 13)).
51. Flexible uses the ECM Additive for all its "white" bags, which are printed bags with a handle cut out of them, and which Flexible calls its "white trade show bags." Flexible's white bags are sold to 20 different distributors that are advertising specialty companies. Flexible also uses the ECM Additive to manufacture a black garbage bag that it manufactures for a veterinary supply company that sells the bags for animal waste. (CCX 809 (Flexible, Dep. at 9-10, 66)).
52. Flexible's gross receipts for 2013 were approximately \$1.8 million. Ten to twenty percent of that revenue is related to products made with the ECM Additive, depending upon the breakdown of the white versus colored bags. (CCX 809 (Flexible, Dep. at 10-11)).

Free-Flow Packaging International, Inc.

53. Free-Flow Packaging International, Inc. ("FP"), headquartered in Fremont, California, manufactures and sells protective packaging products and packaging systems. In addition to selling plastic products, FP also makes, produces, and designs machinery that makes the products. (CCX 810 (FP, Dep. at 13)).
54. Among FP's plastic products are polystyrene packing "peanuts," polyethylene air cushions, polyethylene foam, and polyethylene "bubble," all of which are used for protection of items during shipping. (CCX 810 (FP, Dep. at 13-14)).
55. Mr. James Blood, the senior vice president and general counsel of FP, is FP's corporate designee. (CCX 810 (FP, Dep. at 12-13, 50, 214)).
56. FP's customers are distributors that distribute and sell to anybody who ships products in boxes. (CCX 810 (FP, Dep. at 15)).
57. FP does not sell any packaging products directly to end-use consumers. (CCX 810 (FP, Dep. at 18)).

58. FP began purchasing the ECM Additive in 2008. From 2008 through 2013, FP purchased approximately 2.2 million dollars' worth of ECM Additive. (CCX 810 (FP, Dep. at 15, 19)).
59. FP sold loosefill product and air cushion product with the ECM Additive. (CCX 810 (FP, Dep. at 17, 22)).
60. FP engaged the services of Stevens Ecology, Dr. Timothy Barber of Environ, and Eden Laboratories, to test the biodegradability of FP's ECM Plastic products. (CCX 810 (FP, Dep. at 57-60, 87, 163); Poth, Tr. 1436, 1475-1479).
61. In 2013, approximately 25% to 30% of FP's total revenues were derived from FP's biodegradable product lines. Because FP was not profitable in 2013, the biodegradable products did not produce a significant amount of profit for FP in 2013. (CCX 810 (FP, Dep. at 211)).

Islands Plastics Bags, Inc.

62. Island Plastics Bags, Inc. ("IPB") manufactures and sells high density and low density polyethylene bags in various dimensions and gauges. In addition, IPB manufactures and sells plastic cutlery. (CCX 811 (IPB, Dep. at 9-10)).
63. Mr. Adrian Hong, general manager for Island Plastic Bags, is IPB's corporate designee. (CCX 811 (IPB, Dep. at 9, 109-110)).
64. IPB is a family business based near Honolulu, Hawaii and has been in business since 1992. (CCX 811 (IPB, Dep. at 9)).
65. IPB has a manufacturing plant in Hawaii and manufacturing partners in China. IPB bags and cutlery are manufactured in China then shipped to IPB's facility in Honolulu or Guam. From there, the products are sent to either distributors or retailers. (CCX 811 (IPB, Dep. at 10-11)).
66. IPB's major customers are distributors, including Triple F. These distributors then sell to other customers, including small shops, restaurants, bars, and grocery stores and grocery chains. (CCX 811 (IPB, Dep. at 56, 59, 66, 70)).
67. IPB first purchased the ECM Additive to manufacture bags in 2008 and has purchased it every year thereafter through 2014. (CCX 811 (IPB, Dep. at 12)).

Kappus Plastic Company, Inc.

68. Kappus Plastic Company, Inc. ("Kappus"), located in Hampton Township, New Jersey, manufactures calendered rigid vinyl sheeting – plastic sheeting that is primarily used in the credit card industry. (CCX 812 (Kappus, Dep. at 11)).

69. Kappus has been manufacturing since 1970. (CCX 812 (Kappus, Dep. at 12)).
70. Ms. Annette Gormly, the vice president of Kappus, is Kappus's corporate designee. (CCX 812 (Kappus, Dep. at 5, 8)).
71. Kappus's customers are primarily credit card companies or card manufacturers. Kappus does not manufacture credit cards on the plastic sheeting. (CCX 812 (Kappus, Dep. at 12)).
72. Kappus's customers are companies, banks, and department stores. (CCX 812 (Kappus, Dep. at 12)).
73. The credit card companies' end-use consumers fall into two categories: users of bank-issued credit cards and purchasers of gift cards sold by retailers at their counters. (CCX 812 (Kappus, Dep. at 12-13)).
74. Kappus purchased the ECM Additive between 2009 and 2013. Kappus's approximate annual revenue from 2009 to 2013 was less than \$5 million. (CCX 812 (Kappus, Dep. at 13)).
75. Kappus manufactured a plastic product containing the ECM Additive called "BioRigidVinyl." (CCX 812 (Kappus, Dep. at 33-34)).

Quest Plastics, Inc.

76. Quest Plastics, Inc. ("Quest") is an injection molding company that primarily makes caps for aerosols, fragrances and cosmetic packaging. Quest takes thermoplastic raw material and converts it into products such as caps, closures, lipstick cases, and other custom molding. (CCX 817 (Quest, Dep. at 9-10)).
77. Mr. James Bean, the president and owner of Quest, is Quest's corporate designee. (CCX 817 (Quest, Dep. at 7, 11)).
78. Quest has been in business for 24 years and is currently located in Torrington, Connecticut. Quest has approximately 30 employees, most of whom work as machine operators or material handlers on the floor. (CCX 817 (Quest, Dep. at 10-12, 14-15)).
79. Quest's customers are mostly small companies in the cosmetics and fragrance industries. Quest deals with larger customers indirectly as a subcontractor of a subcontractor. (CCX 817 (Quest, Dep. at 19, 23)).
80. Quest sells its products primarily to companies in the eyelet industry that makes metal perfume caps. Quest makes the plastic liners that go inside those caps. (CCX 817 (Quest, Dep. at 18)).

81. Quest does not sell any products to consumers. Quest is “fairly removed” from the end-use customer. (CCX 817 (Quest, Dep. at 41-42)).
82. Quest’s annual revenue for 2013 was \$3.1 million. (CCX 817 (Quest, Dep. at 12)).
83. Quest purchased the ECM Additive to serve a customer, Technical Sourcing Solutions, which wanted to manufacture biodegradable golf tees. The customer initially contacted Quest to manufacture golf tees out of reprocessed styrene. The customer added the request for the biodegradable aspect subsequently. Quest has been manufacturing the golf tees since the beginning of 2013. Manufacturing the golf tees represents roughly \$4,000 in revenue for Quest. (CCX 817 (Quest, Dep. at 19-22)).

3. Respondent’s Fact Witnesses

a. Mr. Robert Sinclair

84. Mr. Robert Sinclair is the president, director, and chief executive officer of Respondent ECM BioFilms, Inc. (“ECM”) or (“Respondent”). (Sinclair, Tr. 745).
85. Mr. Sinclair assumed leadership of ECM in 2000. He manages all daily operations of the company and is primarily responsible for communicating with clients concerning ECM’s technology. (Sinclair, Tr. 745, 757; Sullivan, Tr. 699).
86. Mr. Sinclair earned his J.D. from Case Western Reserve University Law School, and his undergraduate degree from Dartmouth College. (Sinclair, Tr. 746).
87. Mr. Sinclair, although not a scientist, has familiarity with scientific issues and experiments. Mr. Sinclair took many classes in biology sciences while in college, developed resistant strains of bacteria for projects, and taught science for six years in the Cleveland and East Cleveland public school systems. (Sinclair, Tr. 760).
88. Mr. Sinclair is a member of the ASTM² D20 committee, the committee on plastics; is the chairman of the ASTM D20.92 subcommittee on plastic terminology; and is on the ASTM D20.96 subcommittee on bio-based and biodegradable plastics, the ASTM D20.95 subcommittee on plastic recyclability, and the ASTM E60 and ASTM E50 committees on sustainability and other environmental issues. (Sinclair, Tr. 778-779).

b. Mr. Kenneth Sullivan

89. Mr. Kenneth Charles Sullivan, Jr. is Chief Financial Officer (“CFO”) of ECM. Mr. Sullivan has been the CFO of ECM since May of 2009 and is responsible for all the accounting, finance, and treasury functions at ECM. (Sullivan, Tr. 690-691).

² ASTM is an abbreviation for ASTM International formerly known as the American Society for Testing and Materials, a voluntary membership organization that develops standard test methods and specifications. (JX 4 at 2).

c. Dr. Timothy Barber

90. Dr. Timothy Barber is presently employed at Environ International Corporation as a principal scientist and office manager. Dr. Barber has a B.S. in chemistry, with a focus in organic chemistry, from State University of New York at Binghamton and obtained a Ph.D. in marine science with a specialization in chemistry from the University of South Florida. Dr. Barber wrote a dissertation on the biogeochemistry of low-molecular-weight hydrocarbons in wetland environments. (Barber, Tr. 2004-2009).
91. Dr. Barber worked at the Florida Marine Research Institute as an analyst and then at Entix as a senior chemist before taking a position with McLaren/Hart-ChemRisk (“McLaren/Hart”) in Cleveland, Ohio. At the Florida Marine Research Institute, Dr. Barber’s responsibilities included collecting data, analyzing data, developing reports, and conducting laboratory work. At Entix, Dr. Barber’s responsibilities included analyzing data, writing reports, and conducting fieldwork. (Barber, Tr. 2006-2007).
92. McLaren/Hart, which no longer exists, was an environmental consultancy that worked primarily for private industry. Dr. Barber was a consultant at McLaren/Hart assisting companies with pollution problems, developing work plans, collecting data, analyzing that information, and writing reports. (Barber, Tr. 2007).
93. Dr. Barber has written approximately thirty peer-reviewed articles on various topics related to anthropogenic or manmade chemicals in the environment, potential toxicity associated with those, as well as fate and transport, persistence, bioaccumulation and ecological risks of those chemicals. (Barber, Tr. 2011).
94. Dr. Barber is a member of the American Chemical Society, the Environmental Toxicology and Chemistry Organization, the International Society of Ecological Economics, and the International Society of Environmental Forensics. (Barber, Tr. 2012).

d. Mr. Thomas Poth

95. Mr. Thomas Poth owns and is the laboratory director of Eden Research Laboratories (“ERL”), formerly Zia Environmental Laboratories. ERL performs ASTM D5511 testing.³ (Poth, Tr. 1437, 1447-1448).
96. Before starting ERL, Mr. Poth managed a laboratory called Assaigai Laboratory in Albuquerque, New Mexico and later managed a laboratory in Midland, Texas. In those roles, Mr. Poth oversaw sales, marketing, and laboratory testing. Mr. Poth then ran the science and engineering design department for RW Technologies, a company that developed water treatment systems using cutting-edge technology. (Poth, Tr. 1438-1439).

³ ERL’s ASTM tests are discussed *infra* F. 1046-1216.

97. ERL works with businesses such as Adidas Group, Reebok, Pactiv, Saucony, and Georgia Pacific, and other, smaller companies. (Poth, Tr. 1443).

e. Mr. Alan Johnson

98. Mr. Alan Charles Johnson is the laboratory director of Northeast Laboratories (“NE Labs”), where he has worked since 1977 and is responsible for overseeing all laboratory operations. Mr. Johnson oversees all biodegradability testing, and often does some of the work himself. (Johnson, Tr. 1554, 1561).

99. NE Labs conducts biodegradation testing, and began doing so in 2005. (Johnson, Tr. 1560).

100. NE Labs performs ASTM D5511 and ASTM D5538 biodegradability testing.⁴ (Johnson, Tr. 1561).

4. Complaint Counsel’s Expert Witnesses

a. Dr. Thabet Tolaymat

101. Dr. Thabet Tolaymat has a B.S. degree and a Ph.D. in Environmental Engineering from the University of Florida. (CCX 893 (Tolaymat Expert Report at 4)).

102. Dr. Tolaymat has been employed by the United States Environmental Protection Agency (“EPA”) from 2004 to present as an environmental engineer and researcher in the fields of solid waste management, bioreactor landfills, waste containment performance, construction and demolition waste landfills, and the fate and transport of environmental pollutants. (CCX 893 (Tolaymat Expert Report at 4)).

103. Dr. Tolaymat’s academic research and research for the EPA has focused primarily on waste disposal and landfills, particularly in evaluating the performance of solid waste containment units (municipal solid waste, hazardous waste and ash mono-fill landfills), bioreactor landfills, organic pollutants, co-disposal of solid waste and hazardous waste, and construction and demolition waste. (CCX 893 (Tolaymat Expert Report at 4)).

104. As part of his responsibilities for the EPA, Dr. Tolaymat provided expert advice regarding solid waste disposal for the World Bank and the United States Agency for International Development (“USAID”), as well as to the countries of Jordan, Taiwan, Russia, and the city of Hong Kong. (CCX 893 (Tolaymat Expert Report at 4-5)).

105. Dr. Tolaymat has authored over fifty journal publications and EPA reports, including peer-reviewed articles on landfill design and management and peer-reviewed articles on biodegradation testing under landfill conditions. (CCX 893 (Tolaymat Expert Report at 4-5); Tolaymat Tr. 115).

⁴ NE Labs’ ASTM tests are discussed *infra* F. 1217-1424.

106. A significant part of Dr. Tolaymat's education, training, and experience has involved conducting and evaluating tests that purport to show biodegradation and/or replicate landfill conditions, including tests based on large bench scale solid waste decomposition (lysimeter) studies. (CCX 893 (Tolaymat Expert Report at 5)).

b. Dr. Stephen McCarthy

107. Dr. Stephen McCarthy has an undergraduate degree in textile chemistry from Southeastern Massachusetts University, a master's degree in chemical engineering from Princeton University, and a Ph.D. in polymer engineering from Case Western Reserve University. (CCX 891 (McCarthy Expert Report at 3)).
108. Dr. McCarthy has been a professor of plastics engineering at the University of Massachusetts Lowell for 30 years. There, he teaches graduate level courses in plastics engineering, including the mechanical behavior of polymers, and polymers and the environment. Dr. McCarthy has served as the director of the University's Bioplastics Institute and Medical Plastics Research Center, the director of the University's Institute for Plastics Innovation, and the Graduate Coordinator for the Plastics Engineering Department. (CCX 891 (McCarthy Expert Report at 3-4); McCarthy, Tr. 359).
109. Dr. McCarthy is also the director at the University of Massachusetts Lowell's Biodegradable Polymer Research Center, where he coordinates and supervises research on biodegradable polymers. His research has led to seven patents related to polymers or plastics engineering. (CCX 891 (McCarthy Expert Report at 4)).
110. Dr. McCarthy is the editor of the *Journal of Polymers and the Environment*, the official journal for the BioEnvironmental Polymer Society, which promotes research to develop degradable polymers. He has authored or co-authored more than a hundred publications related to polymer or plastics engineering, including peer-reviewed articles specifically on biodegradable blends. (CCX 891 (McCarthy Expert Report at 4); McCarthy, Tr. 370).
111. Dr. McCarthy is a member of the American Society for Testing and Materials (now known as ASTM International, Inc.) and has belonged to other professional associations related to biodegradable polymers and plastics engineering, including the Bio/Environmentally Degradable Polymer Society, Society of Plastics Engineers, Biomaterials Society, American Chemical Society, and the Materials Research Society. (CCX 891 (McCarthy Expert Report at 4-5)).

c. Dr. Shane Frederick

112. Dr. Shane Frederick received a Ph.D. in decision sciences from Carnegie Mellon University. (CCX 890 (Frederick Expert Report at 3)).
113. Dr. Frederick is a professor at Yale University's School of Management, where he has taught courses in consumer behavior, behavioral economics, and marketing. He has

worked as a research assistant in the Psychology Department at Princeton University and was a lecturer at the Woodrow Wilson School of Public and International Affairs. (CCX 890 (Frederick Expert Report at 3)).

114. Dr. Frederick has studied and published extensively concerning judgment and decision-making, with a focus on the role of cognitive abilities on preferences, preference measurements, and cognitive biases. He has published extensively in peer-reviewed journals, including: *Journal of Marketing Research*, *Journal of Consumer Research*, *Journal of Consumer Psychology*, *Management Science*, *Psychological Science*, *Journal of Experimental Psychology: General & Organizational Behavior and Human Decision Processes*. In addition, Dr. Frederick is on the editorial board of the *Journal of Organizational Behavior and Human Decision Processes*, and *Economic Psychology*, and an associate editor at *Management Science*. (CCX 890 (Frederick Expert Report at 3)).
115. Dr. Frederick's work involves conducting and evaluating survey research, including internet-based research tools such as Google Consumer Surveys and Amazon Mechanical Turk. Dr. Frederick has conducted hundreds of studies using both paper and pencil and web-based survey tools. (CCX 890 (Frederick Expert Report at 3-4)).
116. Dr. Frederick is affiliated with Yale's Center for Consumer Insights, which partners with corporations and academics to help understand the evolving dynamics of consumer behavior, and has advised corporations including Pepsico, Kimberly Clark, and AMC Networks on incorporating insights from consumer psychology. (CCX 890 (Frederick Expert Report at 4)).

d. Dr. Frederick Michel

117. Dr. Frederick C. Michel earned an undergraduate degree in chemical engineering and in biochemistry and a master's degree and a Ph.D. in chemical engineering from Michigan State University. Dr. Michel then did a postdoctoral research fellowship at the National Science Foundation Center for Microbial Ecology. (CCX 895 (Michel Rebuttal Expert Report at 3); Michel, Tr. 2831).
118. Dr. Michel is currently a tenured associate professor in the Department of Food, Agriculture and Biological Engineering at the Ohio State University, with an adjunct appointment in the Department of Chemical and Biomolecular Engineering. (CCX 895 (Michel Rebuttal Expert Report at 3)).
119. For the past 25 years, Dr. Michel has conducted research on a wide range of environmental topics, including the biodegradation of plastics, bioplastics, biofoams and natural fibers in anaerobic digesters, composting systems and in soils. Dr. Michel has authored over 40 peer-reviewed publications and many other reports and papers in these areas. (CCX 895 (Michel Rebuttal Expert Report at 3)).

120. Dr. Michel serves as editor of the *Compost Science & Utilization Journal*, attends U.S. Composting Council meetings, and has consulted for the U.S. Composting Council for six or seven years. Dr. Michel was the co-editor for proceedings at the 2002 Symposium on Composting and Compost Utilization and the section editor for Test Methods for the Examination of Composting and Compost. (Michel, Tr. 2834, 2837, 2918-2921).
121. Dr. Michel is the head of the compost research group for Ohio Agricultural Research and Development Center-Food, Agricultural, and Biological Engineering. Dr. Michel has consulted for AllTreat Organic Composting, DuPont, a member of the Biodegradable Products Institute (“BPI”), Indian Summer Composting, Amylex, and International Paper, companies that sell compostable products. (Michel, Tr. 2918-2922).

5. Respondent’s Expert Witnesses

a. Dr. Ranajit Sahu

122. Dr. Ranajit Sahu earned his undergraduate degree in mechanical engineering from the Indian Institute of Technology and his master’s degree and Ph.D. in combustion from the California Institute of Technology. Within the coursework of these post-graduate programs, Dr. Sahu studied polymer science, specifically the applicability of organic chemistry and chemical engineering, and the manufacturing of polymers into useful articles. (Sahu, Tr. 1730-1734).
123. Dr. Sahu is a Qualified Environmental Professional certified by the Air and Waste Management Association and a Certified Environmental Manager certified by the State of Nevada. (Sahu, Tr. 1748, 1758).
124. Dr. Sahu has worked for Parsons Corporation, a large engineering and architectural firm, where he performed environmental consulting, often in the area of solid waste disposal in landfills, incinerators, and other disposal methods, and where he managed a testing group, which conducted field-testing, laboratory testing, third-party laboratory analysis, and data evaluation. (Sahu, Tr. 1735-1737).
125. Since December 1999, Dr. Sahu has been an independent consultant, providing a variety of consulting services in a wide range of fields. Dr. Sahu has extensive experience in the field of polymer science, including as an independent consultant working with various bathroom fixture manufacturers to assess the degradation and manufacturing waste of their polystyrene and styrene-based products, and as an independent contractor with fuel industry consortia. (Sahu, Tr. 1737-1741).
126. Dr. Sahu has conducted multiple projects dealing with waste containment in landfills, including municipal solid waste landfills and worked on multiple projects involving landfill gas extraction, treatment, and measurement. (Sahu, Tr. 1741-1744).

127. Dr. Sahu currently works with a small development company managing a major project involving the siting, construction and closure of a four million cubic yard landfill. (Sahu, Tr. 1744-1745).
128. Dr. Sahu has been retained and qualified as an expert witness in environmental matters in multiple administrative proceedings and several state and federal judicial proceedings. (Sahu, Tr. 1747).
129. Dr. Sahu has been a member of ASTM for three or four years, and currently serves on numerous committees. Dr. Sahu has advised ASTM on the interaction of the fuel mix with plastics and polymers in fuel systems. (Sahu, Tr. 1750).
130. Through his involvement with ASTM and his work as an independent consultant, Dr. Sahu is very familiar with a wide range of ASTM standards and protocols. (Sahu, Tr. 1750-1751).

b. Dr. Morton Barlaz

131. Dr. Morton Barlaz has an undergraduate degree in chemical engineering from the University of Michigan and a master's degree and Ph.D. in civil and environmental engineering from the University of Wisconsin. Dr. Barlaz's Ph.D. focused on the microbiology of solid waste decomposition in landfills. (Barlaz, Tr. 2168).
132. Dr. Barlaz has published approximately 115 peer-reviewed publications and one-half to two-thirds of those are associated with some aspect of biodegradation. (Barlaz, Tr. 2169-2170).
133. Dr. Barlaz is professor and head of the Department of Civil Construction and Environmental Engineering at North Carolina State University. (Barlaz, Tr. 2167).
134. Dr. Barlaz runs a research program for North Carolina State University in the areas of solid waste management, biodegradation, decomposition, chemical and biological reactions in landfills, and the application of life cycle analysis to solid waste management systems. (Barlaz, Tr. 2168).
135. In his research program at North Carolina State University, Dr. Barlaz has conducted numerous tests on the biodegradation of various components of municipal solid waste, including: anaerobic biodegradability tests at reactor scale, vessels from one-half to two and a half gallons, measuring methane generation from municipal solid waste or specific components of municipal solid waste; and biochemical methane potential tests, which are tests of anaerobic biodegradability. (Barlaz, Tr. 2170-2171).
136. Dr. Barlaz has been hired by the EPA as an expert in the fields of waste management and biodegradation. (RX 853 (Barlaz Expert Report at 27-28)).

137. Dr. Barlaz is familiar with ASTM and its protocols, and has drafted a protocol for radiolabel testing of biodegradability that was ultimately adopted by ASTM. (Barlaz, Tr. 2172).
138. Dr. Barlaz recently completed a project funded by the Plastics Environmental Council to evaluate the effect of different inocula on biodegradation rates for the purpose of developing a protocol for biodegradability testing that is more flexible than the ASTM 5511 protocol. (Barlaz, Tr. 2172-2173).
139. Complaint Counsel's expert, Dr. Tolaymat, recognizes Dr. Barlaz as an authority in the field of biodegradability of municipal solid waste and landfill gas, has consulted Dr. Barlaz on a number of questions concerning landfill biodegradation and has accepted a number of Dr. Barlaz's recommendations to Dr. Tolaymat's work product for the EPA. (Tolaymat, Tr. 156, 184, 233-234).

c. Dr. Ryan Burnette

140. Dr. Ryan Burnette earned his undergraduate degree in biochemistry and two minors in chemistry and environmental sciences and his Ph.D. in biochemistry and molecular biology from Virginia Polytechnic Institute and State University. Dr. Burnette's doctoral dissertation focused on signal transduction via enzymatic pathways with response to environmental stimulus, how organisms respond to their environment, the signaling cascades, the small molecules, the enzymes involved in that signal transduction pathway, applied across a variety of organisms. (Burnette, Tr. 2360-2361).
141. Dr. Burnette has worked with numerous pre-eminent microbiologists in the field of anaerobic microbiology and much of his own research involves anaerobic microorganisms. (Burnette, Tr. 2365-2366).
142. Dr. Burnette has worked for Hatcher-Sayre, Inc., an environmental consulting firm, as an environmental scientist testing soil samples, landfills, groundwater, and water. (Burnette, Tr. 2366).
143. Dr. Burnette is currently the vice president of the Biological Safety Division at WIRB-Copernicus Group ("WCG"), a clinical services organization that provides support to a variety of biopharmaceutical and academic research programs. Dr. Burnette and the WCG assist customers with the design of laboratories, containment, disinfection, decontamination, and infection prevention. (Burnette, Tr. 2367-2368).

d. Dr. David Stewart

144. Dr. David Stewart received an undergraduate degree in psychology from the University of Louisiana at Monroe, then Northeast Louisiana University, and earned a master's degree in general psychology from Baylor University and a Ph.D. in personality and social psychology from Baylor University. (Stewart, Tr. 2494-2495).

145. Dr. Stewart is currently the president's professor of Marketing and Business Law at Loyola Marymount University where he teaches advertising and promotion management, marketing strategy, and introductory MBA marketing. (Stewart, Tr. 2492, 2496).
146. Dr. Stewart has taught extensively in the field of conduct and methodology of surveys, teaching marketing research at the undergraduate, graduate, and doctoral levels, and has taught courses on research methodology, psychometrics, and experimental design. (Stewart, Tr. 2498-2499).
147. Prior to his work in education, Dr. Stewart was a research manager for Needham, Harper & Steers Advertising in Chicago (now DDB Chicago). In that capacity, Dr. Stewart provided internal consultation services on research design, conducted an annual omnibus lifestyle survey of consumers in the United States, and tested creative content prior to its presentation to clients. (Stewart, Tr. 2499-2500).
148. Dr. Stewart has served as the editor of the *Journal of Marketing* and the *Journal of the Academy of Marketing Science* and is currently serving as the editor of the *Journal of Public Policy and Marketing*. As editor, Dr. Stewart has reviewed those papers and the survey methodology used in their preparation. Approximately half of the papers submitted to those three journals use survey methodology as a basis for empirical presentation. (Stewart, Tr. 2500-2501).
149. Dr. Stewart has been published in more than 200 peer-reviewed journals, proceedings volumes, and book chapters, over half of which contained survey research. (Stewart, Tr. 2501).
150. Dr. Stewart is a member of the following academic and trade associations: The American Marketing Association; The American Statistical Association; INFORMS (management science professional organization); The Association for Consumer Research; The Society for Consumer Psychology; The Classification Society; The Society for Personality and Social Psychology; and The Academy of Management. He is a past president of the Society for Consumer Psychology and of the Academic Council for the American Marketing Association. (Stewart, Tr. 2500-2502).
151. In the 1990s, Dr. Stewart served two, three-year terms as a member of the joint professional advisory committee to the United States Census, and in that role advised the Census Bureau in the design of its various data collection activities, including the census. (Stewart, Tr. 2503-2504).

B. BACKGROUND ON ECM AND ECM'S PRODUCT AND SALES

1. Respondent ECM BioFilms, Inc. and the ECM Additive

152. Respondent ECM BioFilms, Inc. is an Ohio-based corporation, started by Patrick Riley of Micro-Tech Research, Inc. ("Micro-Tech") in 1998. Its principal place of business is

listed as Victoria Place, Suite 225, 100 South Park Place, Painesville, OH 44077. (Answer ¶ 1; Sinclair, Tr. 747, 756-757).

153. Micro-Tech owns the ECM Additive technology, and ECM licenses the technology from Micro-Tech. (JX 3).
154. On average, ECM has employed six employees. (CCX 819 (Sinclair, Dep. 327-328)).
155. ECM's employees include Robert Sinclair (president and CEO), Kenneth Sullivan (CFO), and one or two administrative employees and one or two sales people, including Tom Nealis, director of sales. (Sullivan, Tr. 698-700).
156. ECM manufactures, advertises, offers for sale, sells, and distributes additives for plastics,⁵ including "MasterBatch Pellets." (Answer ¶ 2; JX 3; JX 4).
157. "MasterBatch" is a concentrate of additives dispersed within a carrier polymer, which is then blended into the base polymer or resin intended to be modified. (JX 4).
158. "ECM Additive" means the product, including "MasterBatch Pellets," that ECM manufactures and sells to plastic manufacturers and distributors. (JX 3; JX 4).
159. The ECM Additive is biodegradable. (JX 3).
160. The formula for the ECM Additive is a trade secret. ECM chose not to patent the ECM Additive because scientists had convinced ECM that it could not be reverse-engineered. (Sinclair, Tr. 777-778).
161. Analytical laboratories attempted to determine the specific ingredients of the ECM Additive, but none has identified the correct formula. (Sinclair, Tr. 777-778; RX 563).
162. Plastics and/or plastic products that contain an ECM Additive are known as "ECM Plastic(s)." (JX 3; JX 4).
163. ECM sells only plastic additive pellets and no other products. (Sinclair, Tr. 766).

2. ECM Supply Chain

164. ECM sells the ECM Additive exclusively to companies that manufacture plastic (or companies that have plastic manufactured for them) and to some distributors who sell the additive to plastic manufacturers ("ECM's Customers"). (Sullivan, Tr. 695-696; Sinclair, Tr. 758-759).
165. ECM's Customers are plastics manufacturers who sell to multiple other, second-layer manufacturers and/or distributors. ECM Plastics will often pass through at least two

⁵ Detailed findings on plastics and polymers are *infra* F. 173-182.

levels in the supply chain, and as many as four or five layers, before ever reaching an end-use consumer. (Sinclair, Tr. 785-786; CCX 811 (Hong, Dep. at 10-11, 112); Sullivan, Tr. 707-708; RX 471).

166. ECM's Customers purchase the ECM Additive in either sixty-five kilogram (65kg) drums or five hundred kilogram (500kg) pallet boxes. (Sinclair, Tr. 764-765).
167. Respondent does not dispute that ECM has sold its product to approximately 300 Customers. (*See* CCFF 23; RRCCFF 23).
168. The ECM Additive is an industrial product used by plastic manufacturers only and is not sold to the general public. (Sullivan, Tr. 695-696, 703-704, 707; Sinclair, Tr. 758-759, 764-767).
169. ECM has no storefront or brick and mortar office. (Sinclair, Tr. 765-766).
170. It can be difficult to determine who is the end-use consumer of some ECM Plastics. For example, it is unclear when a company such as Amazon ships a product in a box containing an ECM Plastic air-cushioned pillow, whether the end-use consumer of the ECM Plastic is Amazon or the recipient of the product from Amazon in a box that contains the air-cushioned pillow. (Sinclair, Tr. 785-786).
171. Some of ECM's plastic manufacturer customers use the ECM Additive to make products for purchase by retailers that sell consumer products, such as grocery stores and restaurants. Other ECM plastic manufacturer customers only make the plastic (such as plastic film), which they sell to other product and package manufacturers, who in turn sell to packagers, retailers, or end-use consumers. (F. 11-12, 19, 21, 25, 31, 40-41, 51, 56-59, 65-67, 68, 71-73, 83; CCX 818 (Sinclair, Dep. at 217); *see also* CCX 800 (BER, Dep. at 10-11)).
172. ECM does not advertise or sell to consumers. (Sullivan, Tr. 707; F. 164-166, 168; *see also* F. 207, 210).

3. Plastics

173. Plastic is a generic term used to describe high-molecular weight polymers. (CCX 891 (McCarthy Expert Report at 10)).
174. A polymer is a substance that has a molecular structure consisting chiefly or entirely of a large number of similar units (monomers) bonded together. (JX 4; RX 458).
175. Plastic additives are materials added to a plastic polymer to produce a desired change in material properties or characteristics. (JX 4).
176. Bioplastic is a type of plastic derived from biological substances rather than petroleum, generally said to be biodegradable. (JX 4).

177. There are various plastics, but synthetic (laboratory-made), petroleum-based plastics are by far the most common. (CCX 891 (McCarthy Expert Report 10); (McCarthy, Tr. 397) (stating that petroleum-based plastics make up the bulk of the plastics used today)).
178. Plastics derived from petrochemicals are strong, durable, and inexpensive to manufacture, which make them ideally suited for commercial applications. These petroleum-based plastics (“conventional plastics”) represent over 90% of the commercial plastic market. (CCX 891 (McCarthy Expert Report at 10); McCarthy, Tr. 397 (stating that petroleum-based plastics make up the bulk of the plastics used today)).
179. Conventional plastics refers to polyolefin plastics that are untreated and not intended to be biodegradable. (JX 4).
180. The most common types of conventional plastics are high-molecular weight polyethylene (“PE”), used to manufacture plastic bags, packaging material, and bottles; and polyurethane (“PUR”), used in medical and industrial applications such as adhesives and paint. Also common is polypropylene (“PP”), used for disposable cups, clothing, storage containers, and DVD covers; and polystyrene (“PS”), which is used to make disposable cutlery and cups, foam packing peanuts, insulation, and fast food containers. (JX 3; CCX 891 (McCarthy Expert Report at 10-11); McCarthy, Tr. 397, 398 (listing examples of products made from different types of plastics)).
181. In North America, conventional plastics like PE or PP primarily come from domestic natural gas and are substances that contain varying formations of hydrocarbon bonds or polymers. (RX 458).
182. The characteristics that make conventional plastics commercially useful – strength, durability, synthetically derived from petrochemicals – make them highly resistant to biological attack. (CCX 891 (McCarthy Expert Report at 12); CCX 880 at 2; McCarthy, Tr. 397-99; Burnette, Tr. 2432-2433).

4. ECM Plastics

183. Plastic manufacturers blend the ECM Additive or MasterBatch Pellets into the base polymer or resin intended to be modified. (JX 4).
184. ECM offers a “load rate” of 70% in its pellets, meaning that every pellet will contain approximately 70% of the active biodegradable formula, along with 30% conventional polymer resin. (CCX 818 (Sinclair, Dep. 118-120)).
185. ECM directs plastics manufacturers to blend the ECM pellets into the manufacturer’s plastics at a 1% rate by weight, to obtain a uniform distribution of the pellet throughout the plastic and at a level that ensures maximum utility without compromising the plastic’s integrity. (Sinclair, Tr. 765, 775-776, 783, 787-788, 790; CCX 20; RX 137).

186. Blending of the ECM Additive requires no additional equipment from plastics manufacturers, so long as the manufacturer is already equipped to blend other additives. (RX 137).
187. For all plastics properly manufactured with the ECM Additive, at least 1% of the final plastic will include the ECM Additive based on weight. (Sinclair, Tr. 783; RX 678).
188. Like many other plastic additives (*e.g.*, coloring agents), manufacturers introduce the ECM Additive into the plastic during the initial blending process. (Sinclair, Tr. 797; RX 135).
189. Plastics are commonly manufactured using one of several techniques, including extrusion molding, injection molding, or blow molding. (Sahu, Tr. 1816-1817; RX 656).
190. Extrusion molding involves a heated plastic compound continuously injected through a long die cast in the desired shape. (Sahu, Tr. 1816; RX 783).
191. There are many different types of plastic polymers, but where ECM Additives are used, the additive is intended to be mixed uniformly throughout the plastic polymer through a heated blending process, as a coloring additive would be. (Sahu, Tr. 1813-1814; RX 520).
192. ECM's customers manufacture many plastic polymers, but the bulk of the plastics incorporating ECM's technology consist of polypropylene ("PP"), polystyrene ("PS"), and polyethylenes ("PE"). (RX 522).
193. Over seventy percent of ECM Plastics are PE film or meshing plastics. Companies frequently use ECM's technology in plastics such as films (*e.g.*, grocery "t-shirt" bags, packaging cushions, etc.). (RX 520; RX 471; RX 849).
194. Manufacturing some plastics with the ECM Additive can require more process modifications than others, so ECM works with potential customers to prevent scorching and other manufacturing problems. (Sinclair, Tr. 762).
195. Although the process for manufacturing plastics with the ECM Additive is an involved process, most ECM customers can accomplish it quite readily. (Sinclair, Tr. 762).

C. ECM'S CLAIMS

1. Background

196. Americans generate about 32 million tons of plastic waste every year, more than half of which ends up in landfills. (JX 3 at 2).

197. Landfills are disposal sites where solid waste is buried between containment layers consisting of soil and other materials to eliminate contamination of the surrounding land. (JX 4 at 4).
198. Municipal Solid Waste (“MSW”) is waste consisting of everyday items discarded by the public, including, *e.g.*, product packaging, grass clippings, furniture, clothing, food scraps, newspapers, etc., but excluding hazardous and commercial waste. (JX 4 at 5).
199. Landfills continue to be the dominant method for managing MSW in the United States. (JX 3 at 2).
200. Due to their recalcitrant nature, plastics pose a growing disposal and environmental pollution problem. (JX 3 at 3).
201. In response to demand, various materials have been introduced to improve the biodegradability of plastics. These include conventional plastics amended with additives meant to enhance biodegradability (*e.g.*, photodegradable, oxo-degradable, and biodegradable additives), bio-based plastics, and natural fiber composites. (JX 3 at 2-3).
202. ECM’s competitors include other additive companies, replacement resin companies, and oxo-degradable companies. (Sinclair, Tr. 775-777).
203. There are competing technologies available, such as bioplastics, which are biodegradable plastic polymers or resins derived from biological substances instead of petroleum. (Sahu, Tr. 1758; RX 748; RX 678).
204. However, bioplastic technologies come at a substantial cost, (Sullivan, Tr. 697; Sinclair, Tr. 768; RX 335), and bioplastics are ordinarily not suitable for strong plastics that are meant for applications that require endurance and lack of malleability. (Sahu, Tr. 1821-1824).
205. ECM’s Customers are motivated to produce biodegradable plastics to meet what they perceive to be their customers’ demand for such products. (CCX 822 (ANS, Dep. at 12-13) (“[m]y customers would call me, [and ask,] do you have [a] biodegradable bag, do you have a green bag[?]”); CCX 809 (Flexible, Dep. at 72) (“There is a lot of backlash against plastic bags. A lot of people don’t like plastic bags.”); CCX 800 (BER, Dep. at 18) (“[Customers] were looking for a product they could mark as degradable to say that they were being, you know, environmentally sensitive. It’s very important in their packaging, that they could...print it right on the package, you know, biodegradable.”); CCX 822 (ANS, Dep. at 13) (“People . . . don’t want to pollute the environment and this [biodegradable plastics] is what they choose to buy.”)).

2. ECM's Marketing and Sales Process

206. ECM markets the ECM Additive to potential Customers through its website, flyers, brochures, and sales presentations ("Marketing Materials"). (Sullivan, Tr. 700, 735-736).
207. ECM's website, which is its principal advertising tool, is geared toward plastics manufacturers and people in the plastics industry. ECM does not advertise to end-use consumers. (Sullivan, Tr. 707).
208. The ECM Additive cannot be purchased over the Internet. (Sinclair, Tr. 766).
209. ECM's advertising budget is approximately \$12,000 per year, which covers periodic updates to the website and other Marketing Materials, as well as the occasional purchase of promotional "give aways" to Customers or shareholders. (Sullivan, Tr. 700).
210. ECM does not do nationwide advertising or advertise in trade journals, or do any "consumer-type" advertising. (Sullivan, Tr. 700-701).
211. In most cases, ECM's potential Customers initiate the first contact with ECM. (Sinclair, Tr. 761).
212. ECM employs a sales manager, Tom Nealis, who has the title of director of sales. However, ECM employs no active sales force. (Sullivan, Tr. 698-700, 761).
213. The process by which a prospective Customer becomes an actual Customer commonly begins with website inquiries submitted by plastics manufacturers (or companies that subcontract the manufacturing to others). The ECM website provides a standard "web inquiry" form that is automatically emailed to ECM. (RX 139 at 2; Sullivan, Tr. 701-702).
214. A potential Customer contact is generally first handled by Mr. Nealis of ECM, who provides the potential customer basic information, such as pricing, and sales literature, and addresses other initial issues. As the sales process comes to involve the technical issues, the potential customer is directed to Mr. Sinclair. (RX 13; Sinclair, Tr. 761; Sullivan, Tr. 701-702).
215. Mr. Sinclair may also respond to potential Customer web inquiries. (RX 139).
216. As the sales process proceeds, the potential Customer will run some sample plastics incorporating the ECM Additive through its manufacturing process, to test whether it can properly manufacture plastics with the ECM Additive. ECM provides samples of the ECM Additive for this purpose. (Sinclair, Tr. 762; Sullivan, Tr. 703-705).

217. As part of the sales process, the potential Customer will ordinarily test ECM Plastics against plastics manufactured without the ECM Additive, to make sure that incorporating the ECM Additive will not adversely affect the plastic product's appearance, strength, or brittleness, or otherwise change the attributes of the plastic product that the potential Customer produces. (Sullivan, Tr. 703, 709; Sinclair, Tr. 762-763).
218. Mr. Alan Poje of ECM advised Customers on plastics extrusion (the mechanics of adjusting the manufacturing process to incorporate the ECM Additive). (JX 3 at 4).
219. ECM Customers perform product performance testing on their finished ECM Additive-infused plastic before ordering the ECM Additive, to be sure that incorporating the ECM Additive does not change other attributes of their product. (Sullivan, Tr. 704-705).
220. ECM Customers perform functionality and qualitative testing, comparing the ECM Additive-infused plastic with their original product. Functionality and qualitative tests will determine whether the plastic containing the ECM Additive is functioning up to the necessary specifications and that there has been no specification deterioration. (Sinclair, Tr. 762-763).
221. Some ECM Customers have conducted biodegradability testing through outside laboratories. (Poth, Tr. 1481; Johnson, Tr. 1576-1577).
222. On average, for a first-time sale, the process from initial contact with a potential Customer to that business becoming an actual Customer of ECM takes six months to a year, and may sometimes take several years. (Sinclair, Tr. 767).
223. Orders for the ECM Additive are completed over the phone and followed-up with a confirmation fax or email. (Sinclair, Tr. 766).
224. Customers place orders directly with ECM and the product is shipped directly from the ECM manufacturing site in Carpentersville, Illinois. (Sinclair, Tr. 765).
225. Mr. Sinclair often provides potential customers with information and answers their questions as well. (RX 93; RX 110; RX 122).
226. Mr. Sinclair will often work with manufacturers' marketing people to educate them on ECM's product and to help them "position" the manufactured plastic product with the manufacturers' customers. (Sinclair, Tr. 763-764).
227. ECM regularly corresponds with customers by email or phone to provide them with any information they require. (E.g., RX 113, RX 115; RX 117-118; RX 126-129; RX 132-135).

228. ECM offered, as a marketing tool to its potential Customers, to meet with potential Customer's customers, to answer questions. (CCX 813 (Nealis, Dep. at 49)).
229. Prior to processing an order, ECM double-checks that its customer understands that the proper loading rate is one percent (1%) by weight. (Sinclair, Tr. 765).
230. ECM provides its Customers with manufacturing instructions to ensure that the product made with the ECM Additive is distributed throughout the plastic and that the ECM Additive is not scorched. (Sinclair, Tr. 762, 783, 787-790).
231. ECM Customers are normally long-term accounts, as opposed to one-time purchasers, that purchase again from ECM, as needed to meet demand from the Customers' customers for biodegradable plastics. (Sullivan, Tr. 705-706).

3. "Biodegradable" and "Biodegradable in a Landfill"

232. ECM claims that its additive technology renders plastic products "biodegradable." (JX 3 at 3).
233. ECM tells its Customers that adding the ECM Additive to their plastics will render their plastic products "biodegradable" without negatively affecting product performance. (Sinclair, Tr. 767).
234. ECM's website states that ECM's additive technology "renders . . . plastic products biodegradable . . ." (CCX 3; CCX 15; CCX 19 (ECM website screenshots); CCX 20 (ECM website screenshots); CCX 24 (ECM website screenshots); CCX 25 (ECM website screenshots)).
235. Each page of ECM's website, ecmbiofilms.com, states at the top: "Additives for Manufacturing Biodegradable Plastic Packaging and Products," with a description of the additive technology. (CCX 22; CCX 19; CCX 24).
236. ECM has distributed brochures aimed at "green business," promising that its technology yields "biodegradable" plastic products that are "priced competitively with, and have the same mechanical characteristics as, traditional non-degradable products." (JX 3 at 3).
237. ECM claims that plastics treated with the ECM Additive will "biodegrade" in a landfill. (JX 3 at 3; CCX 3; CCX 6; CCX 7 at 7; CCX 11; CCX 12; CCX 15; CCX 19 at 5; CCX 242 at 15; CCX 276; CCX 372).
238. On October 12, 2012, the FTC published revisions to the FTC's Guides For The Use Of Environmental Marketing Claims with regard to "degradable" claims ("Green Guides"). The Green Guides added the following: "It is deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal. Unqualified

degradable claims for items that are customarily disposed in landfills, incinerators, and recycling facilities are deceptive because these locations do not present conditions in which complete decomposition will occur within one year.” (16 C.F.R. § 260.8(c)).

239. Prior to issuance of the revised Green Guides in October 2012, ECM’s logo depicted a green tree, with the name “ECM” in the “tree” and the word “biodegradable” below at the base of the “tree.” (CCX 8; *see* CCX 3; CCX 259A). Below is a representation of this ECM logo:



240. Mr. Sinclair does not know of any ECM Customer who believes that ECM Plastics completely decompose into elements found in nature within one year of customary disposal. (Sinclair, Tr. 785).
241. An implied claim that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year, is not reasonably clear or conspicuous on the face of the Marketing Materials claiming that ECM Plastics are “biodegradable,” and/or “biodegradable” in a “landfill.” A confident conclusion cannot be drawn that a significant minority of reasonable ECM Customers or other reasonable consumers would interpret these claims of ECM to convey the message that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year. (F. 234-237).
242. An implied claim that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year, is not reasonably clear or conspicuous on the face of the ECM logo. A confident conclusion cannot be drawn that a significant minority of reasonable ECM Customers or other reasonable consumers would interpret ECM’s logo to convey the message that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year. (F. 239).
243. Based on a facial analysis alone, and considering the language and images of ECM’s “biodegradable” logo, the overall net impression of the logo is that ECM Plastics are “biodegradable,” and the logo is not reasonably interpreted to be claiming that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year. (F. 239).
244. The claim that ECM intended to convey with the logo is that plastics made with the ECM product are biodegradable. (CCX 819 (Sinclair, Dep. at 432)).

4. **Complete Biodegradation in a Landfill Within “9 Months to 5 Years” and “In Some Period Greater Than a Year”**

245. Prior to the revision to the Green Guides in October 2012 (*see* F. 238), ECM’s Marketing Materials included express representations that plastics treated with the ECM Additive will “fully biodegrade,” in a “landfill,” in a period of “9 months to 5 years.” For example, a one-page flyer, CCX 3, appeared as follows:

MASTERBATCH PELLETS

ECM BioFilms, Inc.
 Manufacturer of Additives That Make Standard Plastic Resins Biodegradable

ECM BioFilms, Inc. sells additives to plastic product manufacturers which allow them to offer their customers biodegradable plastic products that can be priced competitively with, and have the same mechanical characteristics as, their traditional, non-degradable products. The revolutionary additive technology, when combined as a one-percent load to the most widely-used plastic resins, renders the finished plastic products biodegradable while maintaining their other desired characteristics.

Plastic products made with ECM additives

- Fully biodegrade in 9 months to 5 years.
- Fully biodegrade wherever they are disposed of where other things are biodegrading (anaerobically and aerobically):
 - In Landfills,
 - In Compost (backyard as well as commercial facilities),
 - Buried in the ground or littered,
 - Agricultural and erosion-control settings.
- Are recyclable.
- Can be made with recycled resins.
- Do not use heat, light or mechanical stress to break them down.
- Do not require special handling (unlike PLA and oxo-degradable products).
- Do not contain heavy metals (unlike most oxo-degradable products).

Plastic Bag Film Samples Buried in Same Soil for a Month

Without ECM	With ECM
673V 11899 7262 18.70 H 3 C	673V 11899 7262 18.70 H 3 C

The process continues until the plastic products become part of the organic components of the soil just like biodegraded sticks or other pieces of wood become part of the soil.

ECM BIOFILMS

ECM BioFilms, Inc.
 Victoria Place – Suite 225
 100 South Park Place
 Painesville, OH 44077, U.S.A.
 Website: www.ecmbiofilms.com

For Sales or Information, contact:
 Phone: 440-350-1400
 Fax: 440-350-1444
 E-mail: sales@ecmbiofilms.com
 U.S. Toll Free: 888-220-2792

ECM
 Biodegradable

Plastic products bearing this logo are wholly biodegradable. Insist on it for the products you use.

CONFIDENTIAL

ECM-FTC-000017
 CCX - 3

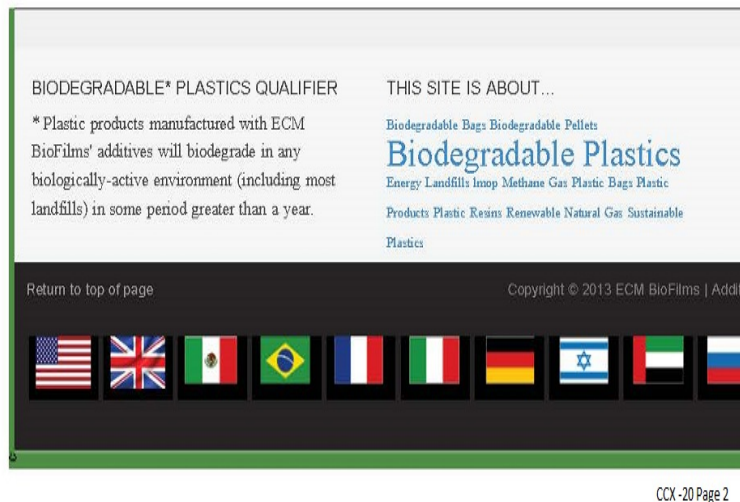
(CCX 3; *see also* CCX 5; CCX 6; CCX 7 at 6; CCX 10, CCX 11; CCX 19 at 5; CCX 24 at 6; CCX 25 at 104, 117, 203, 208; CCX 259A; *see also* CCX 809 (Flexible, Dep. at 20); *see also* CCX 822 (ANS, Dep. at 13); CCX 812 (Kappus, Dep. at 14)).

246. Based on the express language used in ECM’s Marketing Materials prior to October 2012, set forth in F. 245 above, and having viewed these Marketing Materials in their

entirety and considered the language, images, and the interaction of all the different elements in these materials, the overall net impression is that plastics treated with the ECM Additive will fully biodegrade, in a landfill, within a time period ranging from 9 months to 5 years. (F. 245; CCX 3; CCX 5; CCX 6; CCX 7; CCX 10; CCX 11; CCX 19; CCX 24; CCX 25; CCX 259A).

247. ECM admits that it previously represented to its Customers that the ECM Additive would cause plastics to biodegrade in 9 months to 5 years. (Sinclair, Tr. 768).
248. At least some of ECM's Marketing Materials included language advising that the rate of biodegradation was dependent on various factors, such as soil conditions and the availability of microbes in the soil. ECM's "Technology Page," immediately after claiming that ECM Plastics "break down in approximately 9 month[s] to 5 years in nearly all landfills . . .," states: "All sorts of factors determine the amount of microbes available in the soil and the soil conditions determine the rate of degradation. The plastic products made with ECM technology basically rely on the microbes in the soil" (CCX 6; CCX 11 at 2).
249. Based on the overall net impression, the language described in F. 248, in context, represents that various factors affect the point in time at which full biodegradation will occur within the 9 months to 5 years' time range. This language does not materially modify, qualify, or disclaim the claim that the period of "9 months to 5 years" was the applicable time range. Thus, such language does not alter the overall net impression conveyed by Respondent that ECM Plastics will fully biodegrade, including in a landfill, within 9 months to 5 years. (F. 246; Sullivan, Tr. 718 (acknowledging that the ECM email stating ECM Plastics "will typically biodegrade in nine months to five years upon their disposal depending on the conditions within the environment they are disposed," means "exactly" what it says, that "it will – it would be in that nine month to five-year period. . . . It does not say 'longer' than that period.")).
250. ECM advised its Customer D&W Fine Pack that the time period of 9 months to 5 years for biodegradation represented a "bell curve," that depended on conditions. (CCX 802 (Leiti, Dep. at 71-73)).
251. ECM understood the revised Green Guides, issued in October 2012, to require a product to fully biodegrade within one year in order to make an "unqualified" "biodegradable" claim. Because ECM Plastics would not fully biodegrade in a landfill within one year, ECM determined that it had to "qualify" its claim to satisfy the revised Green Guides. (Sinclair, Tr. 771).
252. In response to the issuance of the revised Green Guides in October 2012, ECM began revising its Marketing Materials to omit references to a biodegradation rate of "9 months to 5 years" and undertook to revise its biodegradability claims in an effort to meet the guidelines in the revised Green Guides. (Sinclair, Tr. 769-770; JX 3 at 3).

253. ECM’s revised Marketing Materials placed an asterisk wherever the word “biodegradable,” appeared, which provided the following text: “Plastic products manufactured with [the ECM Additive] will biodegrade in any biologically-active environment (including most landfills) in some period greater than a year.” An example of this revision is reprinted below:



(CCX 20).

254. ECM’s website, as revised after issuance of the revised Green Guides, included the following language:

The basic concept is that biodegradation is a natural process that occurs around the world but at various speeds due to various conditions. Plastics with our additives behave like sticks, branches or trunks of trees. Due to this fact, we do not guarantee any particular time because the time depends on the same factors that the biodegradation of woods and most other organic materials on earth depend – ambient biota and other environmental conditions. Under specific composting conditions with additional accelerants sprayed on them, some customers have reported biodegradation in as little as a couple of months. Under the more usual, commercial composting conditions using high heat processes, a time frame of around some period greater than a year is a reasonable expectation.

(RX 681 at 61).

255. An implied claim that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year is not reasonably clear or conspicuous on the face of ECM’s claim, as set forth in ECM’s Marketing Materials revised after publication of the revised Green Guides, that: “Plastic products manufactured with [the ECM

Additive] will biodegrade in any biologically-active environment (including most landfills) in some period greater than a year.” It cannot be concluded with confidence that a significant minority of reasonable ECM Customers or other reasonable consumers viewing this claim would interpret the claim to convey the message that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year. F. 253.

256. ECM also revised its logo (F. 239) after publication of the revised Green Guides in October 2012, by placing the following text directly underneath the word “biodegradable”: “Plastic products manufactured with [the ECM Additive] will biodegrade in any biologically-active environment (including most landfills) in some period greater than a year.” (CCX 13). A depiction of the revised logo is set forth below:



257. An implied claim that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year is not reasonably clear or conspicuous on the face of the ECM logo, as revised after publication of the revised Green Guides. A review of the revised ECM logo, considering all the elements, does not lead to a confident conclusion that a significant minority of reasonable ECM Customers or other reasonable consumers would interpret the statement in the logo that ECM Plastics will biodegrade including in most landfills, “in some period greater than a year,” to convey the message that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year. (F. 256).
258. Based on a facial analysis alone, and considering the language and images of ECM’s “biodegradable” logo as revised after issuance of the revised Green Guides in October 2012, the overall net impression of the logo is that ECM Plastics are “biodegradable” and will biodegrade, including in a landfill, in some period greater than a year, and the logo is not reasonably interpreted to be claiming that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year. (F. 256).
259. ECM permanently discontinued its claims of biodegradation within “9 months to 5 years,” in approximately November or December 2013, when it removed such claims from its website. On a few occasions in 2013, Mr. Nealis of ECM mistakenly sent out older brochures that contained the “9 months to 5 years” claim. (CCX 819 (Sinclair Dep. at 275-276); Sinclair, Tr. 770-771; CCX 813 (Nealis, Dep. at 244-245)).

260. ECM intends to not make the “9 months to 5 years” claim again at any time in the future. (Sinclair, Tr. 771).
261. In October 2012, upon issuance of the revised Green Guides, ECM notified its Customers that, based on the new Green Guides, they should qualify their “biodegradable” claims, because the time frame of a year or less, in the revised Green Guides, did not “fit” their products. (Sinclair, Tr. 1610-1611).
262. Following publication of the revised Green Guides, ECM issued an email to its Customers which stated in part:

If you have evidence that your products with our additives will fully biodegrade in one year or less in the environment where it will be customarily disposed you may still make an unqualified claim of “biodegradable” for those products. But for most of our customers’ plastic products with our additives whose customary disposal is in a landfill, they will not be able to use that unqualified claim.

(RX 35-RX 77).

263. No customer has ever asked Mr. Nealis to provide a narrower time frame than some period greater than a year. (CCX 813 (Nealis, Dep. at 111)).
264. No customer has ever asked ECM what “some period greater than a year” means. (CCX 813 (Nealis, Dep. at 112)).

5. “Tests Prove” ECM’s Claims

265. Prior to publication of the revised Green Guides in October 2012, based on the overall net impression of ECM’s Marketing Materials, ECM claimed that independent tests, including ASTM D5511, proved that the ECM Additive caused ECM Plastics to fully biodegrade in a landfill in a period of 9 months to 5 years. CCX 6, titled, “Our Technology for the Biodegradation of Plastic Products,” refers to specific ASTM testing and further includes the following language: “ECM engaged several renowned testing laboratories to independently establish the biodegradability of plastics made with ECM’s additives. The tests concluded that the products were fully biodegradable under both aerobic and anaerobic conditions. . . . The plastic products made with our additives will break down in approximately 9 month[s] to 5 years in nearly all landfills” *See also* CCX 5 (referring to “9 months to 5 years” biodegradation rate and then stating: “[W]e certify the full biodegradation of most all plastic products manufactured with at least a one percent load of our additives. We can certify this situation due to the internal and external studies that have cost us hundreds of thousands of dollars. . . . We have had the various test data analyzed by independent scientists and their conclusions and some of the data have been sent to you in the presentation package and are what we base our certification on.”). (CCX 5; CCX 6; *see also* CCX 10; CCX 11).

- 266. ECM issued a “Certificate of Biodegradability” to its Customers (F. 269). Every Customer that confirmed that it would manufacture its plastic in accordance with ECM’s manufacturing specifications would be issued ECM’s Certificate of Biodegradability. (CCX 1; CCX 14; Sinclair, Tr. 783-784; *see also* CCX 455; CCX 727 at 6; CCX 800 (BER, Dep. at 29); CCX 802 (D&W, Dep. at 20-23); CCX 803 (DTE, Dep. at 25-26); CCX 804 (Eagle, Dep. at 23-24); CCX 809 (Flexible, Dep. at 40-41); CCX 810 (FP, Dep. at 33); CCX 811 (IPB, Dep. at 12-18); CCX 812 (Kappus, Dep. at 24-25); CCX 813 (Nealis, Dep. at 49); CCX 817 (Quest, Dep. at 29); CCX 822 (ANS, Dep. at 17-18).
- 267. ECM did not offer ECM’s Certificate of Biodegradability to customers of ECM’s Customers. (CCX 813 (Nealis, Dep. at 49)).
- 268. The purpose of the Certificate of Biodegradability was to show that ECM Plastics had been tested and are biodegradable. ECM’s Customers wanted to see data from an outside lab. (CCX 818 (Sinclair, Dep. at 93); CCX 813 (Nealis, Dep. at 20)).
- 269. The form of the Certificate appears as follows:

CONFIDENTIAL



ECM-FTC-000015
CCX - 1

(CCX 1)

- 270. After issuance of the revised Green Guides in October 2012, ECM revised the Certificate of Biodegradability to incorporate the revised ECM logo (*see* F. 256) referring to biodegradation in “some period greater than a year.” (CCX 14).

271. ECM's Certificate of Biodegradability defines a degradable plastic in the same way as biodegradability is defined by ASTM. (Sinclair, Tr. 785; CCX 1; CCX 14; F. 269).
272. ECM's "Certificate of Biodegradability" claims to "certify that numerous plastic samples, submitted by ECM Biofilms, Inc., have been tested by independent laboratories in accordance with standard test methods approved by ASTM, ISO [International Organisation for Standardization] and other such standardization bodies . . ." Among the test methods cited was the ASTM D5511 test. (CCX 1; CCX 14).
273. ECM's Certificate of Biodegradability states that the tests "certif[y] that plastic products manufactured with ECM additives can be marketed as biodegradable" and the certificate itself can be "used by [the customer] to validate its claims to the biodegradability" of ECM Plastic. (CCX 1; CCX 14).
274. Based on the language and images of ECM's Certificate of Biodegradability, as it appeared prior to issuance of the revised Green Guides, the overall net impression of the Certificate of Biodegradability is that ECM Plastics are biodegradable and that testing by independent laboratories proves that ECM Plastics are biodegradable. (F. 269; CCX 1; *see also* RPF 319 and RB at 26, 188 (admitting that Certificate of Biodegradability claims ECM Plastics are "biodegradable")).
275. Implied claims that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year, and that independent testing proves such claim, are not reasonably clear or conspicuous on the face of ECM's Certificate of Biodegradability, including as revised after issuance of the revised Green Guides in October 2012. A review of ECM's Certificate of Biodegradability, including as revised, and considering all its elements, does not lead to a confident conclusion that a significant minority of reasonable ECM Customers or other reasonable consumers would interpret ECM's Certificate of Biodegradability, including as revised, to include the messages that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year, and/or that independent testing proves that ECM Plastics completely biodegrade in a landfill within one year. (F. 269-274).
276. Based on a facial analysis alone, and considering the language and images of ECM's Certificate of Biodegradability, including as revised after issuance of the revised Green Guides in October 2012 (to include revised ECM logo), ECM's Certificate of Biodegradability is not reasonably interpreted as claiming that ECM Plastics completely biodegrade into elements found in nature, in a landfill, within one year, and/or that independent testing proves that ECM Plastics completely biodegrade in a landfill within one year. (F. 258, 269-270).

277. ECM often provided the “McLaren/Hart” or “ChemRisk” assessment to its Customers. (JX 3 at 4; Sinclair, Tr. 1702-1703; *e.g.*, CCX 334; CCX 335; CCX 336; CCX 337; CCX 338; CCX 339).⁶

6. “Passing Down” of ECM’s Claims

278. ECM advertises on its website, www.ecmbiofilms.com. (*E.g.*, CCX 25; CCX 725).

279. The ECM website is publicly available and has been visited by at least some end-use consumers. (CCX 326; CCX 819 (Sinclair, Dep. at 312-314)).

280. ECM has provided its Customers with its Marketing Materials, and its logo, and encouraged its Customers to use these materials for its Customers’ marketing of ECM Plastics to their own customers. (CCX 816 (Poje, Dep. at 37); CCX 822 (ANS, Dep. at 20-21); CCX 350 (ECM providing flyers that “may be used for marketing”); CCX 364 (“You and your customers can use the attached logos...and their related promotional material.”); CCX 368 (giving customer’s “marketing department” permission to use ECM’s flyer “as they see fit”); CCX 369 (recommending making sales “using the tools that we have given you”); CCX 370 (attaching “sales tools you may find helpful for your sales team”); CCX 373 (attaching “a good tool for your sales team”); CCX 387 (attaching marketing materials “for your sales team”); CCX 390 (attaching “flyer that might be useful for your sales people”)).

281. In some instances, ECM would offer to provide, and/or would provide, guidance on advertising copy. (CCX 283 (offering to Customer to “work together on particular language that [downstream customer] would want”); CCX 307 (correcting advertising claim drafted by downstream customer Down-to-Earth); CCX 308 (suggesting specific copy for biodegradable claim on bags); CCX 309 (same); CCX 320 (offering to review information to place on packaging, and advising to include ECM web address on packaging); CCX 397 (approving Customer’s claim that bags will decompose in 9 months to 5 years); CCX 562 (suggesting specific advertising language to place on bag made of ECM Plastic)).

282. When asked by Customers, Mr. Sinclair has provided opinions or feedback about labeling language being proposed for ECM Plastic products. (Sinclair, Tr. 786-787; RX 90; RX 117).

283. Most ECM Customers have their own specific individuals performing marketing functions. (Sinclair, Tr. 763).

284. ECM has provided its logo for use by ECM’s Customers. Some Customers asked ECM for the logo to place on their product. (CCX 816 (Poje, Dep. at 52); *see, e.g.*, CCX 320

⁶ The ChemRisk or McLaren/Hart report refers to the February 1999 report commissioned by Microtech Research and prepared by ChemRisk, a service of McLaren/Hart, Inc., titled, “Ecological Assessment of ECM Plastic.” (CCX 266E; Sinclair, Tr. 1702-1703).

(ECM transmitting logo by email); *see also* CCX 316; CCX 319; CCX 320; CCX 358; CCX 359; CCX 361; CCX 364).

285. Respondent admits that the following exhibits introduced by Complaint Counsel represent photographs of ECM Plastic products that reach end-use consumers. These exhibits demonstrate that some ECM Customers placed generalized “biodegradable” claims that did not state any biodegradation rate, including the ECM “biodegradable” logo, on plastics made with the ECM Additive, including products that would reach end-use consumers, such as plastic dinnerware, straws, and “clam shell” carry-out containers, restaurant and grocery bags, trash bags, and shampoo and conditioner bottles. (CCX 97-100, 103-104, 107; 109-151; RB at 171-172 n.215).
286. Some of ECM’s plastic manufacturer customers used a “9 months to 5 years” in a “landfill” claim in advertising to their own customers, frequently in language mirroring that in ECM Marketing Materials. (CCX 34 (Memo from AirPouch plastic film manufacturers to “Sales and Distributors” referring to ECM Additive and claiming biodegradation within 9 months to 5 years claims for AirPouch “Sales and Marketing Alert”); CCX 37 (website ad for BioPVC biodegradable plastic film referring to breakdown in a landfill within 9 months to 5 years); CCX 38 (Buckeye Packaging advertisement claiming biodegradable packaging materials will breakdown in a landfill within 9 months to 5 years); CCX 50 (Flambeau Industrial and Packaging Group landfill claim in ad for storage cases and boxes); CCX 57 (Kappus Plastic Company advertisement for BioRigid Vinyl stating it will breakdown within 9 months to 5 years); CCX 105 (Placson Films advertisement for films and bags that have “been tested to successfully biodegrade within 9 months to 5 years under most environmental conditions”); RX 418 (9 months to 5 years and landfill claims on FP International ad for Cello brand air cushions); CCX 565 (FP International advertisement for polystyrene loosefill claiming biodegradation “within 9 months to 60 months in the presence of other microorganisms, when present in a landfill or in soil”); *see also* CCX 812 (Kappus, Dep. at 22-23) (stating that Kappus printed ECM’s information, and put the information on a letter to customers on Kappus letterhead, including the 9 months to 5 year time period for biodegradation); CCX 812 (Kappus, Dep. at 35-36) (stating that the Kappus advertisement for BioRigidVinyl claiming breakdown within 9 months to 5 years was based on ECM marketing materials)).
287. ECM Customer Eagle Film Extruders, Inc. (“Eagle Film”) (F. 37-43) would forward ECM’s Marketing Materials directly to its customers, so that they could contact ECM themselves. Eagle Film would direct its customers to contact Mr. Sinclair at ECM to answer questions. (CCX 804 (Eagle, Dep. at 21-22, 32)).
288. Customers of ECM Customer ANS Plastic Corporation (“ANS”) (F. 9-13) contacted ECM directly. (CCX 822 (ANS, Dep. at 23-24)).
289. ANS manufactured plastic bags printed with the ECM logo, which customers of ANS, such as grocery stores or pet stores, would give to their customers. ANS estimates that it manufactured “millions” of such bags. (CCX 822 (ANS, Dep. at 26-27)).

290. ECM Customer Flexible Plastics, Inc. (“Flexible”) (F. 44-52) asked for and received a copy of ECM’s logo, and placed the logo on cases of plastic bags that Flexible sold to its veterinary supply customer. (CCX 809 (Flexible, Dep. at 24-28)).
291. When customers of Flexible had questions about the biodegradability of Flexible’s bags, the standard practice was to send the customer to ECM’s website. Flexible had sent a copy of some technical and pricing information it had received from ECM to its “white bag” distributors (*see* F. 51), which were all being made with the ECM Additive. Flexible did not distribute ECM Marketing Materials to its customers. (CCX 809 (Flexible, Dep. at 32-33, 38-40)).
292. ECM Customer Island Plastic Bags (“IPB”), a plastic bag manufacturer (F. 62-67), stated in an advertisement for IPB’s “Bio Ultra Blend” trash liners, that it was using “ECM BioFilms’ technology” which will cause the liners to “completely degrade [including in a landfill] in 9 months to 5 years depending on conditions.” IPB further stated in an advertisement that “[t]ests by independent laboratories conclude that the films treated with the ECM additive are biodegradable under short and long-term conditions where the film is exposed to oxygen and over a longer period of time without oxygen depending on the amount of exposure to other biodegrading materials.” (CCX 627; *see also* CCX 811 (IPB, Dep. at 40) (IPB provided ECM marketing materials containing claim of biodegradation in a landfill within 9 months to 5 years to downstream customer Down to Earth)).
293. IPB and a distributor, Triple F, met with Down to Earth (“DTE”), a grocery store chain (F. 32-36), regarding use of the ECM Additive for DTE’s plastic grocery bags. IPB told DTE that ECM Plastics are biodegradable, and that biodegradation would occur within 9 months to 5 years. DTE was encouraged to visit ECM’s website, which DTE did. DTE also received pricing sheets, a certificate, and general information concerning ECM products and technology, as attachments to an email originating from ECM and forwarded to DTE. (CCX 803 (DTE, Dep. at 22-26)).
294. IPB informed DTE that IPB had been certified by ECM. DTE interpreted the sentence in the form certificate that “plastic samples submitted by ECM BioFilms, Inc. have been tested by independent laboratories in accordance with standard test methods approved by ASTM, ISO and other such standardization bodies to determine the rate and extent of biodegradation of plastic materials,” to mean that ECM had tested their materials using accepted industry standards. (CCX 803 (DTE Dep. at 26-28)).
295. DTE did not interpret ECM’s Certificate of Biodegradability to be providing a time frame of 9 months to 5 years for biodegradation. (CCX 803 (DTE, Dep. at 32)).
296. DTE downloaded and reviewed the McLaren/Hart report (F. 277) from ECM’s website, prior to deciding to purchase bags made from ECM Plastic. (CCX 803 (DTE, Dep. at 33-34)).

297. Beginning on April 22, 2009, DTE placed ECM's logo, along with a claim of complete biodegradation within 9 months to 5 years in a landfill, on its grocery bags, which are placed at the check-out counter for use by DTE's customers in packing their purchased groceries. (CCX 307 (DTE asking for logo and providing proposed language for bag); CCX 44; CCX 45; CCX 803 (DTE Dep. at 40-43, 45, 47-48; CCX 811 (IPB Dep. at 44-47 (describing artwork for DTE grocery bags))).
298. DTE sent its artwork for its plastic bags to ECM, noting "FYI." ECM did not recommend any changes with respect to the "9 months to 5 years" in a "landfill" claim. (CCX 803 (DTE, Dep. at 50-56)).
299. DTE advised ECM by email of the text that DTE intended to have printed on DTE's plastic bags, stating "I'd like to include the ECM logo (which I have) and a statement explaining the attributes of interest to consumers," including the information that the bag will "fully biodegrade in 9 months to 5 years, depending on the amount of oxygen they are exposed to" DTE asked for ECM's comments or suggestions for the text. (CCX 307 at 2).
300. DTE's supplier, IPB (F. 62-67), manufactured ECM Plastic bags reflecting the "nine months to five years" claim for "50 to 100" different customers. In total, IPB alone manufactured "about 10 million" such bags. (CCX 811 (IPB, Tr. 57, 99)).
301. DTE purchased about 700,000 plastic bags reflecting the 9 months to 5 years claim, each year for approximately 5 years, for a total of 3.5 million bags. DTE has somewhere between 50,000 and 100,000 unique customers that would have received at least one of DTE's plastic bags. (CCX 803 (DTE, Dep. at 48-49)).
302. It is reasonable to infer that DTE's customers were exposed to the 9 months to five years claim. (F. 297, 300-301).
303. DTE used language from ECM Marketing Materials to prepare a press release in connection with DTE's "roll-out" of biodegradable plastic grocery bags on Earth Day, 2009, and provided a draft of the release to ECM and to IPB for review. DTE prepared the press release because it wanted people to know that DTE was doing its part to contribute to a more "environmentally sound operation." The press release included a link to ECM's website and noted that "[t]ests by independent laboratories concluded that [ECM Plastics] are biodegradable under short- and long-term conditions where the film is exposed to oxygen, and over a longer period of time without oxygen, depending on the amount of exposure to other biodegrading materials." (CCX 307; CCX 497; CCX 803 (DTE, Dep. at 64-66)).
304. DTE sent ECM and others, including IPB, an email attaching the draft press release referred to in F. 303 because the press release was making technical claims about ECM's technology, as to which DTE did not feel "expert enough." Mr. Poje of ECM responded to DTE by email, "I like it!" (CCX 803 (DTE, Dep. at 69-71); CCX 497).

305. Some of ECM's Customers provided the Certificate of Biodegradability to their downstream customers, including for the purpose of proving to their customers that the ECM Plastic is biodegradable. (CCX 822 (ANS, Dep. at 18; 28; CCX 800 (BER, Dep. at 30) ("Q. Why did you give [the certificate] to each customer that purchased the product? A. To certify that it was biodegradable . . ."); CCX 800 (BER, Dep. at 18) ("Originally one of my customers asks how can you prove that my bag is biodegradable, they get the certificate..."); CCX 804 (Eagle, Dep. at 25-26) ("Q. And is this a certificate that you forward to your own customers who are interested in buying blown film containing the ECM additive? A. Yeah."); CCX 811 (IBP, Dep. at 18) ("Q. In fact, IPB regularly sent copies of the certificate to prospective customers of Island Plastic Bags. A. Yes. Q. IPB did that to provide prospective customers with assurance that ECM bags would in fact biodegrade. A. Yes."); CCX 809 (Flexible, Dep. at 50-51 ("[I]f somebody wants to see evidence that our bags are biodegradable, this is what I would provide to them."); CCX 34 ("Airpouch Sales & Marketing Alert" stating that "[s]ending this [certificate] to your customer should be your first response for validation"); CCX 257 (ECM Customer providing certificate to its customer); CCX 258 (same); CCX 261 (same); CCX 345 (Customer asking ECM for certificate because it "[h]elps me with sales."); CCX 351 (Customer asking ECM for certificate "hot rush back to me as my customer in California is going to drop our products without some sort of proof that our products [are] biodegradable"))).
306. ECM Customer Kappus Plastic Company ("Kappus") (F. 68-75) did not provide its ECM Certificate of Biodegradability directly to any of Kappus' customers, but if a customer purchased from Kappus, Kappus would provide certification. (CCX 812 (Kappus, Dep. at 26-29, 45-46)).
307. A Certificate of Biodegradability, issued to SL Plastic Co. LTD, appeared on the website of the company "Champ," an apparent wholesaler of golf tees. (CCX 39 at 5).
308. Some ECM Customers have copied the language from the Certificate of Biodegradability verbatim in their own marketing materials. (CCX 812 (Kappus, Dep. at 22) ("We basically took the information that ECM had on their paperwork and moved it to our letterhead, transposed it on our letterhead . . ."); CCX 812 (Kappus, Dep. at 26-27) (explaining that most of the language in Kappus' product certification to customers was taken from ECM's marketing materials); CCX 62, CCX 458, CCX 459 (customer certifications with ECM certification language)).
309. ECM's logo has appeared on plastic bags manufactured by some of ECM's Customers. (CCX 822 (ANS, Dep. at 24); CCX 73-CCX 75; CCX 118; CCX 623 (restaurant bag with ECM logo); F. 297).
310. Plastic bag manufacturer and ECM Customer ANS (F. 9-13) estimates that it sold millions of bags with the ECM logo to ANS wholesale and distributor customers. (CCX 822 (ANS, Dep. at 26)).

311. No Kappus products produced with the ECM Additive contained any sort of biodegradable logo. (CCX 812 (Kappus, Dep. at 22)).
312. Kappus conveyed to its customers that it was selling a biodegradable product through a letter it submitted, on Kappus' letterhead, in which it reprinted information from ECM's materials, including the time frame of 9 months to 5 years. ECM was not mentioned. (CCX 812 (Kappus, Dep. at 22-23)).

D. SURVEY EVIDENCE

1. Expert Qualifications and Findings

313. Complaint Counsel's expert, Dr. Frederick, has never before testified as an expert. (CCX 860 (Frederick Expert Report at 5 ¶ 9)).
314. Dr. Frederick is not familiar with standards applying to the evaluation of survey evidence in FTC proceedings, or any other federal administrative proceedings. (Frederick, Tr. 1185-1187).
315. Dr. Frederick does not believe there are any specific criteria that a survey must meet in order to be valid, and, although he believes there are aspects that make a survey better or worse, Dr. Frederick had no specific criterion in mind. (Frederick, Tr. 1185, 1187-1191; RX 858 (Frederick, Dep. at 186)).
316. Respondent's expert, Dr. Stewart, has served as an expert witness for the FTC multiple times, in cases including: *Kraft* (Docket No. 9298), *Novartis* (Docket No. 9279), and *POM Wonderful* (Docket No. 9344). Dr. Stewart was retained as an expert by the FTC in matters against *QVC* (Docket No. C-3955) and *John Beck* (FTC Matter No. 072 3138). Dr. Stewart has also been retained by various respondents in cases brought by the FTC, including *Pantron* (U.S. District Court Case No. CV88-6696 (C.D. Cal.), *Schering* (Docket No. 9232), and *Guaranty Life* (FTC Matter No. 092 3169). (Stewart, Tr. 2505-2508).
317. In most of the cases listed in F. 316, Dr. Stewart opined on surveys. In approximately half of those cases, Dr. Stewart designed a survey, and in many of those cases, Dr. Stewart gave rebuttal testimony concerning the opposing party's surveys. (Stewart, Tr. 2508-2509).
318. Complaint Counsel had emailed Dr. Stewart earlier in these proceedings, and expressed interest in him serving as Complaint Counsel's expert witness in this matter; however, Dr. Stewart had already been retained by Respondent. (Stewart, Tr. 2504-2505).
319. Dr. Stewart is unaware of a single instance in which his testimony or survey was not accepted by either the Administrative Law Judge ("ALJ") or the Commission. (Stewart, Tr. 2509).

320. In the *Kraft* decision, Dr. Stewart's survey was accepted by the ALJ and cited by the full Commission as supportive of its decision. (Stewart, Tr. 2506).
321. Dr. Stewart has served as a survey expert in federal court "a couple of dozen times" and in none of those cases has his survey been deemed to be unreliable or been rejected by the court. (Stewart, Tr. 2520-2521).
322. Dr. Stewart is highly qualified in the field of consumer surveys. (F. 144-151, 316-321).
323. Weighing the qualifications of Dr. Stewart and of Dr. Frederick, Dr. Stewart is much more qualified in the field of designing, implementing, reviewing, and evaluating consumer surveys than Dr. Frederick, and Dr. Stewart's opinions are entitled to greater weight. (F. 117-121, 144-151, 313-321).
324. Having reviewed, evaluated, and weighed the opinions of both Dr. Stewart and Dr. Frederick, and the bases therefor, Dr. Stewart's opinions are well supported and are more well reasoned, credible, and persuasive than the opposing opinions of Dr. Frederick.

2. Survey Evidence Generally

325. In Dr. Stewart's experience, having served as an expert witness for the FTC, the FTC accepts and applies the standards that are articulated in most professional organizations, as well as in the Manual for Complex Litigation. (Stewart, Tr. 2525).
326. While in his expert report Dr. Stewart references principles for acceptable survey research as outlined in the Manual for Complex Litigation, these standards represent a much broader set of understood and accepted principles. The broadly understood and accepted principles for accepting survey research include that: 1) the population was properly chosen and defined; 2) the sample chosen was representative of that population; 3) the data gathered was accurately reported; 4) the data was analyzed in accordance with accepted statistical principles; 5) the questions asked were clear and not leading; 6) the survey was conducted by qualified persons following proper interview procedures; and 7) the process was conducted so as to ensure objectivity (the study was double blind). (Stewart, Tr. 2525, 2598-2599; RX 856 (Stewart Expert Report at 10)).
327. The subject of public perception of biodegradation and biodegradation of plastics as a field of consumer survey research has not been researched extensively. (Stewart, Tr. 2510-2511).
328. Given the current understanding and state of knowledge with respect to consumer perception of biodegradation, open-ended questions, that allow consumers to offer responses in their own words, are "much more suitable, much more appropriate, much more informative, than closed-ended questions." (Stewart, Tr. 2510, 2516).

329. When beginning consumer perception work in a new area, open-ended questions are essential. (Stewart, Tr. 2509-2510, 2516-2518; RX 856 (Stewart Expert Report at 7)).
330. Given the limited amount of research work done in the field of public perception of biodegradation and biodegradation of plastics, it is very important to allow consumers to express themselves in their own words, and to fully describe their beliefs in detail. This can only be done through a personal interview, either in person or by telephone, and the use of open-ended questions. (Stewart, Tr. 2510-2511).
331. Open-ended questions with a personal interviewer, either face to face or by telephone, affords the opportunity to explore in depth what people's perceptions are. (Stewart, Tr. 2510).
332. One reason why surveyors need to perform more work involving open-ended questions and interviews early in the exploration of a topic such as biodegradation is so that surveyors can be sure that when they do finally design closed-ended questions, they give people the full array of response options. (Stewart, Tr. 2517).
333. Closed-ended questions are questions where a list of possible responses to a question are provided to the respondent, and where the respondent must choose only one from the responses that were provided, in order to give an answer to the question. (Stewart, Tr. 2513).
334. Close-ended questions inherently suggest greater homogeneity within a sample of respondents than may actually exist, because close-ended questions exist in a universe with only four or five possible responses. (Stewart, Tr. 2516-2617; RX 856 (Stewart Expert Report at 7)).
335. "Misleading homogeneity" occurs when a sample or a population is characterized "as being more alike, more similar, [or] more homogenous than is actually the case." (Stewart, Tr. 2518).
336. "Relevant population" means the group of people to whom the researcher wants to extrapolate the results of the survey. (Stewart, Tr. 2532).
337. Screening questions are a set of preliminary questions that are asked at the very beginning of a survey to determine whether or not a respondent should receive the substantive questionnaire or whether they should be excluded. An example of a screening question is asking whether a respondent is male or female, so that the researcher can assure that the respondents as a whole will be roughly 50% male and 50% female. (Stewart, Tr. 2534).
338. Screening questions are used for qualifying people and for assuring a more representative sample. (Stewart, Tr. 2541).

339. It is a big mistake to have no screening questions. Without screening questions, the surveyor cannot exclude people that are atypical and likely to introduce error into the results. (Stewart, Tr. 2537).
340. A survey on biodegradation that does not contain screening questions has the potential for introducing significant error into the survey, and calls into question the validity of the survey. (Stewart, Tr. 2537).
341. When asking people about the meaning of a term, such as “biodegradable,” as a precursor it must first be assessed that the respondent has some knowledge base for responding to the question. Otherwise the response is random, or simply a guess, and is not meaningful. (Stewart, Tr. 2533-2534).
342. In the field of survey research, “sampling” means the process by which researchers select a subset of individuals from a larger population. In general, appropriate sampling procedures are designed to assure that the subset that researchers select are generally and broadly representative of the larger population. (Stewart, Tr. 2538).
343. The primary principle to guide the selection of a sample is to create and implement a sampling plan that will provide the researcher a representative sample, meaning a sample that is like the larger population to whom the researcher wishes to extrapolate the results. (Stewart, Tr. 2538).
344. A survey without screening questions is not capable of being analyzed for the general representativeness of the sample. (Stewart, Tr. 2537).
345. “Double blind” means that the interviewers and any of other personnel directly involved with collecting or “coding” the data⁷ were not aware of the sponsor or purpose of the research, nor were the respondents aware of either the purpose or the sponsor of the research. (Stewart, Tr. 2553-2554).
346. Where a survey is double-blind, it is unlikely that a respondent or interviewer will seek to be helpful by offering a response that they think is consistent with what the researcher is looking for. (Stewart, Tr. 2554).
347. A survey that is not double-blind calls into question the validity of that survey. (Stewart, Tr. 2554).
348. It is customary when coding responses to use coders who are “blind” to the purpose of the research. It is also customary to use multiple coders to provide a “reliability check” on the coding judgments. (RX 856 (Stewart Expert Report at 13)).

⁷ As set forth here at F. 390, “coding” of survey responses refers to the process by which responses are classified into response categories for the purpose of summary and analysis. (CCX 860 (Frederick Expert Report at 13-14 and n.12)).

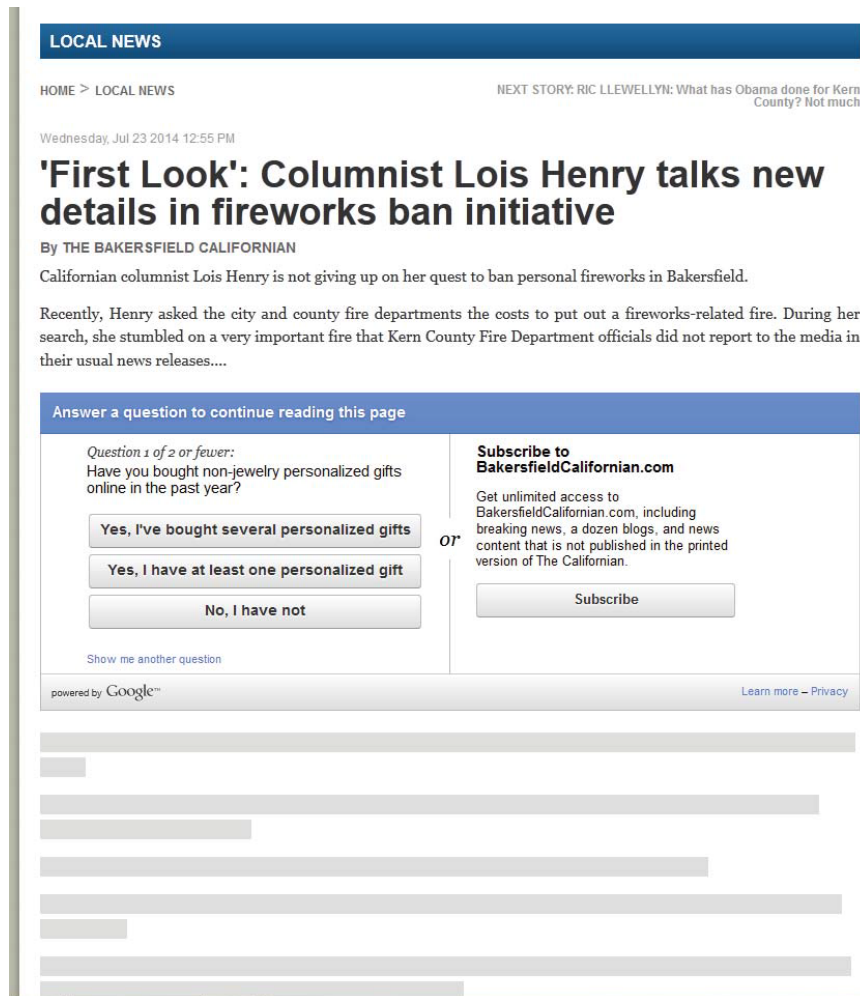
349. Blinding of coders is very important when coding open-ended questions because the coders are, in effect, transforming the data into categories of responses. This is the essence of data analysis. (Stewart, Tr. 2557).
350. To the degree that the coders have a prior understanding of what the researcher is looking for, that prior understanding can influence what codes the coders arrive at and how they code the data. (Stewart, Tr. 2557)
351. Leading questions, questions that ask a question and suggest an answer, are not appropriate. (Stewart, Tr. 2567).
352. Validity of a survey refers to accuracy, *i.e.*, does the survey accurately measure what it is intended to measure. (Frederick, Tr. 1042).

3. The Google Survey

a. Generally

353. Complaint Counsel's expert, Dr. Frederick, elected to conduct his own research for this proceeding in order to "test the robustness of the APCO and Synovate results" (*see* F. 455-497) and also to "gain further insight into consumer perception concerning biodegradable claims." (CCX 860 (Frederick Expert Report at 11)).
354. For his survey research for this litigation, Dr. Frederick decided to use a survey product offered by "Google Consumer Surveys." (Frederick, Tr. 1060; CCX 867 at 1).
355. Respondent's expert, Dr. Stewart, reviewed, among other things, Dr. Frederick's report and the raw data from Dr. Frederick's Google survey, showing original responses and how the response were coded, which had been produced to Respondent. (RX 856 (Stewart Expert Report at 6); Frederick, Tr. 1133-1134; CCX 863).
356. Google Consumer Surveys markets its survey product as a new approach to "market research" and as a tool for those who "need to pre-test a marketing campaign, prioritize new product initiatives, or even gauge a reaction about a recent event. . . . Now, with Google Consumer Surveys, you can easily conduct market research or even automatically track your brand to inform important business decisions." (CCX 867).
357. In a Google survey, an internet user will encounter a "pop-up" survey question when attempting to access content on a website. The user is blocked from access to the desired content unless the user answers the survey question or pays for access to the content without answering the survey question. (CCX 860 (Frederick Expert Report at 12); Frederick, Tr. 1062-1064; CCX 976).
358. A single question survey, such as that described in F. 357, is called a "micro-survey." (Frederick, Tr. 1062).

359. Below is a representative image of how a Google survey question is presented to a website visitor seeking certain content. (CCX 860 (Frederick Expert Report at 12); Frederick, Tr. 1062-1064; CCX 976).



- 360. Google has contracts with internet content providers to present survey questions to internet users who would otherwise be blocked from accessing their content. (Frederick, Tr. 1062-1063).
- 361. Dr. Stewart is not aware of any article relying on Google Consumer Survey data that has been accepted by a peer-reviewed journal. (Stewart, Tr. 2679-2680).
- 362. The article titled, “*The Limits of Attraction*,” published in the peer-reviewed journal, *Journal of Marketing Research*, and authored in part by Dr. Frederick, cites, but does not rely upon, Google Consumer Surveys. The sole reference is in a footnote and the reference was neither supportive nor non-supportive of what was actually contained in “*The Limits of Attraction*” article. The article does not rely on Google Consumer Survey data at all. (CCX 977; Stewart, Tr. 2680-2682, 2807-2808).

363. While market research professionals recognize that Google is making an effort to enter the survey research business with the Google Consumer Surveys product, it is an untested product. (Stewart, Tr. 2683).

b. Dr. Frederick's choice to use a Google Consumer Survey

364. The FTC paid Dr. Frederick a flat fee of \$40,000 to be an expert witness in this case. The less Dr. Frederick had to pay for a survey, on assistants, and on costs, the more money he would net as compensation for his work in this case. (Frederick, Tr. 1201).

365. An important factor in Dr. Frederick's choice to use a Google Consumer Survey was cost. He chose a Google Consumer Survey over other internet survey methods because a Google Consumer Survey was less expensive. The other factor important to Dr. Frederick was his familiarity with Google Consumer Surveys. (Frederick, Tr. 1206; RX 858 (Frederick, Dep. at 123)).

366. In total, Dr. Frederick's Google survey cost an estimated \$2,000 for the survey and another approximately \$5,400 for assistants, for a total of \$7,400. By way of comparison, Dr. Stewart's telephone survey for this proceeding cost approximately \$37,500. (Frederick, Tr. 1203; Stewart, Tr. 2648; RX 856 (Stewart Expert Report at 5, 23)).

367. Some survey organizations such as Synovate (*see* F. 480) maintain a panel of individuals, who will receive an email requesting participation in a survey, and a link to the survey site. The participants are compensated for their participation. Dr. Frederick knew of, but chose not to perform, an internet panel survey for this proceeding. (Frederick, Tr. 1046, 1197, 1279-1280).

368. Dr. Frederick knew of, but chose not to perform for this proceeding, a survey based on an in-person interview. (Frederick, Tr. 1197).

369. When choosing to use a Google Consumer Survey for his research in this case, Dr. Frederick was unaware of any administrative litigation in which the FTC had relied upon Google Consumer Survey data as a basis for decision. (Frederick, Tr. 1191).

370. As of the date of Dr. Frederick's deposition in this case, Dr. Frederick had never actually seen a Google Consumer Survey question live on a website. (Frederick, Tr. 1320).

c. Questioning methodology

371. In Dr. Frederick's Google survey, no single person was ever presented with more than one question. (Frederick, Tr. 1223-1224).

372. It is very difficult to draw any inferences about the validity of research based on an answer to a single question, particularly when the researcher does not know anything

about that particular respondent and cannot validate the response. Where there are multiple questions to the same respondent, the multiple responses can be compared, which allows the researcher to glean some sense of the totality of the respondent's perceptions. (Stewart, Tr. 2605).

373. When there is only one question asked of a survey respondent, a researcher cannot know really what the response means or indicates. (Stewart, Tr. 2605).
374. The perception of consumers with respect to the meaning of the term, "biodegradable," or "biodegradability," cannot be addressed with a single question. A good open-ended question might provide some dimension of consumer perception of the terms, but it will not provide other dimensions, such as nuances, dependencies, or context effects. (Stewart, Tr. 2606).
375. When there is only one question asked of a survey respondent, the researcher cannot know whether it is a sincere response, and/or whether it is a response that would be subject to qualification if there had been a follow-up question. (Stewart, Tr. 2605-2606).
376. Google limits the number of characters in a survey question. (Frederick, Tr. 1214-1215).
377. In three separate instances, Dr. Frederick had to revise questions he wanted to ask survey respondents because his proposed questions contained too many characters according to Google. (Frederick, Tr. 1215).
378. Dr. Frederick used four types of questions for the Google survey: open-ended questions, binary questions, multichotomous questions, and hybrid questions. (Frederick, Tr. 1215-1216).
379. For Dr. Frederick's Google survey, with an open-ended question, a survey respondent can type in whatever he or she wants. In a binary question, the respondent can click either the "yes" button or the "no" button. In a multichotomous question, the respondent can choose one of five answers. In a hybrid question, respondents are restricted to providing a numeric answer. (Frederick, Tr. 1215-1216).
380. Some of Dr. Frederick's questions presented the ECM "biodegradable" logo; some questions used other "biodegradable" logos not belonging to ECM; and some questions used the word, "biodegradable," in the question, without associated images. (CCX 860 (Frederick Expert Report Appendix at 27-45)).
381. None of the Google survey questions asked the survey respondent how the respondent interpreted the word "biodegradable." None of the Google survey questions asked the survey respondent whether a claim of "biodegradable" communicated any message concerning the rate for complete biodegradation. In general, the majority of the questions asked, in varying ways, "how much time," or "how long" the respondent

thinks, or estimates, that a “biodegradable” item will take to decompose. (CCX 860 (Frederick Expert Report Appendix at 27-45)).

d. Disinterest bias

382. Because questions in the Google survey are answered by survey respondents in exchange for access to internet-based content in which they may be interested, the questions are at best a distraction and barrier to survey respondents, whose objective is to access information, not to complete a survey. This type of disruptive questioning creates a disinterest bias. (RX 856 (Stewart Expert Report at 11)).
383. Disinterest bias refers to the fact that if people are uninterested in a survey, if they are disengaged, or, even worse, if the survey serves as an interruption for an activity in which they are more interested, those people will be likely to give insincere, random, and often nonsensical responses to simply get past what is essentially an interruption in what they were doing before being confronted by the survey. (Stewart, Tr. 2608-2609, 2611-2612; RX 856 (Stewart Expert Report at 11)).
384. The Greenbook Blog, which Dr. Stewart references on the phenomenon of disinterest bias, is a publication that is well-known in the practicing market research community and among well-read researchers. (Stewart, Tr. 2611; RX 856 (Stewart Expert Report at 11 n.7)).
385. A person who does not take a survey question seriously is more likely to answer that question insincerely, whimsically, or with just a guess. (Frederick, Tr. 1313-1314).
386. Incorporating “protest” responses into a data set affects the integrity of the data analysis. (Stewart, Tr. 2665-2666).
387. For the binary and multichotomous questions posed by Dr. Frederick in the Google survey, Dr. Frederick does not know whether any answers given by respondents were valid. Dr. Frederick believes that some respondents were actually just clicking buttons at random in order to get through the survey. (Frederick, Tr. 1220).
388. There is no way to know how many responses to Dr. Frederick’s Google survey questions were “protest” or “bypass” responses, because all the questions required a response before the respondent could access the desired internet content. (Stewart, Tr. 2666).
389. It cannot be inferred from the average number of seconds that a respondent took to answer the Google survey “pop-up” question that the respondent was taking the survey question seriously. Dr. Frederick acknowledged that numerous factors may cause respondents to take, on average, 20 seconds to answer their “pop-up” question, including performing other computer work in another window or on another screen, or taking a telephone call. Dr. Frederick cannot know what caused his survey respondents

to wait 20 seconds before keying in a response to his survey questions. (Frederick, Tr. 1342-1344).

e. Coding methodology

390. Dr. Frederick defined “coding” of survey responses to refer to the process by which responses are classified into response categories for the purpose of summary and analysis. For example, for Dr. Frederick’s Google survey, the open-ended questions about biodegradation times required that the responses be coded into time categories. Thus, for open-ended questions about biodegradation times, Dr. Frederick would “code” responses such as “3 months,” “6 months,” “between 5 and 9 months,” “a little less than a year,” and “1 year” as “instances of the category ‘one year or less.’” (CCX 860 (Frederick Expert Report at 13-14 and n.12)).
391. According to Dr. Frederick, a degree of judgment is required in order to code responses. (Frederick, Tr. 1283).
392. Dr. Frederick used a “bright-line” rule that “any response containing both a numeric specification and an accompanying temporal unit” was coded, and other responses were not coded. (CCX 860 (Frederick Expert Report at 12 n.7); CCX 865 (Frederick Rebuttal Expert Report at 6); Frederick, Tr. 1128).
393. In tabulating the Google survey data, Dr. Frederick coded only those responses that reported a time interval regarding biodegradation. Dr. Frederick excluded responses that did not fit his bright-line numeric rule because those responses could not be accurately translated in a specific estimate of biodegradation time. Thus, Google survey responses such as “it depends,” or “I don’t know,” to questions about biodegradation rates were eliminated from Dr. Frederick’s calculations of his Google survey results. (CCX 865 (Frederick Rebuttal Expert Report at 6); Frederick, Tr. 1122-1128; Stewart, Tr. 2809-2810).
394. In Dr. Frederick’s expert report, and in the appendix to the report that sets forth the results from the Google survey questions, the number of responses that were not coded is identified as a bracketed subscript reported to the right of the effective sample size (the number that were coded). For instance, “N= 408_[73]” means that the reported statistics summarize 408 coded responses, and that uncoded responses exist for another 73 respondents. (CCX 860 (Frederick Expert Report at 12 n.7)).
395. Out of 29,000 total responses, only approximately 21,000 (approximately 72%) were coded. (CCX 860 (Frederick Expert Report at 12 n.7)).
396. It is not appropriate for a researcher not to code a response because that response does not fit into a desirable structure, or to “force-fit” responses into a pre-existing structure. Ignoring significant portions of data in computing statistics misrepresents the data. As Dr. Stewart stated: “[Y]ou don’t report data statistics based only on what was

convenient and fits your definition of an appropriate response. You need to report all of the data and the statistics accordingly.” (Stewart, Tr. 2601-2602).

397. Ignoring some data is not reporting the data accurately. (Stewart, Tr. 2601).
398. Dr. Frederick’s coding methodology, as described in F. 393, is particularly egregious because it reduces the denominator of the percentage results reported by Dr. Frederick, which has the effect of inflating the reported percentages. (RX 856 (Stewart Expert Report at 12)).
399. Dr. Frederick’s strict numeric approach to coding responses is improper because it limits the range of responses considered, and by definition creates greater homogeneity of responses than would be the case if the respondents were allowed more latitude in responding. (Stewart, Tr. 2606-2607).
400. The implications of Dr. Fredrick’s failure to code a response suggesting that the respondent “does not know” the answer are: 1) that no one can know how many people who gave a response that Dr. Frederick coded might have actually not known an answer, but gave a response he or she thought valid to get through the survey wall; and 2) that to, the extent “don’t know” is a perfectly reasonable response, the researcher needs to include those individuals who do not know into the total sample; the “don’t know” responses cannot be ignored simply because they did not give the type of answer the researcher wanted. (Stewart, Tr. 2614; *see also* Stewart, Tr. 2668 (stating that if “I don’t know” responses were included in data set, the distribution of the total responses “would be different because some of those people actually don’t know, and so the fact they don’t know will change the overall distribution even if there are a few people who say ‘don’t know’ because they are less certain. But the overall distribution would be quite different.”)).
401. Dr. Frederick chose to code responses, in answer to questions regarding biodegradation times, of “one nanosecond,” “forever,” “24 hours,” “immediately,” “17 days,” “one hour,” “one second,” “a human lifetime,” “10,100 years,” “ten minutes,” “122 minutes,” “one minute,” “one hour,” “ten seconds,” “276.5 days,” “one second,” “ten minutes,” “minutes,” “22 days,” “72 hours,” “30 minutes,” “45 seconds,” “a week,” “90 minutes,” “60 seconds,” “a few days,” and “one hour.” (Frederick, Tr. 1302-1305; RX 951; *see* RX 856 (Stewart Expert Report at 12)).
402. Dr. Frederick chose to code, in answer to a question regarding biodegradation times, a response that stated, “never.” (Frederick, Tr. 1302; RX 951).
403. The combination of coding nonsensical responses while eliminating plausible responses that did not fit Dr. Frederick’s strict numerical rules had the effect of distorting the data. (RX 856 (Stewart Expert Report at 12)).
404. The Google survey data was not analyzed in accordance with accepted statistical principles. (F. 392-403; RX 856 (Stewart Expert Report at 12-13)).

405. Dr. Frederick and Mr. Andrew Meyer, Dr. Frederick's graduate student, coded almost all of the responses to the Google survey, with Dr. Frederick performing most of the coding. (Frederick, Tr. 1282-1285).
406. Both Dr. Frederick and Mr. Meyer knew that ECM was the Respondent in this case, that the FTC was also in the case, and that Dr. Frederick's research was going to be used in a case by the FTC against ECM. (Frederick, Tr. 1285-1286, 1289-1290, 1316-1317; RX 858 (Frederick, Dep. at 176)).
407. Dr. Frederick's coding process was not double-blinded; the people involved in the actual coding were not blind to what results might have been desired or expected by Complaint Counsel and/or the FTC. (Stewart, Tr. 2604; F. 405-406).
408. Dr. Frederick's failure to use blind coders for his Google survey deviates from customary practice and may infect the survey with bias. (RX 856 (Stewart Expert Report at 12-13)).

f. Representativeness of sample

409. Google Consumer Surveys seeks to infer respondents' demographic features, including gender, approximate age, geographic region, and whether the respondent resides in an urban, suburban, or rural area. With respect to age and gender, Google infers demographic information based on the respondent's browsing history as recorded in a DoubleClick advertising cookie. (CCX 874 at 3; CCX 868 at 3).
410. Google infers the respondent's location based on the computer's internet protocol ("IP") address, and then uses this information to further infer the respondent's income and urban density "by mapping the location to census tracts and using the census data to infer income and urban density." (CCX 868 at 3; *see also* CCX 874 at 3).
411. Google provides only indirect circumstantial evidence or information on survey respondent's demographics. Google draws inferences about demographics, such as gender and age, based on the respondent's IP address and "cookies" as well as other information indicating the respondent's website visits. (Frederick, Tr. 1229-1230).
412. Dr. Frederick does not know which websites among Google's contracted internet content providers featured his survey questions. (Frederick, Tr. 1208).
413. Dr. Frederick did not choose the websites, or the number of websites, on which his questions were posted. (Frederick, Tr. 1213).
414. Dr. Frederick declined to pay the additional fee to include two-part questions that would have provided direct information about the respondent population. (Frederick, Tr. 1230-1231).

415. Dr. Frederick rejected the option of including screening questions for his Google survey, which are questions used for qualifying people and assuring a more representative sample. (Frederick, Tr. 1224; F. 338).
416. It is difficult for Google to draw accurate inferences about demographics for several reasons. Google's inferred demographics can be wrong, for example, when multiple members of a household visit websites from a single computer. In addition, cookies can be deleted and website history may be insufficient. (Frederick, Tr. 1229-1230).
417. According to an assessment of Google Consumer Surveys published by the Pew Research Center in November 2012: "For approximately 30-40% of [GCS] users, demographic information is not available – either because their cookies are turned off but more often because the [GCS] algorithm cannot determine a trend from the websites visited as recorded in their DoubleClick advertising cookie that would suggest what gender or age they are." (CCX 874 at 3).
418. If a family of four shares one computer, and one of those users answers a Google Consumer Survey question, neither Google nor the surveyor can know which of those four users answered the survey question. (Frederick, Tr. 1337-1338).
419. A valid IP address of a survey respondent can only tell Google the location, but not the age, nationality, or gender of the person who answered the survey question. (Frederick, Tr. 1239).
420. The Google survey population is not defined by an age and there is no lower bound. (Stewart, Tr. 2600).
421. Dr. Frederick does not know whether people can access a Google Consumer Survey on a mobile device. (Frederick, Tr. 1329).
422. Dr. Frederick does not know what percentage of global internet users use a mobile device as their primary or exclusive means of using the Internet. (Frederick, Tr. 1331).
423. Dr. Frederick does not know what percentage of internet users block cookies or what percentage of internet users mask their identities online. (Frederick, Tr. 1335).
424. Dr. Frederick does not know what percentage of internet users rely on Google Chrome's feature that allows you to browse privately. (Frederick, Tr. 1334-1335).
425. Dr. Frederick's Google survey failed to properly choose and define a population, because it is not clear what the population was that he was analyzing. Rather, the population is defined in terms of who participated in the survey, which is not an appropriate way to define a population. (Stewart, Tr. 2600).
426. There is no way to know whether Dr. Frederick's Google survey population was representative or not. Dr. Frederick did not collect demographic information. All that

is known about the population is that they happened to go to a set of undefined, unidentified websites. (Stewart, Tr. 2600-2601).

427. There is no way to ascertain the degree to which the sample of respondents surveyed in the Google survey is representative of any identifiable population; the sample itself is unknown and unknowable, because there is no verification of respondents with the Google survey; rather, information on respondents is merely inferred by Google from information associated with or that resides on a computer. (RX 856 (Stewart Expert Report at 10-11); Frederick, Tr. 1228-1229).
428. The opinion in Dr. Frederick's expert report on page 12 that Google Consumer Surveys "tend to yield similar results to other internet panels," relied on the opinions of Nate Silver, of the New York Times' *FiveThirtyEight* blog, and also references an article co-authored by Google. However, Dr. Frederick was not aware of Mr. Silver's blog post, or the cited Google article, when he drafted his expert report. (CCX 860 (Frederick Expert Report at 12-13); Frederick, Tr. 1195-1196).
429. Complaint Counsel drafted three of the four references on page 7 of Dr. Frederick's expert report, namely the Google Consumer Surveys Product Overview reference, the Google article reference, and the Nate Silver reference. (Frederick, Tr. 1195).
430. Complaint Counsel drafted the "see" reference to Nate Silver's blog on page 13 of Dr. Frederick's expert report: "See N. Silver, *FiveThirtyEight*, The New York Times (Nov. 10, 2012) ('Perhaps it won't be long before Google, not Gallup, is the most trusted name in polling.')." Complaint Counsel also drafted the statement on page 12 of Dr. Frederick's report that, in predicting the results of the 2012 Presidential Election, Google survey results "best[ed] better-known rivals such as Gallup, CNN, and Rasmussen." (CCX 860 (Frederick Expert Report at 12-13); Frederick, Tr. 1195-1196).

g. Conclusions as to the Google survey

431. Dr. Frederick's Google survey does not meet generally accepted standards for survey research. (F. 326; Stewart, Tr. 2598; RX 856 (Stewart Expert Report at 10)).
432. The Google survey conducted for this litigation cannot be characterized as a valid survey. It was the asking of one question of an individual who happened to come to a particular website. The Google survey does not meet the typical definitions of a survey as would be used in the marketing and survey profession. (Stewart, Tr. 2596).
433. At least one purpose of Dr. Frederick's Google survey was to demonstrate that, despite its flaws, the APCO survey (F. 455-479) produced valid and reliable results. To this extent, the Google survey was not intended to be an objective analysis of what people believe about biodegradability. (Stewart, Tr. 2616; RX 856 (Stewart Expert Report at 8 n. 4)).

434. Dr. Frederick’s Google survey is not reliable and is not valid, and the results cannot be relied upon to draw any conclusions, including about consumer interpretation of “biodegradable” claims, the validity of any other surveys, or for any other purpose. (Stewart, Tr. 2604; F. 355-434).

h. Relevant survey questions and results

435. Dr. Frederick’s assertion that 20%-52% of consumers “infer” that plastic products labeled “biodegradable” “will biodegrade within a year” is based on the responses to 12 open-ended questions that Dr. Frederick crafted for the Google survey, designated as questions 3A –3K.⁸ (CCX 860 (Frederick Expert Report at 16, Appendix at 30-33)).
436. Google survey questions 3A-3K (F. 438-447) do not inquire whether a plastic product labeled “biodegradable,” including a plastic product carrying the ECM “biodegradable” logo, conveys any message as to an amount of time for complete biodegradation, and/or if so, what amount of time is communicated. Questions 3A-3K did not ask the respondents what they believe is meant by “biodegradable.” (CCX 860 (Frederick Expert Report Appendix at 30-33)).
437. Questions 3A-3K of the Google survey (F. 438-447) ask, in varying ways, for respondents to provide their “best estimate of the amount of time,” or to report “how long,” or “how much time” they think that, a plastic product that is labeled “biodegradable” “would” or “will take” to decompose or biodegrade. In this regard, the questions asked by Dr. Frederick were leading because the questions assumed that the term “biodegradable” necessarily denotes a length of time, and assessed only what time period the respondent estimates, believes, or thinks is appropriate. (CCX 860 (Frederick Expert Report Appendix at 30-33)).
438. Question 3A of the Google survey asked, “Suppose a plastic package is labeled biodegradable. How long do you think it will take to biodegrade?” According to Dr. Frederick’s calculations, 31% of respondents selected within one year. (CCX 860 (Frederick Expert Report Appendix at 30)).
439. Question 3B of the Google survey asked the respondent to report “[h]ow much time” the respondent thinks a plastic package labeled “biodegradable” would take to biodegrade. Dr. Frederick calculated that 28% of respondents indicated within one year. (CCX 860 (Frederick Expert Report Appendix at 30)).
440. Question 3C of the Google survey asked, “If a plastic package is labeled ‘biodegradable,’ how long will it take to decompose?” According to Dr. Frederick’s calculations, 44% of respondents selected within one year. (CCX 860 (Frederick Expert Report Appendix at 30)).

⁸ There appear to be two questions labeled 3G in Dr. Frederick’s Google survey. See CCX 860 (Frederick Expert Report Appendix at 31). The first question 3G will be referred to herein as question 3G(1). The second question 3G will be referred to herein as question 3G(2).

441. Questions 3D-3F of the Google survey displayed an image along with the word “biodegradable,” such as the following,



and asked if the respondent saw the symbol on a plastic water bottle, “how long” it would take to “decompose.” Dr. Frederick calculated that 52% (3D), 50% (3E), and 45% (3F) of respondents, respectively, reported less than one year. (CCX 860 (Frederick Expert Report Appendix at 30)).

442. Question 3G(1) of the Google survey displayed an image along with the words “biodegradable & compostable,” as follows,



and asked, “if you saw this label on a plastic water bottle, how long would it take to decompose?” Dr. Frederick calculated that 47% of respondents indicated within one year. (CCX 860 (Frederick Expert Report Appendix at 30); *see also* question 3G(2) (asking, “If you saw this label on a plastic water bottle, how long do you think it would take to decompose?” According to Dr. Frederick’s calculations, 52% of respondents replied within one year).

443. Questions 3H, 3I, 3J, 3K of the Google survey included images of ECM’s “biodegradable” logo. These images were digitally edited or altered (“photoshopped”) and created electronically by superimposing the ECM logo onto other electronic images. (CCX 860 (Frederick Expert Report Appendix at 31-33); Frederick, Tr. 1265, 1316).

444. Google survey question 3H presented the image of a plastic container photoshopped to display the ECM “biodegradable” logo, as follows,



and asked the respondent: “What is your best estimate of the amount of time it would take for this container to biodegrade? Dr. Frederick calculated that 22% of respondents indicated less than one year. (CCX 860 (Frederick Expert Report Appendix at 31); Frederick Tr. 1265).

445. When question 3J of the Google survey was revised to read, “What is your best estimate of the amount of time it would take for this container (which bears the symbol ‘ECM biodegradable’) to biodegrade,” as calculated by Dr. Frederick, 34% indicated less than one year. (CCX 860 (Frederick Expert Report Appendix at 32)).

446. Google survey question 3I showed the image of a plastic bag photoshopped to display a large ECM logo, as follows,



and asked, “What is your best estimate of the amount of time it would take for this plastic bag to biodegrade?” According to Dr. Frederick’s calculations, 20% indicated less than one year. (CCX 860 (Frederick Expert Report Appendix at 33)).

447. Google survey question 3K showed the image of a plastic bag photoshopped to display a large ECM logo, as shown above in F. 446, and asked, “What is your best estimate of the amount of time it would take for this plastic bag (which bears the symbol ‘ECM biodegradable’) to biodegrade?” Dr. Frederick calculated that 38% of respondents estimated less than one year. (CCX 860 (Frederick Expert Appendix Report at 33)).

448. Question 3Q of the Google survey asked: “Suppose a plastic page is labeled biodegradable, and is claimed to biodegrade in “*nine months to five years.*” What is your best estimate of the amount of time it will take to biodegrade?” Dr. Frederick coded 345 responses and did not code 138 responses. According to Dr. Frederick’s calculations, 6% responded less than one year, and 7% responded, one year. (CCX 860 (Frederick Expert Report at 17, Appendix at 35) (italics in original)).

449. Question 3R of the Google survey asked: “Suppose a plastic package is labeled biodegradable, and is claimed to biodegrade in “*some period greater than a year.* What is your best estimate of the amount of time it will take to biodegrade?” Dr. Frederick coded 296 responses and did not code 183 responses. Based on Dr. Frederick’s calculations, 6% responded less than one year, and 7 percent responded, one year. (CCX 860 (Frederick Expert Report at 17, Appendix 35) (italics in original)).

450. Dr. Frederick’s opinion that “a substantial minority of respondents believe that a product bearing a ‘biodegradable’ label . . . will break down into elements found in nature” is stated to be based on the responses to Questions 6, 7 and 8A-8F of the Google survey. The Google survey did not have any questions designated 8D, 8E or 8F. (CCX 860 (Frederick Expert Report at 16); CCX 860 (Frederick Expert Report Appendix at 37-39)).

451. Questions 6, 7, 8A-8C, 9B and 9C of the Google survey asked variations of the question whether a container that is labeled biodegradable will “break down completely into elements found in nature,” and offered a “yes” or “no” response. When the question also displayed a plastic container with the ECM logo, according to Dr. Frederick, 37% responded “yes.” When the question displayed a plastic bag with the image of the ECM biodegradable logo, the “yes” response rate was 42%. When the question displayed the image of the ECM biodegradable logo, and further stated in the question that the container “bears the symbol ‘ECM biodegradable,’” the “yes” response rate was 39% for a plastic container and 45% for a plastic bag. (CCX 860 (Frederick Expert Report Appendix at 37-41)).
452. In support of his opinion that a significant minority of consumers “understand” that a “biodegradable” product will biodegrade in a landfill, Dr. Frederick relies in part on questions 10B and 13B of the Google survey. (CCX 860 (Frederick Expert Report at 13)).
453. Question 10B of the Google survey presented a plastic bag photoshopped with a large ECM biodegradable logo, as follows,



and asked, “Will this plastic bag biodegrade in a landfill?” According to Dr. Frederick, 42% responded, “yes.” (CCX 860 (Frederick Expert Report Appendix at 43)).

454. Question 13B of the Google survey displayed the image of the ECM biodegradable logo and asked, “Will a plastic product bearing the logo below biodegrade in a landfill?” Dr. Frederick calculated that 63% responded, “yes.” (CCX 860 (Frederick Expert Report Appendix at 44)).

4. The APCO Survey

455. In 2006, the American Plastics Council (“APCO”) commissioned an approximately 1000-respondent telephone survey regarding consumer perceptions about the terms “biodegradable” and “compostable” (the “APCO” survey). (RX 596; *see also* Frederick, Tr. 1037; CCX 860 (Frederick Expert Report at 7)).
456. The form of questions used in the APCO survey was premature given the state of knowledge of the topics covered by the APCO survey. (Stewart, Tr. 2513).
457. The response options given in the APCO survey were incomplete. (Stewart, Tr. 2513).

458. Dr. Frederick’s opinions in this case rely in part on the APCO survey. (*See* CCX 860 (Frederick Expert Report at 9)).

459. With respect to the matters upon which Dr. Frederick was asked to opine for this litigation, the most pertinent question in the APCO survey was APCO question 4. APCO question 4 asked:

If a package is labeled “biodegradable,” what should be the maximum amount of time that it should take for that package to decompose?

(CCX 860 (Frederick Expert Report at 9); *see also* Frederick Tr. at 1044 (identifying APCO question 4 as “the most pertinent question” because it directly asked “how much time people think things take to biodegrade”)).

460. APCO question 4 does not inquire whether the label “biodegradable” *conveys* any message as to whether the item will decompose in a particular amount of time, and/or if so, what specific amount of time is *conveyed*. Rather, the question asks only for the respondent’s opinion of the “maximum amount of time” a “biodegradable” package “should take” to decompose. (F. 459).

461. APCO question 4, like all other questions in the APCO survey, was a “closed-ended” question, in that “there was a list of possible responses that were presented to the respondent, and the respondent needed to choose from one of the responses that was presented in order to give an answer.” (F. 333, 459, 462).

462. APCO question 4 provided respondents with 6 substantive answer options: “One month or less,” “Three months,” “Six months,” “One year,” “Two to four years,” or “Five years or more.” (RX 597 at 2).

463. The responses to APCO question 4 were:

One month or less	19.2%
Three months	6.6%
Six months	8.3%
One year	26.1%
Two to four years	4.7%
Five years or more	16.5%
Other	0.5%
Unsure (not read)	17.4%
Refused (not read)	0.7%

(RX 597 at 2).

464. To support his opinion that a significant minority of consumers understand that a “biodegradable” product will biodegrade in a landfill, Dr. Frederick relies in part on the

responses to APCO question 2, set forth in F. 465, below. (CCX 860 (Frederick Expert Report at 13, 53)).

465. APCO question 2 and its responses are set forth below:

From what you know, if something is labeled ‘biodegradable,’ does that mean it will decompose in:

	Yes	No	Unsure
The natural environment	86%	8%	6%
A landfill	83%	11%	6%
Your backyard	80%	15%	5%

(CCX 860 (Frederick Expert Report at 13, 53)).

466. The APCO survey uses closed-ended questions, which are unhelpful and misleading when there are many possible answers, qualifications, and contextual nuances. (Stewart, Tr. 2512-2513; RX 856 (Stewart Expert Report at 7); RX 858 (Frederick, Dep. at 35-36, 165)).
467. APCO question 4 is flawed because, with four of the six time period response options being one year or less, the response categories carry the “strong suggestion that the experimenter expects these are the responses that people are going to give . . . causing people to give those responses in greater numbers than they would if the question used a different design.” (Frederick, Tr. 1045).
468. APCO question 4 presents an example of the misleading homogeneity inherent in closed-ended questions. For the question: “what should be the maximum amount of time that it should take for that package to decompose,” F. 459, four of the six time period response options are a year or less, while only two time period response options are longer than two years. (RX 856 (Stewart Expert Report at 7-8); Frederick, Tr. 1045; F. 463).
469. Dr. Frederick agrees with Dr. Stewart that the biggest problem with question 4 of the APCO survey “is the allocation of response options” described in F. 468. (RX 856 (Stewart Expert Report at 7-8); Frederick, Tr. 1045).
470. The response options in the APCO survey to questions about how long it should take for something to biodegrade were not balanced. (Stewart, Tr. 2514).
471. APCO survey question 4 is invalid as inherently biased because it offers many more opportunities to select an answer that reflects one year or less than reflect a longer time period. (Stewart, Tr. 2514-2415).

472. Two-thirds of the response options in the APCO survey to the question of how long it should take for something to biodegrade were one year or less, which predisposes people to select a short time frame than a longer time frame. (Stewart, Tr. 2514).
473. Random responses to APCO question 4 would result in 66% (two-thirds) of the responses falling into one of the four choices of one year or less. (RX 856 (Stewart Expert Report at 8)).
474. APCO survey question 4 created a sense of far greater homogeneity than actually exists. (Stewart, Tr. 2519).
475. The APCO survey afforded respondents no opportunity for any dependencies or contexts. (Stewart, Tr. 2519).
476. The APCO study has the potential to introduce bias because of the way in which response options were presented and because of the use of the word “should.” Use of the word “should” in APCO question 4 could be interpreted by respondents “as referring to what would be desirable, as in, ‘*Wouldn’t it be nice if packages decomposed this quickly,*’ rather than assessing their judgment of how long such decomposition would, in fact, take.” (Frederick, Tr. 1270; CCX 860 (Frederick Expert Report at 9-10)).
477. The APCO survey is invalid for the purpose of drawing conclusions about people’s perceptions about how long biodegradation takes because it does not provide adequate opportunity for consumers to offer their perceptions of how long it would take for something to biodegrade, while at the same time providing response options that are biased in favor of the “one year” time period. (Stewart, Tr. 2514-2515; F. 455-463, 466-476).
478. Although Dr. Frederick’s report opined that the APCO survey was “reasonably valid,” he testified at trial that the APCO survey standing alone could not be deemed valid. (Frederick, Tr. 1042, 1173; CCX 860 (Frederick Expert Report at 8-9)).
479. Dr. Frederick’s opinion that the APCO survey is “reasonably reliable and valid” despite its flaws, is unpersuasive and is rejected. (See CCX 860 (Frederick Expert Report at 7-10)).

5. The Synovate Survey

480. In 2010, the company EcoLogic engaged a survey firm, Synovate, to conduct a 2000-respondent internet panel survey (the “Synovate” survey). (CCX 94 at 1-2; Frederick, Tr. 1046-1047).
481. EcoLogic procured the Synovate survey in connection with the public comment period for the FTC’s then-proposed revisions to the Green Guides (See F. 238). EcoLogic wanted to conduct consumer research into consumer comprehension of packaging that

biodegrades in a landfill and/or composting environment, so that it could report findings and recommendations to the FTC. (CCX 94 at 1).

482. The Synovate survey is flawed because it inappropriately uses closed-ended questions when asking about biodegradation times. (Stewart, Tr. 2515; *see* F. 328-334).
483. Dr. Frederick’s opinions in this case rely in part on the Synovate survey. (*See* CCX 860 (Frederick Expert Report at 10)).
484. With respect to the matters upon which Dr. Frederick was asked to opine for this litigation, the most pertinent question in the Synovate survey was Synovate question 19. (CCX 860 (Frederick Expert Report at 10)).
485. Synovate question 19 asked: “What do you believe is a reasonable amount of time for a ‘biodegradable’ plastic package to decompose in a landfill? Please select one.” (CCX 860 (Frederick Expert Report at 11, 50)).
486. The responses to Synovate question 19 were:

Less than 1 year	25%
Less than 5 years	45%
Less than 10 years	17%
Less than 20 years	6%
Less than 40 years	3%
40 years or greater	4%

(CCX 860 (Frederick Expert Report at 11, 50)).

487. Synovate question 19 does not inquire whether a plastic package labeled “biodegradable” conveys any message as to whether the package will decompose within a particular amount of time, and/or if so, what specific amount of time is conveyed. (F. 485).
488. Synovate question 19 is flawed because, in asking what the respondent believes is a “reasonable” amount of time for a biodegradable plastic package to decompose, the question could be interpreted to be asking the respondent what he or she “would like to happen, what kind of product should be produced” or what is “a goal” to which “we should aspire.” (Frederick, Tr. 1050; CCX 860 (Frederick Expert Report at 11)).
489. Synovate question 19 is flawed because it is a closed-ended question. (Frederick, Tr. 1049-1051, 1276-1277, 1280).
490. To support his opinion that a significant minority of consumers understand that a “biodegradable” product will biodegrade in a landfill, Dr. Frederick relies in part on the responses to Synovate question 5. Synovate question 5 and its responses are set forth below:

If something is labeled “biodegradable,” where will it decompose? If you are not sure, please take your best guess. [Select all that apply.]

In the open environment (land or water) as litter	51%
In a landfill	72%
When buried in our backyard	43%
In a home composting device	46%
In a commercial composting facility	51%
None of these	2%

(CCX 860 (Frederick Expert Report at 13, 48)).

491. Misleading homogeneity exists in the Synovate survey. The Synovate survey offers a limited number of responses; the time frames are listed in absolutes; and there are a relatively small number of those time frames. The bias in the response options is toward the longer end of the time frame, rather than the shorter end of the time frame, as in the APCO survey. (Stewart, Tr. 2519-2520; Frederick, Tr. 1049-1051).
492. Both Dr. Stewart and Dr. Frederick believe that the APCO and Synovate surveys are flawed. (Frederick, Tr. 1045, 1049-1051; Stewart, Tr. 2513-2517; RX 856 (Stewart Expert Report at 5-9)).
493. Dr. Frederick faults both the APCO and Synovate surveys for having closed-ended rather than open-ended questions. (Frederick, Tr. 1280).
494. Both the APCO and Synovate surveys have “serious limitations.” (Stewart, Tr. 2593).
495. The Commission stated in the FTC’s Green Guides Statement of Basis and Purpose, issued with the 2012 revision to the Green Guides that “[t]he Synovate study results suggest that respondents’ answers may have been not only biased but also influenced by a tendency to avoid extreme answers” and that “[r]eliable real world conclusions cannot be drawn from the Synovate study.” (<http://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-green-guides/greenguidesstatement.pdf> at 121).
496. The Commission stated in the FTC’s Green Guides Statement of Basis and Purpose issued with the 2012 revision to the Green Guides that both the APCO and Synovate surveys “may be faulted for lacking control groups and presenting the timeframe questions with close-ended, rather than open-ended, answers but they nevertheless are the only studies in the record.” (<http://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-green-guides/greenguidesstatement.pdf> at 121).
497. The APCO and Synovate surveys have little probative value beyond suggesting that there is variability in what consumers understand about biodegradability. (RX 856 (Stewart Expert Report at 9)).

6. The Stewart Survey

498. In the spring of 2014, in connection with his work on this case, Dr. Stewart performed a 400-participant landline telephone survey. (Stewart, Tr. 2494, 2687; RX 856 (Stewart Expert Report at 18, 20)).
499. Dr. Stewart chose to use 400 as a sample size because it is near the number (384) that is considered by researchers to be the point at which one reaches “diminishing returns” in terms of sample size. Increasing the sample size beyond 400 does not achieve greater statistical precision. Survey research generally uses samples of around 400. (Stewart, Tr. 2544-2545).
500. Dr. Stewart decided to conduct a telephone survey because he believed this would result in a more representative sample than that which would result from interviewing people in selected malls (a “mall intercept” survey). (Stewart, Tr. 2526-2527).
501. Dr. Stewart’s survey was designed, *inter alia*, “to determine how representative consumers who purchase products made from or packaged in plastic perceive the meaning of the term ‘biodegradability.’” (RX 856 (Stewart Expert Report at 15)).
502. Dr. Stewart’s survey had the objective of understanding the perceptions of consumers as to the meaning of the term “biodegradable,” complete with any contingencies, dependencies, or context effects that consumers might bring to bear. (Stewart, Tr. 2531).

a. Methodology

503. Dr. Stewart wrote the questions used in his survey. (Stewart, Tr. 2527, 2529).
504. Other than ECM’s attorneys providing Dr. Stewart with the initial issue, “what does ‘biodegradable’ mean to consumers,” it was entirely Dr. Stewart’s responsibility to design, implement, and interpret the survey. (Stewart, Tr. 2528-2529).
505. Dr. Stewart designed the survey, the sampling plan, and the set of questions in his survey. (Stewart, Tr. 2552).
506. In terms of the validity of a survey, it is far better for a “protest response” (see F. 382-386) to be a hang up of the telephone – thus providing the researcher absolutely no data – than entering a protest response into a survey which actually becomes incorporated into the larger data set and is ultimately used in an analysis. (Stewart, Tr. 2665-2666).
507. Dr. Stewart coded every response to his survey. Dr. Stewart’s codes classified the actual responses of the survey participants. (Stewart, Tr. 2810-2811).
508. Dr. Stewart assured that the design of his survey was “double-blind,” meaning that the interviewers and other personnel directly involved with collecting or coding the data were not aware of the sponsor or purpose of the research, nor were the survey

respondents aware of either the purpose or the sponsor of the research. (Stewart, Tr. 2553-2554).

509. Where a survey is double-blind, it is unlikely that a respondent or interviewer will seek to be helpful by offering a response that they think is consistent with what the researcher is looking for. (Stewart, Tr. 2554).
510. The totality of the questions asked in Dr. Stewart's survey provided a much brighter and richer picture of people's perceptions of biodegradability than if Dr. Stewart had asked only one question of each respondent. (Stewart, Tr. 2812-2813).
511. Dr. Stewart's survey used interviewers who could ask follow-up questions and use probes to obtain more complete answers from respondents. (Stewart, Tr. 2526).
512. The interviewers in Dr. Stewart's survey were live callers who were well-trained professional interviewers who were assisted in their work by "computer-assisted telephone interviewing technology" ("CATI"), which provides means by which the interviewers' work could be monitored and for capturing responses of the survey respondents. (Stewart, Tr. 2527, 2530-2531).
513. CATI is essentially hardware and software that is designed to create a structure to assist interviewers in the design and implementation of a telephone survey. CATI automates the dialing of telephone numbers so that it takes the control of what number is dialed away from the interviewer. (Stewart, Tr. 2530).
514. Once CATI reaches a telephonic connection with a potential respondent, CATI causes the interviewer's monitor to bring up one question at a time so that there is no opportunity for the interviewer to deviate from the order of questions. After recording a response from a respondent, the interviewer clicks a "continue" button that brings up the next question in the survey. (Stewart, Tr. 2530-2531).
515. Dr. Stewart's survey used a random digit dialing approach so that the telephone numbers were randomly selected, which helps assure a more representative sample. (Stewart, Tr. 2541).
516. One source Dr. Stewart used to obtain telephone numbers was Scientific Telephone Sampling, a firm that is in the business of generating samples for survey research. Scientific Telephone Sampling generated a random-digit dialing sample by taking listed phone numbers that are publicly available and by randomly changing the last two digits in order to create a true random sample of telephone numbers in the sense that the resulting sample includes unlisted numbers. (Stewart, Tr. 2545-2546).
517. Dr. Stewart obtained an "age-enhanced" supplementary sample from Survey Sampling, Incorporated ("Survey Sampling"), a company that does preparation, analysis, and provision of names and telephone numbers for survey research, which provided a larger percentage of households known to contain younger consumers. (Stewart, Tr. 2546).

518. Dr. Stewart combined the random-digit dialing sample obtained from Scientific Telephone Sampling and the age-enhanced sample from Survey Sampling to create the final source of telephone numbers that were used for dialing for his survey. (Stewart, Tr. 2546).
519. Both Scientific Telephone Sampling and Survey Sampling are well-known and highly respected providers of sample lists in survey research. (Stewart, Tr. 2549).
520. Prior to asking any survey questions, interviewers clarified to potential respondents that the call was for research purposes and not for telemarketing. (RX 856 (Stewart Expert Report at 19)).
521. Dr. Stewart included screening questions in his survey in order to ensure that the respondents surveyed were representative of the relevant population. (Stewart, Tr. 2551; *see* F. 337-338).
522. Dr. Stewart defined the relevant population as adults in the United States, age 18 and older, who indicated that they had some general understanding of what the term “biodegradable” means. (Stewart, Tr. 2532).
523. Dr. Stewart chose to exclude from his survey people who indicated that they did not have a general understanding of the term “biodegradable,” because it makes no sense to ask people the meaning of a term when they have already self-identified that they do not know what that term means. If people who had no general understanding of the term “biodegradable” were to participate in Dr. Stewart’s survey, they would simply be guessing, offering random responses, and not be giving meaningful responses to the survey questions. (Stewart, Tr. 2533).
524. Dr. Stewart’s survey’s population excluded anyone who Dr. Stewart thought was atypically knowledgeable on the subject of biodegradation, such as a person who worked in the waste industry. Screening to exclude those who may provide atypical answers to a survey is common. (Stewart, Tr. 2532-2533, 2536).
525. Non-probability sampling is where the researcher does not know in advance what the probability of selecting any one individual is, because a respondent can simply refuse to participate in the survey. Most of the work done by marketing researchers involves non-probability samples because people can decline to participate in the surveys. Dr. Stewart’s sample in his survey was a non-probability sample because respondents could refuse to participate. (Stewart, Tr. 2540-2541).
526. Dr. Stewart’s survey included screening questions asking about the respondent’s age, gender, general employment status, and whether the respondent was knowledgeable or not about the term “biodegradable.” (Stewart, Tr. 2535).

527. The gender and age screening questions in Dr. Stewart's survey were designed to assure that his survey had an adequate number of people of each gender and within each age category. (Stewart, Tr. 2535).
528. Dr. Stewart established "soft" quotas, or ranges, for the demographics in his survey to ensure that men and women, as well as various age categories, were well represented in the survey sample. (Stewart, Tr. 2551).
529. California Survey Research Services ("CSRS") programmed Dr. Stewart's questionnaire into the computer-assisted telephone interviewing technology under Dr. Stewart's direction. Dr. Stewart has relied upon CSRS in a variety of contexts for more than 20 years. (Stewart, Tr. 2528).
530. CSRS is a well-known firm specializing in telephone, mail, and internet surveys and has been in the business of conducting surveys for 30 years. (Stewart, Tr. 2552).
531. CSRS coded the responses to Dr. Stewart's survey. It would have been problematic for Dr. Stewart to code the answers to his survey because the fact that he knew the purpose of the research could influence how he coded the data. (Stewart, Tr. 2554-2555).
532. All of the interviewers who implemented Dr. Stewart's survey were trained in general interviewing techniques and also were specifically trained to the protocol that was used in Dr. Stewart's survey. Supervisory personnel trained the interviewers, answered the interviewers' questions, were on-site at the time the interviewing took place, and could therefore address any problems that arose during the survey. (Stewart, Tr. 2558-2559).
533. Supervisory personnel had the ability to randomly monitor the interviewing as it was taking place in real time, so that they could determine whether the interview was actually taking place and whether the protocol was actually being followed. The fact that supervisory personnel were able to listen to interviews in real time assures a higher degree of integrity and attention to instructions among the interviewers. (Stewart, Tr. 2558-2559).
534. The interviewers had an opportunity for debriefing to discuss any questions, problems, or issues that arose after they completed a practice interview. Interviewers' ability to participate in briefing ensures a higher quality and efficiency of the interviewing process and acts as a way to standardize the interviewers. (Stewart, Tr. 2560).
535. The coders in Dr. Stewart's survey reviewed the responses to the open-ended questions to determine the broad categories that would seem to capture the responses. The categories that best captured respondents' responses to open-ended questions in Dr. Stewart's survey became the "code book," which was approved by Dr. Stewart. (Stewart, Tr. 2564-2565).

536. All verbatim responses to Dr. Stewart's survey were coded independently by two coders and any disagreements were resolved in discussion. (Stewart, Tr. 2556-2557; RX 856 (Stewart Expert Report at 23)).
537. All but two of Dr. Stewart's survey questions were open-ended. (RX 856 (Stewart Expert Report at 20)).
538. Dr. Stewart's main questionnaire, which was the substantive questionnaire, used the "funnel approach." A funnel approach starts with general open-ended questions and progresses to more specific open-ended questions, and finally to some closed-ended questions. (Stewart, Tr. 2566).
539. By allowing respondents to answer the survey questions in their own words, Dr. Stewart was able to identify any qualifications, dependencies, and contexts that might be present in a respondent's answer. (Stewart, Tr. 2562).
540. Dr. Stewart's screener questionnaire contained 6 questions, and his main questionnaire contained about 15 questions. (Stewart, Tr. 2569).
541. Not every respondent was asked every question in Dr. Stewart's main questionnaire. If a survey respondent disconnected the phone call during the survey, that respondent's answers were not counted and that respondent was recorded as a "terminate." (Stewart, Tr. 2569-2570).
542. Dr. Stewart designed and conducted his survey in accordance with well-established principles of survey research offered in litigation, as articulated in the *Manual for Complex Litigation*. (Stewart, Tr. 2522; RX 856 (Stewart Expert Report at 16)).
543. In Dr. Stewart's survey, 19% of respondents were aged 18-34, 23% of respondents were aged 35-49, 29% percent of respondents were aged 50-65, and 29% of respondents were aged 66 and older. (Stewart, Tr. 2572; RX 605 (Stewart Expert Report Appendix D at 3)).
544. In Dr. Stewart's survey, 201 respondents were female and 199 respondents were male. (Stewart, Tr. 2572; RX 605 (Stewart Expert Report Appendix D at 2)).
545. The work for Dr. Stewart's survey cost \$37,500. (Stewart, Tr. 2648; RX 856 (Stewart Expert Report at 22)).

b. Relevant questions and responses

546. Question 1 of Dr. Stewart's survey asked: "When you hear the term 'biodegradable' what does that mean to you?" Eighty-two percent of the survey respondents replied with something about disintegration, decomposition, or breakdown. The remaining 26% of survey respondents mentioned something about safety, but the majority of these

respondents also mentioned something about breaking down or decomposition. (RX 856 (Stewart Expert Report at 24); Stewart, Tr. 2586).

547. Question 2 of Dr. Stewart's survey asked: "Is the fact that a product or package is biodegradable important to you?" Seventy-one percent answered yes, and 29% answered no. (RX 856 (Stewart Expert Report at 24)).
548. Question 4 of Dr. Stewart's survey asked: "If something is biodegradable, how long do you think it would take for it to decompose or decay?" This question elicited a very wide range of responses. (RX 856 (Stewart Expert Report at 25)).
549. The most common answer to question 4 of Dr. Stewart's survey, by far, offered by 39% of the survey respondents, was that it depends on the material or type of product. No other single response was offered by more than 6% of the respondents. Other responses referred to differences in materials or context: 6% stated that paper degrades faster; 6% stated that plastic does not degrade or takes a long time to degrade; 5% indicated that it depends on the climate or other conditions, or how the product is disposed; 3% indicated that vegetation decomposes more quickly; and 3% stated that it depends on size. In total, 68% of the survey respondents gave answers to question 4 that indicate recognition of differences in the rate of decomposition related to type of material and/or the context. (RX 856 (Stewart Expert Report at 25); Stewart, Tr. 2580).
550. Question 4a of the Stewart survey was a "yes" or "no" question which asked: "Do you think there are differences in the amount of time it takes for different types of products to biodegrade, decompose or decay?" Ninety-eight percent replied, "yes." Question 4b asked those who believed such differences exist: "What differences exist in the time for different types of products to biodegrade, decompose or decay?" Various differences were cited, including the type of product, the size of the product, the environment, and the climate conditions. (RX 856 (Stewart Expert Report at 26); RX 605 (Stewart Expert Report Appendix D at 22-23)).
551. Answers to the question whether "if something is biodegradable, how long do you think it would take for it to decompose or decay," in Dr. Stewart's survey, must be put into the context of answers to other questions in the survey, such as questions 4a and 4b (F. 550), which indicate wide recognition of differences in the rate of biodegradation. (Stewart, Tr. 2581; RX 856 (Stewart Expert Report at 26)).

c. Summary and conclusions

552. Dr. Stewart's survey was designed in a fashion that is very consistent with accepted standards and best practices in the design of survey research. (Stewart, Tr. 2587; F. 326, 507-544).
553. Not one respondent to Dr. Stewart's survey understood biodegradation to mean the complete breakdown of the substance into elements in nature within one year after customary disposal. (Stewart, Tr. 2583).

554. Based on Dr. Stewart's survey, consumers interpret the term, "biodegradable," to mean the process by which a product breaks down or decays; and consumers understand that the time for this process varies depending on the materials involved and that the process of biodegradability is not always, or even often, a rapid process. (F. 546, 548-549; Stewart, Tr. 2579; RX 856 (Stewart Expert Report at 25-26)).
555. Based on Dr. Stewart's survey, no significant minority of Americans define "biodegradation" to mean that a product will completely biodegrade into elements in nature within one year after customary disposal. (Stewart, Tr. 2586).
556. Based on Dr. Stewart's survey, there is little evidence that consumers' understanding of biodegradability is restricted to decomposition processes that occur within one year or less. (RX 856 (Stewart Expert Report at 26)).

d. Manufacturers Pilot Survey

557. Dr. Stewart conducted a pilot survey of manufacturers of plastic ("Manufacturers Pilot Survey"). (Stewart, Tr. 2587).
558. ECM provided Dr. Stewart with a list of 200 ECM customers in order to conduct the Manufacturers Pilot Survey. (Stewart, Tr. 2637-2639).
559. For the Manufacturers Pilot Survey, ECM provided a customer list to Dr. Stewart that included names and telephone numbers of individuals that were identified as most knowledgeable about the manufacture of plastics and the components that would be acquired for that process. (Stewart, Tr. 2588).
560. ECM provided to Dr. Stewart a list of representatives from customer organizations who were involved in the purchase of materials for the manufacturer of plastics. (RX 856 (Stewart Expert Report at 27)).
561. The Manufacturers Pilot Survey was conducted in an attempt to ascertain whether more knowledgeable purchasers have a more common understanding of biodegradability. (Stewart, Tr. 2588; RX 56 (Stewart Expert Report at 27-28)).
562. The pilot survey had a limit of 20 hours of calling. (Stewart, Tr. 2588).
563. Representatives from ten of ECM's customers participated in the pilot survey of manufacturers of plastic, which was also implemented by CSRS. (RX 856 (Stewart Expert Report at 27-28)).
564. The pilot survey of manufacturers of plastics was not developed into a full-blown study because the respondents were people who were difficult to contact, and in 20 hours of interviewing time, CSRS was only able to conduct interviews of 10 respondents. (Stewart, Tr. 2806).

565. The sample size of the Manufacturers Pilot Survey is too small to support any conclusions. (CCX 865 (Frederick Rebuttal Expert Report ¶ 17)).

E. SUBSTANTIATION

1. Landfill Conditions

566. Landfilling is the largest management option for municipal solid waste (“MSW”) in the United States. About 54 percent of solid waste is managed in that capacity. (JX 3 at 2; Tolaymat, Tr. 126).

567. MSW is waste that is generated in the residential, commercial, and institutional sectors. (Barlaz, Tr. 2177).

568. MSW composition, roughly, is paper, 20 percent; food waste, 20 percent; plastics, 10 percent; and glass, 3 to 5 percent. (Barlaz, Tr. 2181).

569. MSW is highly heterogeneous. (Barlaz, Tr. 2175; RX 853 (Barlaz Expert Report at 4)).

570. Active landfills are dynamic and heterogeneous environments. (CCX 893 (Tolaymat Expert Report at 10)).

571. It is very, very difficult to describe a “typical” landfill. (Barlaz, Tr. 2193).

572. The range of moisture content, temperatures, and oxygen levels in landfills can be considerable. (Barlaz, Tr. 2205-2208).

573. With respect to microbial composition, it would be unreasonable to expect or identify a “one-size-fits-all” description of an MSW landfill because the diversity of potential environments presented in landfills is vast with too many variables, which, in turn, leads to a proliferation of many different types of microorganisms. (Burnette, Tr. 2387-2388).

a. Temperature

574. Landfill temperatures are not controlled, but are often a result of environmental conditions. A landfill in a hot climate such as Florida would have a higher temperature than a similar landfill in a cold climate such as Alaska. (CCX 893 (Tolaymat Expert Report at 12 n.7)).

575. Landfills often have major temperature variations, even within the same landfill. (Barlaz, Tr. 2208-2209; Sahu, Tr. 1842-1844).

576. Dr. Barlaz has seen landfills where steam has been emitted from one side of the landfill, while on the other side of the same landfill, the temperatures might be in the range of 100 degrees Fahrenheit. (Barlaz, Tr. 2208).
577. Temperatures in MSW landfills in the United States range between 20 and 40 degrees Celsius (between 68 and 104 degrees Fahrenheit) and average around 37 degrees Celsius (98.6 degrees Fahrenheit). (CCX 893 (Tolaymat Expert Report at 12); Barlaz, Tr. 2208-2209 (37 to 40 degrees Celsius is most typical)).
578. United States landfills generally operate at mesophilic⁹ temperatures. (Tolaymat, Tr. 139-140). *See also* RRCCFF 420 (“ECM agrees that, in very general terms, the range of temperatures wherein landfills usually operate are in the mesophilic range.”).

b. Oxygen

579. Most landfills in the United States are required by federal regulations to operate with oxygen content below 5%. (Tolaymat, Tr. 138-139) (describing effects of EPA regulations on landfill oxygen levels). *See also* RRCCFF 419 (“ECM agrees that MSW landfill environments are predominantly anaerobic, but not exclusively so.”).
580. There is oxygen in landfills, to the extent that it comes from waste materials, water, and other chemicals. (Barlaz, Tr. 2189-2190).
581. Every reaction in which a microbe gains energy or has a source of energy is an oxidative reaction. (Barlaz, Tr. 2190).
582. Oxidative reactions need not involve oxygen, and they occur in anaerobic systems. (Barlaz, Tr. 2191-2192).

c. Moisture

583. Moisture content is important for biodegradation and a higher rate of biodegradation is expected in areas of landfills with high moisture content. (Tolaymat, Tr. 146).
584. The phrase “dry tomb” landfill is misused because the implication of the term is that if moisture is not being actively added to a landfill, then it is a dry tomb landfill, which is false. (Barlaz, Tr. 2197-2198).
585. There are many landfills that, by virtue of infiltration of rainwater alone, are not dry tomb landfills. (Barlaz, Tr. 2199).
586. The range of moisture content in landfills can be considerable. (Barlaz, Tr. 2206).

⁹ “Mesophilic” refers to a class of microorganisms that have optimal temperature around 98.6 degrees Fahrenheit. (Barlaz, Tr. 2228). *See* F. 733-739.

587. A landfill in Florida, where it rains a lot, will have a higher moisture content than a landfill in Arizona, where there is hardly any rain at all. (Tolaymat, Tr. 146; Barlaz, Tr. 2207 (landfills in regions that are arid tend to be dryer)).
588. Within a landfill, there can be pockets of dry and very moist areas. (Barlaz, Tr. 2205-2206; Tolaymat, Tr. 274) (explaining that, in one part of a landfill that he went to, Dr. Tolaymat was able to read a newspaper that was ten years old, whereas, on another side of the landfill cell,¹⁰ it was “really gooey, black waste.”).
589. Dr. Barlaz has seen moisture readings on approximately a thousand samples of MSW from various landfills, ranging from 15 to 18 percent at the low end, to above 40 percent at the high end. (Barlaz, Tr. 2206).
590. Complaint Counsel’s expert, Dr. Tolaymat, testified that, without the active addition of moisture, the typical moisture content in United States landfills is between 15 and 30%, and that in areas where “ponding”¹¹ occurs, he has seen samples extracted from landfills at 50 to 55% moisture content. (Tolaymat, Tr. 145, 274).
591. Leachate is a liquid that percolates through waste material in a landfill. (JX 4 at 5).
592. Leachate recirculation increases overall moisture content, and also helps balance the moisture levels within the same landfill. (Barlaz, Tr. 2205).
593. Peer-reviewed studies, some co-authored by Dr. Tolyamat, conclude that the addition of leachate recirculation seems to promote biogas production and increase moisture content. (RX 851 (Tolaymat, Dep. at 82-86); RX 898; RX 899; RX 900).
594. Some landfill operators spray waste with leachate as the waste goes into the landfill, which also accelerates biodegradation. (Barlaz, Tr. 2200).
595. Dr. Tolaymat acknowledged that landfill operators practice spray application of liquid to waste, leachate recirculation, and other methods to increase moisture content. (Tolaymat, Tr. 273-278).
596. More and more landfills are now recirculating leachate or taking in commercial liquids from other sources and adding it to waste. Those landfills are operating to enhance waste decomposition. (Barlaz, Tr. 2200).

¹⁰ A landfill cell is the whole area where trash is compacted. Landfill cells are considered distinct entities and operate as distinct units, similar to buildings that are next to each other on the same block. (Tolaymat, Tr. 272).

¹¹ Landfill operators apply a daily cover, sometimes consisting of soil. When it rains or leachate migrates through the landfill cell and hits the daily cover, this results in ponding – leachate getting stuck on top of the daily cover. Once ponded water exists in a landfill, it is very difficult to rid the landfill of the ponded water. (Tolaymat, Tr. 273).

597. When Dr. Barlaz recently performed a landfill gas study on more than 15 landfills around the country, he found that more than two-thirds of those landfills were spray-applying leachate to the working face of the landfill, although those landfills were not calling themselves “bioreactors.” (Barlaz, Tr. 2201).
598. A landfill might collect around 300 gallons per acre per day of landfill leachate. (Barlaz, Tr. 2205-2506).

d. Biodegradation in a landfill

599. Biodegradation processes are highly variable in the heterogeneous landfill environment, where you have different microenvironments throughout the landfill. This means the level of biodegradation and activity will be variable in the landfill environment. (Sahu, Tr. 1768-1770).
600. The differing pockets of activity and varying conditions in a landfill will have an effect on the rate of biodegradation. (Sahu, Tr. 1770-1771).
601. Researchers have identified many specific microorganisms that populate MSW landfills. (Burnette, Tr. 2390).
602. Landfill leachate carries microorganisms; contains carboxylic acids, humic matter, ammonia, and other chemicals; and has nutrients in the form of dissolved ammonia and phosphate, which are major nutrients or macronutrients, and contain trace metals, which are nutrient sources for microorganisms. (Barlaz, Tr. 2203-2205).
603. Landfills contain species within the phyla Proteobacteria, Firmicutes, and Thermotogae, which are large families that contain many forms of individual bacteria. (Burnette, Tr. 2390-2392).
604. There are also fungi present in landfills that have been identified in the peer-reviewed literature and are responsible for biodegradation. (Burnette, Tr. 2372, 2394, 2392).
605. MSW landfills contain bacteria, fungi, and other microorganisms that secrete enzymes capable of completing biodegrading processes. (Sahu, Tr. 1865-1866; Burnette, Tr. 2372-2373).
606. Scientists have published information concerning the types of bacteria and microorganisms that are found in nature (including MSW landfills), which have also been shown to biodegrade conventional plastics. (Sahu, Tr. 1868-1869; RX 855 (Sahu Expert Report at 34)).
607. In peer-reviewed literature, scientists have used DNA sequencing to identify many species existing in landfills that are capable of degrading plastics. (Burnette, Tr. 2390-2392; RX 854 (Burnette Expert Report at 10)).

e. Anaerobic biodegradation

608. Anaerobically biodegradable materials have the potential to generate methane. (Barlaz, Tr. 2183-2184).
609. Stoichiometry is the relationship between the chemical composition of reactants of an equation (those materials on the left side), and the end products (the materials on the right side). (Barlaz, Tr. 2185).
610. Principles of stoichiometry deal with conservation of mass, and are applicable to the conversion of substrates to methane during anaerobic biodegradation. (Barlaz, Tr. 2185-2187).
611. To microorganisms, MSW represents a source of food or energy, so if there is energy to be gained by consuming or attacking a substrate, they will do it. (Barlaz, Tr. 2186).
612. In general, the process of anaerobic biodegradation involves hydrolysis reactions that eventually produce products such as butyric acid, acetic acid, hydrogen, and carbon dioxide. (Barlaz, Tr. 2186).
613. Butyric acid is then attacked by microorganisms referred to as acetogenic, which convert the butyric acid to acetic acid and carbon dioxide. (Barlaz, Tr. 2186-2187).
614. Methanogenic archaea use either the acetic acid or hydrogen plus carbon dioxide and convert either of those substances to methane. (Barlaz, Tr. 2187).
615. The concerted activity of at least four trophic groups of microorganisms enables the conversion of materials to methane and carbon dioxide. (Barlaz, Tr. 2187).
616. Microbes may secrete some waste products of metabolism to the environment as a product of biodegradation. (Barlaz, Tr. 2188).
617. Cell mass is also a product of biodegradation, meaning that carbon extracted from waste may consume the carbon for growth rather than convert carbon to methane or gas. (Barlaz, Tr. 2188).
618. In an anaerobic test system, the ratio of methane gas to carbon dioxide is usually in the range of 1:1, but may appear more like 60% methane and 40% carbon dioxide, because carbon dioxide can dissolve into the liquid phase. (Barlaz, Tr. 2188-2189).
619. Significant anaerobic biodegradation occurs in MSW landfills, and the prime evidence for that is the production of methane in those landfills. (Barlaz, Tr. 2174).

f. Methane

- 620. MSW contains chemical compounds that have methane potential. (Barlaz, Tr. 2183-2184).
- 621. All MSW landfills have the potential to produce gases, and those gases are a signature of biological activity. (Sahu, Tr. 1846).
- 622. The gases generated from MSW landfills show that there are biological reactions occurring, and so the gases are indicative of underlying biological activity in the landfill. (Sahu, Tr. 1847).
- 623. Landfills can produce substantial amounts of methane gas emissions. (Barlaz, Tr. 2174-2175; 2192-2193).
- 624. Methane is the end product of biodegradation in landfills. (Barlaz, Tr. 2174).
- 625. There are about 2,000 MSW landfills in the United States and commercial quantities of methane are recovered from at least 600 of them. (Barlaz, Tr. 2174, 2197).
- 626. Dr. Barlaz has seen landfills that make 250 to 500 cubic feet of landfill gas (at 50% methane) per minute. (Barlaz, Tr. 2192).
- 627. The gases generated from MSW landfills show that there are biological reactions occurring and are indicative of underlying biological activity in the landfill. (Sahu, Tr. 1847).
- 628. Methane production is clear evidence that MSW landfills are biologically active because methane is the direct result of anaerobic metabolism. (Burnette, Tr. 2384-2385).

g. Degradation times in landfills

- 629. Waste that is disposed in MSW landfills will undergo aerobic biodegradation to some degree, particularly in the early stages after waste disposal and before the waste is compacted and covered. (Barlaz, Tr. 2214; Sahu, Tr. 1839-1840).
- 630. Because landfill environments are highly variable with respect to moisture content and temperature, even within a single landfill, landfill conditions can support many different rates of biodegradation, including accelerated rates of biodegradation in areas of high moisture or temperature. (Sahu, Tr. 1768-1771).
- 631. Decay rates fluctuate in landfills. The rate at which a material biodegrades in a landfill is described by its first order decay rate, which can be converted to the material's half-life. The decay rate models of even the most degradable MSW components, food waste

and grass, do not predict complete biodegradation within one year. (RX 853 (Barlaz Expert Report at 3, 14, Table 1); Barlaz, Tr. 2296-2297).

632. If a material is disposed in a landfill, then for the purpose of determining whether it biodegrades, it does not matter whether it degrades in two, ten, or twenty years. (Barlaz, Tr. 2283-2284).

2. Scientific Evidence on the Definitions of Biodegradability

a. Dr. McCarthy's definition of "biodegradability"

633. Complaint Counsel's degradable polymer expert, Dr. McCarthy, used in his expert report a definition for biodegradable provided to him by Complaint Counsel. Footnote one of Dr. McCarthy's report states:

Complaint Counsel asked me to assume that the unqualified marketing claim 'biodegradable' means that the entire treated plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (*i.e.*, incinerator, landfill, or recycling). I use this definition and the scientific definition of biodegradable interchangeably in this Expert Report, because there is no substantive difference between the two that affects my analysis or my opinions.

(CX 891 (McCarthy Expert Report at 5 n.1); McCarthy, Tr. 482-483) ("footnote one definition"). This opinion is unsupported, unpersuasive, and rejected. (F. 634-675).

634. In the words of Dr. McCarthy, his expert report was the result of a "collaborative effort" between Dr. McCarthy and Complaint Counsel. (McCarthy, Tr. 482-483).
635. When Dr. McCarthy was asked, "[c]an you identify for me the content in footnote one that you yourself drafted?" he stated, "[p]robably the scientific definition part of it." (McCarthy, Tr. 487).
636. Dr. McCarthy's report does not contain a specifically designated "scientific definition" but does, later in his report, define biodegradation "as a chemical process by which microorganisms such as bacteria and fungi use the carbon found in organic materials as an energy source (*i.e.*, as a food source)." (CCX 891 (McCarthy Expert Report at 8)).
637. This later definition of biodegradation (F. 636) does not have the "within one year" or completeness requirements contained in the footnote one definition in Dr. McCarthy's expert report. (RX 855 (Sahu Expert Report at 13 n.11)).
638. Although Dr. McCarthy initially testified that the definition in footnote one of his expert report – that "'biodegradable' means that the entire treated plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one

year after customary disposal (*i.e.*, incinerator, landfill, or recycling)” is “equivalent” to the scientific definition and is “interchangeable” with the scientific definition of biodegradable, Dr. McCarthy subsequently testified he would like to change his testimony regarding the footnote one definition being “interchangeable” with the scientific definition because “‘interchangeable’ . . . is a bit strong.” (McCarthy, Tr. 486-487, 496).

639. Dr. McCarthy’s expert report does not contain any citations to any scientific literature to support the definition set forth in footnote one of his report – that the entire treated plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (*i.e.*, incinerator, landfill, or recycling). (CCX 891 (McCarthy Expert Report at 5 n.1); RX 855 (Sahu Expert Report at 11)).
640. No peer-reviewed literature defines “biodegradation” to be limited to a complete breakdown of plastic into elements found in nature within one year after customary disposal. (Barlaz, Tr. 2281; Sahu, Tr. 1773).
641. No scientist has published a peer-reviewed article defining biodegradation to be limited to the complete breakdown of a plastic or material into elements found in nature within one year after customary disposal. (Burnette, Tr. 2376) (further explaining, “in microbiology and in biochemistry, it’s rare that we think of things in terms of completion. We certainly don’t put rates on things that we don’t have a clear definition for.”)).
642. Complaint Counsel’s expert, Dr. Michel, has never defined biodegradation as having to result in a complete breakdown of material into elements found in nature within one year after customary disposal in any of his peer-reviewed articles. (Michel, Tr. 2908).
643. Dr. McCarthy admitted that he was unaware of any instance in which a peer-reviewed article concerning plastics biodegradation ever defined the term, “biodegradable” as entailing a complete break down and return to nature within one year after customary disposal. (McCarthy, Tr. 493-494).
644. While Dr. McCarthy opines in his expert report that ECM could have performed confirmatory testing to show biodegradation by conducting a gas evolution test showing at least 60% conversion to methane and carbon dioxide within 18 months (F. 848), such testing would not be able to show complete biodegradation within “one year.” (RX 855 (Sahu Expert Report at 12)).
645. Dr. McCarthy is unaware of any instance in which a peer-reviewed article concerning plastics biodegradation defined the term “biodegradation” as entailing a complete breakdown and return to nature within one year after customary disposal. (McCarthy, Tr. 493-494).

646. Dr. McCarthy has defined the terms “biodegradable” or “biodegradation” in articles he has authored. He has never, in any of his published scientific literature, defined “biodegradable” to mean that the entire plastic will completely break down and return to nature within one year after customary disposal. (McCarthy, Tr. 487-488).
647. Dr. McCarthy co-authored an article titled, “*Advances in Properties and Biodegradability of Co-Continuous, Immiscible, Biodegradable, Polymer Blends.*” In that article, Dr. McCarthy concluded that certain test samples were biodegradable without proving that the samples completely biodegraded within one year after customary disposal. (McCarthy, Tr. 577-579, 582; RX 940).
648. Dr. McCarthy co-authored an article titled, “*Biodegradable Blends of Bacterial Polyesters with Polyethylene and Polystyrene.*” No author of “*Biodegradable Blends of Bacterial Polyesters with Polyethylene and Polystyrene*” established that the polyethylene and polystyrene blends that were tested completely broke down and returned to nature within one year after customary disposal. (McCarthy, Tr. 586; RX 945).
649. Dr. McCarthy, in 2003, authored a chapter titled, “*Biodegradable Polymers*” in the text titled, “*Plastics and the Environment.*” In this chapter, Dr. McCarthy stated that “[t]he definition of biodegradable polymer varies greatly among scientists, manufacturers, and consumers.” (McCarthy, Tr. 488-490; RX 924 at 359).
650. Because manufacturers had different definitions of the term “biodegradable,” ASTM International, formerly known as the American Society for Testing and Materials (“ASTM”), developed an agreed-upon definition (F. 679). (McCarthy, Tr. 492-93).
651. Dr. McCarthy has relied upon the ASTM definition of the term “biodegradable” in a publication that he wrote on biodegradable polymers in 2003. (McCarthy, Tr. 494-95).
652. The ASTM definition for biodegradation involving plastic at the time Dr. McCarthy wrote the chapter in 2003 (F. 649) was: “‘plastic designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties’... in which the degradation results from the action of naturally-occurring micro-organisms such as bacteria, fungi, and algae.” (McCarthy, Tr. 495; RX 924 at 359).
653. The ASTM definition (F. 652) does not define “biodegradable” to mean that there is a complete break down and return to nature of the treated plastic within one year after customary disposal. (McCarthy, Tr. 494).
654. Dr. McCarthy is the editor of the *Journal of Polymers and the Environment*, formerly the *Journal of Polymer Degradation*. In this role, Dr. McCarthy evaluates the scientific merits of articles, and edits and determines which articles are published in the *Journal of Polymers and the Environment*. No article would appear in the *Journal of Polymers and the Environment* without Dr. McCarthy’s approval. (McCarthy, Tr. 509-513, 527).

655. Dr. McCarthy reviewed an article titled, “*Biodegradable Polymers-A Review on Recent Trends and Emerging Perspectives*” that was published in the *Journal of Polymers and the Environment* in June 2011. (McCarthy, Tr. 511-512; RX 925).
656. In “*Biodegradable Polymers-A Review on Recent Trends and Emerging Perspectives*,” the authors state that “[t]he various definitions of biodegradation depend on the field of application of the polymers (biomedical area or natural environment). Many different definitions have officially been adopted, depending on the background of the defining standard organizations and their particular interests.” (McCarthy, Tr. 527-528; RX 925).
657. In “*Biodegradable Polymers-A Review on Recent Trends and Emerging Perspectives*,” the authors list a series of sources for the definition of “biodegradable” and “biodegradation” that are within the universe of biomedical and the natural environment literature. With the exception of the ASTM D6400 protocol, the “Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities,” (CCX 91), not one of the definitions recited in that paragraph includes a requirement that treated plastics break down and return to nature within one year of customary disposal. (McCarthy, Tr. 511-513, 527-529; RX 925).
658. Dr. McCarthy’s writings, outside of this litigation, that define biodegradation do not include the qualifier that an item must completely break down within a period of one year. (Sahu, Tr. 1783-1785).
659. Dr. McCarthy invented some polymer blends that are the subject of a United States patent, patent number 5,883,199 (“’199 patent”). (McCarthy, Tr. 534-535; RX 756).
660. Dr. McCarthy reviewed each specification in the ‘199 patent and signed a declaration affirming the validity of each specification before submitting the ‘199 patent to the United States Patent and Trademark Office. (McCarthy, Tr. 548).
661. Dr. McCarthy extrapolated from the five blends tested in the ‘199 patent to classify additional blends not tested as biodegradable. (McCarthy, Tr. 549-550; RX 756).
662. The ‘199 patent allows a blend of a homopolymer to be biodegradable. (McCarthy, Tr. 598; RX 756).
663. In the ‘199 patent, Dr. McCarthy reported on testing that he had done with various blends of degradable and nondegradable polymers, indicating that Dr. McCarthy understands that a blend of degradable and nondegradable polymers can degrade. (Sahu, Tr. 1893).
664. Dr. McCarthy did not establish in the ‘199 patent that any of the polymer blends in the ‘199 patent would biodegrade completely within one year after customary disposal. (McCarthy, Tr. 545-546; RX 841 (McCarthy, Dep. at 76-77); RX 756).

665. In the '199 patent, McCarthy does not define biodegradation as something that should be complete within one year. Instead, his patent discusses ways of making blends of different polymers of different types and states that his patent allows a user to make a formulation of plastics that can provide a desired degree of biodegradation within a given period of time. Dr. McCarthy does not say the blend will completely biodegrade or that the biodegradation must be complete within one year. (Sahu, Tr. 1784-1785).
666. Under an agreement with the University of Massachusetts (UMass), Dr. McCarthy assigned his '199's patent rights to UMass. UMass is patent number '199's assignee. In exchange, Dr. McCarthy receives a 10% profit share of the royalty stream. (RX 761; RX 757; McCarthy, Tr. 523-524; RX 841 (McCarthy, Dep. at 57-59)).
667. Metabolix Corporation ("Metabolix") is the exclusive licensee of a biodegradable polymer covered by the '199 patent. (McCarthy, Tr. 523; RX 209; RX 756).
668. Dr. McCarthy acknowledged that Metabolix's products compete directly with ECM's technology for market share. (McCarthy, Tr. 538-408; RX 841 (McCarthy, Dep. 64-66)).
669. As of the date of the hearing, Dr. McCarthy had received about \$28,000 in royalties as a result of the patent he invented, under which Metabolix is the exclusive licensee. (McCarthy, Tr. 524, 612).
670. To the extent Metabolix's sales increase based on a reduction in the market for the ECM Additive, royalties from the patent will increase and Dr. McCarthy's income from those royalties will increase as well. (See RX 841 (McCarthy, Dep. at 51-52, 55-61)).
671. The definition of "biodegradable" used by Dr. McCarthy in footnote one of his report follows the language of the FTC's Green Guides, which state that "[i]t is deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal." (Compare CCX 891 (McCarthy Expert Report at 5 n.1) with RX 347, at § 260.8(c)).
672. Under the definition of "biodegradable" used by Dr. McCarthy in footnote one of his expert report, if a plastic biodegrades to 95 percent on the 364th day after customary disposal, and biodegrades to 100 percent on the 366th day, the item would not satisfy McCarthy's definition of "biodegradable." (McCarthy, Tr. 525-26; RX 841 (McCarthy, Dep. at 28-29)).
673. Not even tree trunks, orange peels, or banana peels -- all generally accepted to be biodegradable in the environment -- can reliably break down into elements found in nature within one year after customary disposal. (McCarthy, Tr. 503-509, RX 841 (McCarthy, Dep. at 187); see also Barlaz, Tr. 2218; Michel, Tr. 2955).

674. Even the most easily biodegradable substances, such as food waste, will not biodegrade in an MSW landfill within one year after customary disposal. (Tolaymat, Tr. 153-154; RX 853 (Barlaz Expert Report at 11); CCX 893 (Tolaymat Expert Report at 16)).
675. In his article, “*Biodegradation of Conventional and Bio-Based Plastics and Natural Fiber Composites During Composting, Anaerobic Digestion and Long-Term Soil Incubation*,” Dr. Michel did not stop his biodegradation test at 365 days and reported that cellulose, a material known to be biodegradable, degraded roughly 74% in approximately 400 days. (CCX 164; Michel, Tr. 2903-2904, 2954-2955).

b. Scientific definitions of “biodegradability”

676. Scientists disagree as to a specific definition of “biodegradable.” (McCarthy, Tr. 491).
677. ASTM develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services. Standards are developed within committees, and membership in the ASTM is open to anyone with an interest in its activities. (CCX 891 (McCarthy Expert Report at 19 n.10)).
678. The ASTM defines biodegradation, as related to plastic products, as the process by which natural biota decompose a plastic product into different chemical materials. (Sinclair, Tr. 782).
679. Based on the record evidence, the ASTM D883-12 definition of biodegradability is:

A degradable plastic is defined as a plastic that is designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties that may vary as measured by standard test methods appropriate to the plastic and the application in a period of time that determines its classification. A Biodegradable Plastic is defined as a degradable plastic in which the degradation results from the action of naturally occurring microorganisms such as bacteria, fungi and algae.

(Sinclair, Tr. 785; CCX 14).¹²

680. There are different variants of the definition of biodegradation, but they all speak to the same idea of degrading the object of interest using biological means. (Sahu, Tr. 1774; Sahu, Tr. 1760 (“[B]iodegradation means different things to different researchers ... or in different contexts.”)).

¹² After an extensive review of the record, it appears that neither party offered ASTM D883-12 into evidence. Respondent, in its proposed finding 1348, proposed this finding, with a citation to the testimony of Mr. Sinclair and to CCX 14, which is Respondent’s Certificate of Biodegradability. See F. 269. Complaint Counsel did not dispute RPF 1348 in its Reply to Respondent’s Proposed Findings of Fact. Therefore, this language is accepted as the ASTM D883-12 definition.

681. In all contexts, biodegradation simply means the breakdown of whatever is the object of interest using biological means, using essentially biota such as bacteria or fungi or other type of naturally occurring or evolving biota in the environment. (Sahu, Tr. 1760).
682. The common scientific definition of biodegradation is degradation by using biological means. (Sahu, Tr. 1782).
683. The scientific literature defining biodegradation does not contain a time restraint or require complete degradation. (Sahu, Tr. 1783).
684. The commonly and scientifically accepted term for biodegradation, to the extent there is any consensus at all, is that the mechanism of degradation is via biotic or biological agents, such as bacteria, fungi, or other living organisms, as opposed to other abiotic degradation pathways. There is not a “scientific” definition that constrains this any further, especially with regard to completeness or an arbitrarily selected time frame. (RX 855 (Sahu Expert Report at 12-13)).
685. Complaint Counsel’s expert, Dr. Michel, has recognized in his testimony concerning cellulose that a biodegradable material is “fully” biodegradable even if it biodegrades only to 44% in a test environment. (Michel, Tr. 2960-2961).
686. The biodegradability of a product describes a property of the material, much like its color or weight or density. A product is either biodegradable, or it is not. (Barlaz, Tr. 2217-2218).
687. A product that is biodegradable will biodegrade at various rates and to various extents based on the external environmental conditions, but will remain biodegradable regardless. (Barlaz, Tr. 2218-2219).
688. Changes in temperature and moisture do not influence intrinsic biodegradability of a material. For example, a piece of paper in a dry environment, at 70 degrees Fahrenheit, will biodegrade because that is an intrinsic property of paper. The moisture and temperature affect the rate of biodegradability, but not whether it will biodegrade. (Barlaz, Tr. 2218-2219).
689. Biodegradation involves microorganisms acting on substrates to break down same. (Burnette, Tr. 2376-2377).
690. Most biologists would agree biodegradation means the biological activity resulting in the breakdown of a substrate of a product. (Burnette, Tr. 2375-2376).
691. There are several definitions of biodegradation used to describe a biological process. In general, biodegradation refers to the chemical alteration, or “breakdown,” of any material as a consequence of biological action. The fundamental requirement of biodegradation is the presence of live (micro) organisms facilitating the mechanism of degradation. (RX 854 (Burnette Expert Report at 4)).

692. From a microbiological standpoint, biodegradation is the conversion of one substance to another substance as the result of biological activity. (Burnette, Tr. 2375).
693. Biodegradation is the conversion of organic matter through the action of bacteria and fungi into more elementary components or elements. (Tolaymat, Tr. 130).
694. Biodegradation is the mineralization of materials as a result of the action of naturally-occurring microorganisms such as bacteria and fungi. (Michel, Tr. 2907-2908; CCX 880).
695. Biodegradation is a process by which microbial organisms sustain their life by eating and metabolizing a material. (Barber, Tr. 2069).
696. Biodegradation is not subject to a time span limitation because it is an ongoing process. (Barber, Tr. 2069).

3. ECM Plastics Will Not Fully Biodegrade in 9 Months to 5 Years in a Landfill

697. The expert testimony in this case establishes that ECM Plastics will not fully biodegrade in 9 months to 5 years in a landfill. (F. 698-702).
698. Complaint Counsel's expert, Dr. McCarthy, opined that ECM Plastics will not fully biodegrade in 9 months to 5 years in a landfill:
- (a) ECM Plastics will not completely biodegrade in periods of time as short as five years. (CCX 891 (McCarthy Expert Report at 26)).
 - (b) Conventional nondegradable plastics treated with 1% ECM Additive will not completely break down into elements found in nature within five years. (McCarthy, Tr. 681-682).
699. Complaint Counsel's expert, Dr. Tolaymat, opined that ECM Plastics will not fully biodegrade in 9 months to 5 years in a landfill:
- (a) Even if ECM Plastics were located in a faster-degrading area of a landfill, they would not degrade in five years or less. Even food scraps will take, on average, seven years to biodegrade. (CCX 893 (Tolaymat Expert Report at 16)).
 - (b) Plastics made with the ECM Additive will not biodegrade completely in five years or less in MSW landfills. (Tolaymat, Tr. 121-122). Even the most biodegradable material would not completely biodegrade in a landfill within 5 years even under optimum

conditions for biodegradability. (Tolaymat, Tr. 153-156 (discussing half-lives and decay rates of various types of waste)).

700. Complaint Counsel's expert, Dr. Michel, opined that ECM Plastics will not fully biodegrade in 9 months to 5 years in a landfill:
- (a) Rebutting Respondent's expert and opining: Dr. Sahu appears to agree with the central point in the case which is that it has not been demonstrated that ECM amended conventional plastics will biodegrade in a landfill in 1 to 5 years. (CCX 895 (Michel Rebuttal Expert Report at 12)).
701. Respondent's expert, Dr. Sahu, opined that ECM Plastics will not fully biodegrade in 9 months to 5 years in a landfill:
- (a) "[T]he expectation that all plastics with the ECM additive added in the usual amount (*i.e.*, at a level of 1 or at most a few percent) should completely . . . degrade in typical landfill conditions, in a time period of 1 year or even 5 years, is unrealistic." (RX 855 (Sahu Expert Report at 8)).
 - (b) Dr. Sahu's report and testimony estimate ECM Plastic would take 30 years to completely biodegrade, possibly up to 100 years on the "very, very high side." (RX 855 (Sahu Expert Report at 44); Sahu Tr. 1953-1954).
702. Respondent's expert, Dr. Barlaz, opined that ECM Plastics will not fully biodegrade in 9 months to 5 years in a landfill:
- (a) "[T]he suggestion that all materials should biodegrade within one or even five years of disposal is not consistent with even the highest rates of biodegradation expected for mixed MSW. When considering the decay rate of even the most degradable MSW components, food waste and grass, models do not predict complete biodegradation within one year." (RX 853 (Barlaz Expert Report at 3)).
 - (b) Plastics generally biodegrade slower than food waste. Food waste, leaves and grass take slightly under five years to biodegrade under accelerated biodegradation conditions. Most, if not all, of the most readily degradable MSW will not completely biodegrade in five years or less. (Barlaz, Tr. 2292-2297).
703. Mr. Sinclair conceded he was "open to the possibility" that the 9 months to 5 years claim might not be correct. (Sinclair, Tr. 986-988).

4. Competent and Reliable Scientific Methods to Prove Biodegradability

a. General standards

704. Competent and reliable scientific evidence is required to show whether plastics containing the ECM Additive are biodegradable under conditions of typical disposal, specifically, in MSW landfills in the United States. (CCX 891 (McCarthy Expert Report at 13); RX 855 (Sahu Expert Report at 11)).
705. Competent and reliable scientific evidence requires the results of appropriately analyzed, independent, well-designed, well-conducted, and well-controlled testing. (CCX 891 (McCarthy Expert Report at 13)).

b. Landfill environment

706. A landfill, by its nature, is different from a controlled laboratory reactor; in the latter, scientists attempt to control the environment to eliminate variables. (Sahu, Tr. 1769-1770).
707. A landfill cannot be standardized or homogenized. (Sahu, Tr. 1769-1770).
708. Without accelerated testing (F. 718), lab tests for biodegradation could take anywhere from 5 to 500 years. It is not practical to try to simulate the landfill ecosystem at that time scale in a laboratory. (Barlaz, Tr. 2212).
709. It would be scientifically unreasonable to design a perfect closed-system test that would be representative of all the potential microenvironments in an MSW landfill. (Burnette, Tr. 2387-2388).
710. In a laboratory closed-system reactor, the test article is not exposed to all of the conditions which it may be exposed to in an MSW landfill. (Burnette, Tr. 2389).
711. Any test fundamentally is trying to capture in a lab environment a very complex ecosystem. Because landfills are heterogeneous, one has to be cautious in projecting rates that you get from a lab environment, which tends to be homogeneous. (Sahu, Tr. 1795-1796).

c. Extrapolation and the rate of biodegradation

712. No one test can support a rate of biodegradation of plastics in landfills. The rate of biodegradation is a matter of scientific judgment. (Tolaymat, Tr. 261-262). *See also* Tolaymat, Tr. 219-224 (when questioned concerning which tests, if any, can be used by a company to prove the rate of biodegradation in an MSW landfill, Dr. Tolaymat did not have one test to recommend).

713. Measurement of the rate of biodegradation at laboratory-scale requires sufficient methane production data over time to calculate a rate. While laboratory experiments are useful to assess whether a material is biodegradable and to assess the relative rate of biodegradability for multiple materials, there is not a uniformly utilized method to extrapolate rate data as measured at laboratory-scale to field-scale landfills. (RX 853 (Barlaz Expert Report at 10); (Barlaz, Tr. 2282) (“[I]t’s very, very difficult to measure rates at either – at field scale either for individual components or for bulk waste, so all we have is the lab.”).
714. In the publicly available peer-reviewed literature and in his experience, Dr. Sahu has not seen any kind of extrapolation to complete biodegradation. In other words, he has not seen a study that has taken a rate derived from a test and then extrapolated from that rate to attempt to state a time period for complete biodegradation. (Sahu, Tr. 1795-1796).
715. Dr. Sahu could not think of any instances where scientists had extrapolated data from gas evolution tests that were conducted for less than a year to conclude that plastics would continue to biodegrade in a natural environment. Rates change due to many factors, and there are good reasons not to extrapolate that far. (Sahu, Tr. 1795-1796).
716. In his ‘199 patent (F. 659), Dr. McCarthy extrapolated gas evolution test data showing a rate of biodegradation reaching 14% in 45 days to label a substrate as biodegradable. (Sahu, Tr. 1894; McCarthy, Tr. 558-560; RX 756).

d. Accelerated testing

717. Research concerning the microbiology of refuse decomposition in the laboratory is by definition “accelerated.” (Barlaz, Tr. 2211-2212).
718. In “accelerated testing,” scientists try to mimic a slow natural process in the lab in a manner faster than would have occurred in nature. Scientists try to speed up in a lab environment the real-world phenomena so that they can get results in a reasonable period of time. (Sahu, Tr. 1924).
719. Accelerated tests are commonly done in engineering, biology, drug testing and almost everywhere where the natural phenomena of interest happens to be of a long time scale. (Sahu, Tr. 1924).
720. Accelerated testing is appropriate for biodegradation studies because biological reactions are generally slower than chemical reactions. With accelerated testing, one can find out about these relatively slow processes in a lab environment within a reasonable period of time. (Sahu, Tr. 1924-1925).
721. Accelerated gas evolution tests on plastics try to mimic the landfill conditions in the lab environment. (Sahu, Tr. 1926).

722. In laboratory-scale closed-system reactor tests, like the ASTM D5511 (F. 759), materials are tested under conditions designed to enhance the rate of decomposition, including the incubation temperature and the use of leachate neutralization and recirculation. (RX 853 (Barlaz Expert Report at 8)).
723. Dr. Tolaymat, Complaint Counsel's expert, agreed that accelerated testing to demonstrate biodegradation is possible. (Tolaymat, Tr. 243-244).
724. Attempting to truly simulate a landfill environment might require testing that spans 100 years. (Barlaz, Tr. 2212) ("it's not practical to try to simulate that kind of ecosystem at the time scale in the laboratory").
725. To see if a slowly degrading material is fully biodegradable, you would have to run a test for ten, fifteen, or twenty years. (Barber, Tr. 2057).
726. Running a test for ten to twenty-five years would be prohibitively expensive. In some cases, testing requires daily monitoring or interaction with the sample. (Barber, Tr. 2058).
727. Running a test for tens of years would be exceedingly difficult because maintaining a viable culture requires monitoring of temperature, water, pH, and nutrients. (Barber, Tr. 2058).
728. Dr. Barber found it very difficult to maintain a real active biological system longer than 12 to 18 months, and the concept of maintaining this level of activity for tens of years in a laboratory is next to impossible. (Barber, Tr. 2058-2059).
729. Once a test that has run for a discrete, reasonable period of time ensures that the amount of material that has been biodegraded is much higher than the amount of additive, so that it is not just the additive that is biodegrading, that indicates that the microbes are attacking the base polymer and there is no reason that the microbes would not continue to attack those base polymers until it was completely biodegraded. (Barber, Tr. 2057).
730. Dr. Tolaymat was unable to give an example of a practical laboratory test that would simulate landfill conditions, but also be accelerated, so that testing would not be required to continue for decades. (Tolaymat, Tr. 247-250).
731. The ASTM D5511 test and other gas evolution tests, including the test used by Dr. McCarthy in his '199 patent, are "accelerated tests" designed to reveal intrinsic biodegradability. (See Sahu, Tr. 1923-1927; Barlaz, 2211-2212; McCarthy, Tr. 547-548).

e. Temperature

732. One way to "accelerate" a biodegradation test is to increase the temperature. (Sahu, Tr. 1926-1927).

733. “Mesophilic” refers to a class of microorganisms that have optimal temperature around 98.6 degrees Fahrenheit. (Barlaz, Tr. 2228).
734. At temperatures above 43 to 44 degrees Celsius, mesophiles are killed off or severely inhibited. (Barlaz, Tr. 2228; Burnette, Tr. 2432).
735. Many bacteria identified in the peer-reviewed literature as responsible for biodegrading plastics fall within the mesophilic range. (Burnette, Tr. 2432-2433).
736. “Thermophiles” have an optimal temperature closer to 60 degrees Celsius or about 130 to 140 degrees Fahrenheit. (Barlaz, Tr. 2228).
737. Mesophilic and thermophilic bacteria function at different temperatures and pace, but they use common and universal mechanisms of action to make energy. (Burnette, Tr. 2430-2431).
738. The difference between mesophilic and thermophilic conditions affects the rate of biodegradation. (Barlaz, Tr. 2228).
739. At a fundamental level, there is no difference in the way thermophilic bacteria metabolize waste versus the way mesophilic bacteria metabolize waste. The particular enzymes involved, however, are different, as is the rate of biodegradation. (Sahu, Tr. 1843-1844).
740. Because bacteria capable of degrading plastics are mesophilic, test conditions (like the ASTM D5511) that promote only thermophilic bacteria may not provide a truly “optimal” environment for assessing total biodegradability. (Burnette, Tr. 2432-2433).

f. Weight loss tests

741. The scientific community does not consider weight loss tests alone sufficient for determining biodegradation. (CCX 892 (McCarthy Rebuttal Expert Report at 10-11); McCarthy, Tr. 414; RX 855 (Sahu Expert Report at 41)).
742. Although weight loss is evidence of decomposition, it is not necessarily a good, accurate measure, because one can have weight loss without having decomposition. (Tolaymat, Tr. 172-173).

g. Gas evolution tests

743. The expert testimony in this case establishes that gas evolution data is a competent and reliable method to prove biodegradability, and it is the most practical and widely used measure of biodegradation in the scientific field. F. 745-749.

744. Tests that rely on gas evolution to detect biodegradation measure the carbon dioxide (CO₂) and methane (CH₄) that evolve as a result of biodegradation. (RX 855 (Sahu Expert Report at 34, 41)).
745. The most typical type of biodegradation test is a gas evolution test, which monitors the end-products of biodegradation. (CCX 891 (McCarthy Expert Report at 15)). Most of the testing used by scientists to assess biodegradability is gas evolution or respiromic testing. (McCarthy, Tr. 413-414).
746. Dr. McCarthy relied on gas evolution data when assessing whether plastic polymers that he designed were biodegradable under anaerobic conditions. (McCarthy, Tr. 547-548; RX 756 at column 11; *see also* Sahu, Tr. 1894-1895; CCRFF 1611).
747. Gas evolution tests are reliable evidence to show biodegradation in landfills. (Tolaymat, Tr. 171).
748. It is conventional wisdom now, with some justification, that the only true indicator of biodegradation is, in fact, gas evolution. (RX 855 (Sahu Expert Report at 41)). Gas evolution testing can provide reliable and competent scientific evidence and is generally relied upon by scientists to show the biodegradability of materials. (Sahu, Tr. 1792, 1896).
749. Data from gas evolution testing is broadly accepted by the scientific community of evidence of anaerobic biodegradation. (Barlaz, Tr. 2246).

h. BMP tests

750. A biochemical methane potential (“BMP”) test is a gas evolution test that evaluates the decomposition of various materials by measuring the amount of carbon that is decomposed in an anaerobic environment. It provides measurements that give one the optimal amount of methane that would be generated from the anaerobic decomposition of a particular substrate. (Tolaymat, Tr. 171-172).
751. The BMP test is performed in a small 160 milliliter glass vial, whereas the ASTM D5511 test is a reactor-scale test, performed in a “high-solids environment.” (Barlaz, Tr. 2220-2224).
752. The BMP test conditions differ dramatically from the typical United States landfill and have a much higher moisture content. (Tolaymat, Tr. 237-238).
753. There are no standards for conducting a BMP test. BMP testing can be modified from laboratory to laboratory. (Tolaymat, Tr. 239; Barlaz, Tr. 2220-2222).
754. In BMP tests, laboratories could choose to follow different protocols when adding types of vitamins and minerals. (Tolaymat, Tr. 237-238; Barlaz, Tr. 2221-2222). Other adaptations to BMP tests include changes to temperature or duration of the test and

modifications to the preparation of the test sample or screening the material by passing it through a 1 millimeter screen. When a laboratory grinds material to be small enough to pass through a 1 millimeter screen, it becomes the consistency of whole wheat flour. (Barlaz, Tr. 2221-2222).

755. A BMP test can be considered as a screening test for anaerobic biodegradation, although the actual volume of methane generated in a landfill may well be less than that measured by a BMP test. (RX 853 (Barlaz Expert Report at 8); Barlaz, Tr. 2231, 2267-2268).
756. BMP tests are not appropriate for testing slower degrading materials, in that the amount of biodegradation observed through the BMP testing is likely to be only a fraction of the total biodegradation possible. (Barlaz, Tr. 2231, 2267-2268).
757. Dr. Barlaz has never used a BMP test to establish rate data. (Barlaz, Tr. 2231, 2267).

i. The ASTM D5511 test

758. The ASTM sets forth protocols established by the scientific community to evaluate materials and has established standard test methods for determining biodegradability of plastics. (CCX 891 (McCarthy Expert Report at 19)).
759. ASTM D5511 is a “Standard Test Method for Determining the Anaerobic Biodegradation of Plastic Materials Under High-Solids Anaerobic-Digestion Conditions.” (CCX 84; CCX 891 (McCarthy Expert Report at 20)).
760. The ASTM D5511 test is a gas evolution test. (CCX 891 (McCarthy Expert Report at 21); RX 855 (Sahu Expert Report at 41)).
761. The ASTM D5511 test is a laboratory-scale reactor test. (Barlaz, Tr. 2222-2223).
762. As compared to the BMP test, a laboratory-scale reactor test is performed in a “high-solids environment,” and it is “more representative of a high-solids matrix as we see in a landfill.” (Barlaz, Tr. 2224).
763. The methodology involved in laboratory-scale reactor testing starts with a composition of “inoculum”¹³ from well-decomposed refuse or MSW. Water is added to the system to achieve the requisite moisture levels and the laboratory monitors the pH, and other variables in the leachate or solution. (Barlaz, Tr. 2224-2225).
764. In laboratory-scale reactor testing, the system is designed to capture gas that is generated in the vessels, including the methane and carbon dioxide in the gas, which is used to calculate the methane generation rate. Controls are used with laboratory-scale

¹³ Inoculum is source material used to introduce microorganisms to an environment. As used in anaerobic test methods, inoculum is an anaerobically digested organic waste that includes all groups of microorganisms required to convert a substrate to methane and carbon dioxide. (JX 4 at 4).

reactors, including an inoculum blank that includes nothing but the decomposed MSW, so that the laboratory can measure the background methane attributable to the inoculum alone. (Barlaz, Tr. 2225-2226).

765. In laboratory-scale reactor testing, the laboratory corrects for background methane attributable solely to the inoculum by subtracting the amount of gas produced by the inoculum blank. Theoretical methane potential is calculated from the chemical formula and the chemical composition of the test materials using stoichiometry. (Barlaz, Tr. 2225-2226).
766. In an ASTM D5511 test, the specimen is exposed to an inoculum from an anaerobic digester operating on household waste as its sole substrate (*i.e.*, sole food source). (CCX 891 (McCarthy Expert Report at 21)).
767. In an ASTM D5511 test, gas collection tubes are connected to the test vessel and gas produced in the vessel is gathered and later measured. (*See* RX 356 at 2 (ASTM D5511 test method, summary and apparatus)).
768. The objective of an ASTM D5511 test is to calculate a percentage of biodegradation based on the gas emissions. (Tolaymat, Tr. 303).
769. Complaint Counsel's rebuttal expert, Dr. Michel, acknowledged that gas evolution testing, like the ASTM D5511 test, is generally recognized in the field as a competent and reliable method to show biodegradation. (Michel, Tr. 2907; CCX 880).
770. Dr. Michel has relied on ASTM D5511 gas evolution testing when assessing whether plastic materials were anaerobically biodegradable. (Michel, Tr. 2904-2905; CCX 880).
771. With proper controls (such as the positive, negative, and inoculum controls), as required and included in the [ASTM] D5511 method . . . an [ASTM] D5511 test should be able to indicate, via gas evolution, if biodegradation of the test article, has, in fact, occurred – and to what extent. (RX 855 (Sahu Expert Report at 41)).
772. The ASTM D5511 tests utilize a negative control by testing an article with an additive and also testing a negative control article, without the additive. (Sahu, Tr. 1919-1921).
773. The ASTM D5511 test method is capable of assessing intrinsic biodegradability. (RX 853 (Barlaz Expert Report at 8); Barlaz, Tr. 2219).
774. The term “intrinsic biodegradability” describes a property of the material, much like its color or weight or density. Intrinsic biodegradability is not going to change no matter where you put that material. (Barlaz, Tr. 2217-2218).
775. From a microbiological perspective, ASTM D5511 or similar laboratory reactor testing is a competent and reliable scientific method to assess biodegradability of materials in landfills. (Burnette, Tr. 2373).

776. Gas evolution tests, like the ASTM D5511 test, are useful for predicting some baseline performance in landfill settings, albeit not optimal, and are a competent and reliable scientific method for assessing biodegradability of materials in landfills. (Burnette, Tr. 2373, 2437-2439).
777. Many laboratories deviate slightly from the ASTM D5511 protocol. (Sahu, Tr. 1922-1923).

i. Landfill environment

778. The ASTM D5511 test is not representative of all possible MSW landfill conditions. However, the ASTM D5511 test does prescribe a methodology that creates an environment that is found in MSW landfills. The ASTM D5511 test is, thus, an appropriate microcosm characteristic of an MSW landfill subset. (RX 854 (Burnette Expert Report at 23)). *See also* Burnette, Tr. 2373, 2439-2440 (The ASTM D5511 test, while not representative of every possible environment in a landfill, is likely to be representative of a subset of environmental conditions in a landfill.).
779. The ASTM D5511 test is an approximation of a landfill environment. It is the closest, most practical, and standardized test currently available for mimicking landfill conditions. (RX 855 (Sahu Expert Report at 42-43)).
780. Complaint Counsel's expert witness, Dr. Michel, chose to utilize the ASTM D5511 test in his testing, in part because it resembles the environment in a biologically active landfill. (Michel, Tr. 2905-2906; CCX 164).

ii. Temperature

781. The ASTM D5511 test method states: "Incubate the Erlenmeyer flasks in the dark or in diffused light at 52°C ($\pm 2^\circ\text{C}$) for thermophilic conditions, or 37°C ($\pm 2^\circ\text{C}$) for mesophilic conditions for a period of normally 15-30 days." (RX 356 at 3 (Section 11.2)).
782. Temperatures in landfills are highly variable, and can often meet or substantially exceed the 52°C that is tested in the ASTM D5511 test. (Barlaz, Tr. 2207-2209; Sahu, Tr. 1842-1844).
783. Although one cannot determine the exact conditions in a particular location within a particular landfill, that is neither the goal nor the appropriate bench-mark for rejecting a test. (RX 855 (Sahu Expert Report at 44)).

iii. Duration

784. The ASTM D5511 test method states: "The digester shall be operating for a period of at least four months on the organic fraction, with a retention time of a maximum of 30 days under thermophilic conditions ($52 \pm 2^\circ\text{C}$). Gas-production yields shall be at least

15 mL at standard temperature and pressure of biogas per gram of dry solids in the digester and per day on the average for at least 30 days.” (RX 356 at 3 (Section 9.1)).

785. The ASTM D5511 test method does not specify a cutoff time or duration for the test and contemplates tests of varying durations: For the test to be considered valid, the positive control must achieve 70% biodegradation within 30 days. The incubation time shall be run *until* no net gas production is noted for at least five days from both the positive control and test substance reactors. (RX 356 at 3 (Section 11.2)) (emphasis added).
786. The ASTM D5511 test method states: “If sufficient biodegradation (a minimum of 70% for cellulose after 30 days, and the deviation among the cellulose replicates is less than 20% of the mean) is not observed within the duration of the test method, then the test method must be regarded as invalid and shall be repeated with fresh inoculum.” (RX 356 at 4 (Section 13.2)).
787. Extending the duration of a D5511 test does not render the data unreliable. As long as the conditions of ASTM D5511 tests are maintained, then there is no reason to simply reject a test based on it having been run longer. (Sahu, Tr. 1928).
788. If an ASTM D5511 test is conducted over an extended period of time, in a lab environment where you can quickly lose biological activity, you have to be aware of the biological activity. Unlike in a landfill where biological systems are being replenished and renewed and have a greater propensity to thrive, a lab environment can quickly lose activity if the biota die. (Sahu, Tr. 1928-1929).
789. Dr. Tolaymat testified that an ASTM D5511 test could be conducted for several years while remaining viable. (Tolaymat, Tr. 251).
790. Complaint Counsel’s rebuttal expert, Dr. Michel, performed biodegradation gas evolution studies in his laboratory that exceeded 500 days. (Michel, Tr. 2899).

j. Limitations of closed-system testing

791. No life is designed to live in a closed-system for a sustained period of time. In the closed-system laboratory environment, there is no way to release or expel the waste products created by the bacterial metabolism. (Burnette, Tr. 2401-2402).
792. It is difficult to maintain adequate biological life in a closed-system laboratory environment for sustained periods of time. Thus, the test environments have a finite life span that may not be adequate to assess the full spectrum of possible biodegradation. (Burnette, Tr. 2374-2375).
793. Limitations of the closed-system test environment are significant because, in the natural environment where those limitations are removed, the biodegradation of test substrates could be even greater. (Burnette, Tr. 2389-2390).

794. In a closed-system reactor test, biodegradation is tested in one possible environment experimentally replicated. Greater biodegradation would be observed if the test material were analyzed in a sampling of different possible MSW landfill environments, such as manipulating oxygen or pH levels. These changes in variables may provide for the rise of different microbial populations that can further the biodegradation process. (RX 854 (Burnette Expert Report at 25)).
795. If in a closed-system laboratory reactor the test material is slowly degrading, then you would not expect to see prolonged biodegradation over time because the microorganisms that would act upon the substrate die. (Burnette, Tr. 2403).
796. Closed-system laboratories may restrict the types of conditions that allow certain bacteria to thrive and, thus, the test environment may unintentionally limit the biodegradation that can be observed. (Burnette, Tr. 2411-2412).
797. In the open landfill environment, while biodegradation may be at varying rates, the total biodegradation should be expected to increase or, at least, continue onward, absent the limitations of a closed-system test. (Burnette, Tr. 2437-2440).
798. Evidence that a plateau has formed in the laboratory tests can signal that the test environment is no longer conducive to biodegradation testing. That is particularly evident where the plateau forms in the positive control, an article known to be biodegradable. (Burnette, Tr. 2401-2402; Sahu, Tr. 1929-1932).
799. The presence of a plateau in the closed-system laboratory tests does not necessarily mean that biodegradation of the test substrate is no longer possible, or that the test substrate is finished biodegrading. (Sahu, Tr. 1931).

k. Inconclusive test results

800. Tests that have inconclusive results, that do not clearly show the signal of biodegradation, do not necessarily prove that the tested plastics are not biodegradable. There are many reasons that might point to the cause of an inconclusive test. (Sahu, Tr. 1938-1939).
801. To properly understand an inconclusive test, the scientist must understand, *inter alia*, the biological activity in the test vessels; know whether the additive was in fact properly mixed and present in the plastic; know whether the plastic was manufactured with the additive properly, such that the additive was not rendered ineffective; and know whether the presence of other additives or impurities may have hindered biodegradation. (Sahu, Tr. 1939-1940).
802. “Negative” tests are not the same thing as “inconclusive” tests, and a test is not truly “negative” until all of the variables have been explored and you still have replicability of results. (Burnette, Tr. 2442).

803. The likelihood of cell death in a closed-system laboratory test is probable without refreshing the system with new nutrients or expelling the waste. (Burnette, Tr. 2442-2443).
804. The untimely death of the microorganisms in the closed-system laboratory test can lead to an inconclusive test with respect to biodegradation testing. (Burnette, Tr. 2443).
805. Inconclusive tests can be the result of an inoculum that is not viable. (Barlaz, Tr. 2272-2273).
806. For slowly degrading substances, there is risk that the inoculum may not remain viable over time in a closed-system laboratory reactor test. (Barlaz, Tr. 2273-2274).
807. The inconclusive test results relevant to this case do not alter Dr. Barlaz's opinion concerning the evidence that shows plastics amended with the ECM Additive were shown to biodegrade anaerobically. (Barlaz, Tr. 2274).

i. Testing proposed by Dr. Tolaymat

808. Complaint Counsel's expert, Dr. Tolaymat, testified that to establish a rate of biodegradation in a landfill, one could conduct lysimeter testing or "*in situ*" testing. (Tolaymat, Tr. 221). This opinion is unsupported, unpersuasive, and rejected. (F. 809-825).

i. Lysimeter testing

809. A lysimeter is a large column of various types of material, which could be stainless steel, designed to hold approximately a ton of solid waste. Lysimeter testing usually involves placing material in a cylinder, making sure it is airtight, and changing temperature or leachate to vary the testing conditions. (Tolaymat, Tr. 226-229).
810. There is no set definition for a lysimeter as used in biodegradation testing. (Barlaz, Tr. 2239).
811. Lysimeter testing may vary considerably from laboratory to laboratory. (Tolaymat, Tr. 228).
812. Dr. Barlaz disagreed with Dr. Tolaymat's position that lysimeter testing should be conducted to test for biodegradation, and Dr. Barlaz "was surprised" that Dr. Tolaymat had used data on settlement and leachate quality to obtain data on the biodegradability of a specific material, which is not scientifically supported. (Barlaz, Tr. 2240-2241).
813. Dr. Barlaz found Dr. Tolaymat's suggested use of lysimeter testing to be unscientific because it would be extremely difficult to gather useable, representative biodegradability data from a large lysimeter design. (Barlaz, Tr. 2241-2242).

814. Assuming it was even possible to get data showing anaerobic biodegradability from a lysimeter test, Dr. Barlaz explained that you would then need to test for multiple years to gather suitable data on a slowly degrading substrate. (Barlaz, Tr. 2242-2243).
815. In testing for anaerobic biodegradation of ECM Plastics in his peer-reviewed study, marked CCX 164, Dr. Michel did not use lysimeter testing. (Michel, Tr. 2906-2907; CCX 164).

ii. *In situ* testing

816. *In situ* testing refers to testing or evaluations conducted in the natural environment where the scientific phenomena generally occur. In the context of landfill biodegradation studies, *in situ* testing refers to tests conducted on or within MSW landfills. (JX 4 at 4).
817. In *in situ* studies, a researcher puts material into a landfill, then at some point, digs it up and evaluates if it is either there, or not there, and if it is there, how much weight did it lose. (Barlaz, Tr. 2236-2237).
818. There are many problems with *in situ* landfill testing, including loss of product samples, which frequently occurs. (Barlaz, Tr. 2237).
819. Also, during *in situ* testing, the researcher cannot determine if weight loss was specifically attributed to biodegradation. (Barlaz, Tr. 2237-2238).
820. When a researcher buries a product in a landfill, one cannot measure methane and CO₂ emissions. (Barlaz, Tr. 2237).
821. Landfill *in situ* studies allow only for qualitative information about a test sample. (Barlaz, Tr. 2238).
822. Practical difficulties also limit the availability of landfill *in situ* testing. Those difficulties include finding cooperative landfills that will work with researchers to maintain access to landfill sites and samples and agree not to deposit additional waste on top of the test area. (Barlaz, Tr. 2238).
823. One cannot get quantitative information on anaerobic biodegradability from an *in situ* landfill test even if it was done perfectly, and the possibility of doing it perfectly is slight at best. (Barlaz, Tr. 2236).
824. According to Dr. Barlaz, “to suggest that [*in situ* landfill studies are] what we have to do to make -- to prove a material is biodegradable to me is, number one, technically it’s not sound because you can’t measure methane and CO₂. And even if ... technically it were sound, you’re imposing this hurdle on people that’s completely unrealistic.” (Barlaz, Tr. 2238-2239).

825. In testing for anaerobic biodegradation of ECM Plastics in his peer-reviewed study, marked CCX 164, Dr. Michel used did not use *in situ* testing. (Michel, Tr. 2906-2907; CCX 164).

m. Testing proposed by Dr. McCarthy

826. Complaint Counsel's expert, Dr. McCarthy, opined that: "at least one confirmatory test must be conducted to establish that the plastic component of the ECM Plastics will biodegrade" and that "ECM could have performed confirmatory testing by radiolabeling or by conducting a gas evolution test showing at least 60% conversion to methane and carbon dioxide within 18 months." (CCX 891 (McCarthy Expert Report at 27)). This opinion is unsupported, unpersuasive, and rejected. (F. 827-860).

i. Radiolabeling testing

827. The opinions of Complaint Counsel's expert, Dr. McCarthy, that to scientifically prove a claim that the plastic – not merely the additive and inoculum – is biodegrading, the claimant must support its claim with at least one test with positive results from C14 labeling of the conventional plastic, (CCX 891 (McCarthy Expert Report at 24), and of Dr. Michel, that "[t]o obtain accurate evidence of biodegradation, experiments are best performed using ¹⁴C-labeled substrates and measuring evolved ¹⁴CO₂ over time" (CCX 895 (Michel Rebuttal Expert Report at 12), are unsupported, unpersuasive, and rejected. (F. 828-847).
828. C-14 testing is radiolabeling testing involving tagging radioisotopes of carbon 14 ("C-14" or "¹⁴C") of a high-molecular weight plastic, such as polyethylene ("PE"), before conducting a gas evolution test. During the gas evolution test, biogases are monitored for the radiolabeled C14. If the radiolabeled carbon is detected in the biogases, then the conventional plastic polymer is undergoing a material transformation through biodegradation. If the radiolabeled carbon is not detected in the biogases, then the observed biogases are likely due to other factors, such as biodegradation of the additive or the inoculum. (CCX 891 (McCarthy Expert Report at 23-24)).
829. Dr. McCarthy does not explain how C14 testing could be done as a practical matter. He does not explain how one can formulate materials with the ECM Additive in small batch quantities, just for C14 testing purposes, nor does he explain the practical impediments associated with such a task – including handling the radiological materials and their proper disposal; contamination and decontamination issues in the manufacturing plant and the laboratory when such tests would be done; or the time and cost involved. (RX 855 (Sahu Expert Report at 47)).
830. Although radiolabeling testing is a powerful and sensitive technique, it is expensive to obtain the starting materials in radiolabeled form. In addition, the location of the radiolabel will influence the results of the test and the label must be placed on the most difficult to degrade carbon atoms. (RX 853 (Barlaz Expert Report at 9)).

831. C14 testing is only a marker test that is helpful where the percentage of biodegradation is so minimal that one cannot discern where it came from. (Barlaz, Tr. 2243-2246).
832. C14 testing not the industry standard or reasonably required by any expert in the field as necessary evidence to show biodegradation of materials. (Sahu, Tr. 1905; Barlaz, Tr. 2244-2246) (Dr. Barlaz would be “surprised” if any expert had performed C14 testing on plastics because it is very difficult to find a company that could properly make the test article, and the impracticalities outweigh any benefit).
833. Dr. Sahu found no evidence that radiolabeled testing is generally accepted as a requirement for biodegradability testing of polymers. (Sahu, Tr. 1794-1795).
834. In the pre-complaint phase of this case, Dr. Sahu searched for a commercial laboratory that could perform radiolabeled testing for ECM and could not find any company able to radiolabel the polymer or create the radiolabeled polymer that would then be subject to further laboratory testing. (Sahu, Tr. 1897-1898).
835. There are difficulties associated with handling radioactive carbon. Aside from the regulatory issues, the laboratory must be prepared to handle the radioactive material and ensuing decontamination and be capable of doing so. (Sahu, Tr. 1902-1903).
836. A testing laboratory would require a considerable amount of C14 to test plastics for biodegradation because the manufacturer must create a commercial-scale product for testing. (Sahu, Tr. 1903).
837. It would be hard to find a lab that could make the properly radiolabeled plastic for C14 testing of plastic polymers. (Barlaz, Tr. 2245-2246).
838. Dr. Michel provided no documentation other than a one-page estimate, which he drafted, regarding the possibility of, and costs associated with, conducting C14 radiolabeling testing on plastic polymers. (Michel, Tr. 2968-2969; CCX 895 (Michel Rebuttal Expert Report Appendix A at 23)).
839. When questioned about the type of evidence required to support biodegradability, Dr. Tolaymat did not mention radiolabeled testing. (Tolaymat, Tr. 112-347).
840. At his deposition, Dr. Tolaymat explained that radiolabeled testing “could be as expensive . . . as doing the study in a landfill environment” and that “[i]t’s not used as frequently.” (RX 851 (Tolaymat, Dep. at 256)).
841. The C14 radiolabeled test method was not used to test biodegradation in Dr. McCarthy’s ‘199 patent. (McCarthy, Tr. 540-542; RX 756 at 8-12).
842. Dr. McCarthy has not used C14 radiological testing in any biodegradation experiments that he has performed at UMass Lowell. (McCarthy, Tr. 563).

843. In his article titled, “*Advances in Properties and Biodegradability of Co-Continuous, Immiscible, Biodegradable, Polymer Blends*,” Dr. McCarthy did not use C14 radiological testing. (McCarthy, Tr. 577-579; RX 940).
844. In his article titled, “*Biodegradable Polymer Blends of Poly(lactic acid) and Poly(ethylene glycol)*,” Dr. McCarthy measured enzymatic degradation through a weight loss study and did not use an ASTM standard testing method or a C14 radiological test. (McCarthy, Tr. 583-584; RX 941).
845. In his article titled, “*Degradation Ranking of Plastics in a Landfill Environment*,” Dr. McCarthy used weight loss as his measure of degradability and did not use C14 radiological testing. (McCarthy, Tr. 585; RX 942).
846. In testing for anaerobic biodegradation of ECM Plastics in his peer-reviewed study, marked CCX 164, Dr. Michel did not use C14 radiolabeling testing. (Michel, Tr. 2906; CCX 164).
847. Dr. Michel has never performed a radiolabeled test to measure biodegradation of plastic polymers or products. (Michel, Tr. 2906).

ii. Sixty percent conversion to methane and carbon dioxide within 18 months

848. The opinion of Complaint Counsel’s expert, Dr. McCarthy, that biodegradation tests must show at least 60% biodegradation to support a claim of complete biodegradation (CCX 891 (McCarthy Expert Report at 15-16), is unsupported, unpersuasive, and rejected. (F. 849-860).
849. Dr. McCarthy provided no literature or documentary evidence showing that scientists in the field require 60% or greater biodegradation before a product can be deemed biodegradable. (See McCarthy, Tr. 359-680; CCX 891 (McCarthy Expert Report); CCRFF 1544).
850. Dr. McCarthy did not perform tests showing at least 60% biodegradation to support biodegradable claims in his ‘199 patent. (Sahu, Tr. 1894; McCarthy, Tr. 558-560; RX 756).
851. In his expert report, Dr. McCarthy wrote that a study to determine whether something is biodegradable must have a negative control. (McCarthy, Tr. 559; CCX 891 (McCarthy, Expert Report at 16)).
852. In his ‘199 patent, Dr. McCarthy labeled a substrate biodegradable even though the rate of biodegradation was lower than 60%, reaching only 14% in 45 days, and where he did not use a negative control. (Sahu, Tr. 1894; McCarthy, Tr. 558-560; RX 756).

853. In the '199 patent, Dr. McCarthy concluded that a substance that biodegraded by 25% in 45 days was biodegradable. (McCarthy, Tr. 630-634; RX 756).
854. Dr. McCarthy's opinion in this case is that a biodegradation study must last long enough for the sample to reach at least 60% biodegradation. (McCarthy, Tr. 637; CCX 891 (McCarthy Expert Report at 15-16)).
855. Dr. McCarthy agrees that, ordinarily, 60% biodegradation of a sample is not something that can occur in just a few minutes. (McCarthy, Tr. 637-638).
856. In an article Dr. McCarthy co-authored, titled, "*The Influence of Injection Molding Conditions on Biodegradable Polymers*," Dr. McCarthy analyzed certain polymers for their rates of biodegradation by conducting a test that lasted five minutes. (McCarthy, Tr. 634-636; RX 969).
857. Dr. McCarthy relied on the tests he reported in "*The Influence of Injection Molding Conditions on Biodegradable Polymers*" to draw conclusions about the biodegradability of polymers. (McCarthy, Tr. 638-639; RX 969).
858. The testing reported in "*The Influence of Injection Molding Conditions on Biodegradable Polymers*" fails to demonstrate 60% biodegradation. (McCarthy, Tr. 639; RX 969).
859. Complaint Counsel's rebuttal expert, Dr. Michel, testified that a "material that only biodegrades 44% to elements found in nature is biodegradable." (Michel, Tr. 2961).
860. There is no consensus in the peer-reviewed literature that a gas evolution should produce 60% biodegradation before a test article can be deemed biodegradable. (Sahu, Tr. 1793).

n. The priming effect

861. In biodegradation tests, where one measures methane generation from the inoculum and methane generation from the inoculum plus substrate to evaluate whether the differential methane is attributable to the substrate, the priming effect theory posits that the difference is not necessarily attributable to the substrate. Instead, the priming effect would say that there is also some methane produced that is over and above that which is produced by the inoculum only, and over and above that which could be attributable to the additive. The basis for the priming effect theory is that, assuming that the additive is biodegraded, not only do you generate methane from the additive, but you have stimulated the microbial community, which gives you additional methane so that the background methane is higher than what you would measure in your inoculum controls. (Barlaz, Tr. 2277-2278).

862. There is no consensus in the peer-reviewed literature as to what the priming effect is, and the degree to which it could be in action during biodegradation testing of plastics. (Sahu, Tr. 1888-1889).
863. The scant information in the peer-reviewed literature concerning the priming effect of a substrate in the test environment has generally been limited to rapidly accessible or degrading substrates like glucose. (Sahu, Tr. 1888-1889).
864. The priming effect theory was first described in the peer-reviewed literature in reference to aerobic systems and with readily degradable substrates. (Barlaz, Tr. 2278).
865. Comparing a potential priming effect from a readily degradable substrate in an aerobic environment to a slowly degradable substrate in an anaerobic environment is not an appropriate comparison scientifically. (Barlaz, Tr. 2280-2281).
866. In the absence of supporting data and any peer-reviewed literature, the priming effect theory, as described by Complaint Counsel's witnesses, is "quite speculative as a way to shoot down a test" or dismiss data. (Barlaz, Tr. 2278-2280).
867. Dr. McCarthy assumed that the ECM Additive was 60% polycaprolactone ("PCL"). In Dr. Barlaz's own research, the amount of degradation solely from PCL was not that significant to stimulate background methane. (Barlaz, Tr. 2279-2280).
868. The amount of biodegradation observed in the ECM tests is much higher than any reasonable interpretation of a priming effect theory. (Barlaz, Tr. 2280-2281).
869. When Dr. McCarthy relied on gas evolution testing to demonstrate that his polymer blends in the '199 patent were biodegradable, Dr. McCarthy did not account for, or even mention, any biodegradation that might result from the priming effect. (Sahu, Tr. 1893-1894; RX 756 at 8-12; CCRFF 2036-2037).

5. How the ECM Additive Works

870. The ECM Additive is introduced to the plastic as a pellet, which is melted together with the plastic resin to form a film or packaging material. (Sahu, Tr. 1813).
871. The ECM Additive goes into the blend uniformly no matter whether it has a high or low weight distribution. It will be present along with varying chain lengths of original polymers that were there in the plastic and as they have cooled down and formed crystalline and amorphous regions. (Sahu, Tr. 1814).
872. The process of adding the ECM Additive into a finished plastic product involves melting the additive pellets and the plastics together, through which they are literally mixed together and compounded. The melted compound is usually extruded or blown and then cooled. As the melt is cooling, it is further processed to make the article, such as a plastic bag. (Sahu, Tr. 1813-1816).

873. ECM Plastics are also manufactured using injection molding. (Sahu, Tr. 1816-1817).
874. When the ECM Additive is melt-compounded into the final plastic, the goal is to disperse the additive evenly throughout the plastic, like a colorant (color additive). (Sahu, Tr. 1814-1815).
875. High temperatures or scorching during the manufacturing process render the ECM Additive ineffective. (Sahu, Tr. 1815).
876. If the ECM Additive has been overheated or scorched, it may not be apparent or obvious to the plastic manufacturer. (Sahu, Tr. 1815).
877. Companies may leave the ECM Additive “on the screw” while manufacturing, which cooks the additive. (Sinclair, Tr. 762).
878. The temperatures used in manufacturing ECM Plastics depend on the materials’ glass transition and melting temperatures. (Sahu, Tr. 1817).
879. The temperature will depend on how the manufacturer would like the viscosity properties of the plastic to be during manufacturing, and how they intend to handle the melt after heating. (Sahu, Tr. 1817).
880. The ECM Additive is introduced into the main plastic resin, like any other additive, such as a colorant. (Sahu, Tr. 1818).
881. Color additives are sometimes not properly mixed with the plastic, and the appearance of the final product clearly shows the inconsistent colors. (Sahu, Tr. 1818).
882. The “dwell time” during manufacturing refers to the residence time, or how long the additive is exposed to high temperatures during manufacturing. (Sahu, Tr. 1836-1837).
883. Because ECM Plastics are melt-compounded, longer dwell times can cause the plastic or additive to denature during manufacturing, which must be carefully avoided to ensure additive efficacy. (Sahu, Tr. 1837-1838).
884. The load rate of the ECM Additive is the mass or percent of the additive that manufacturers add to a melt. (Sahu, Tr. 1819).
885. The customary load ratings for color additives are anywhere from 0.5 percent to 2 or 3 percent. (Sahu, Tr. 1819-1820).
886. Molecular weight is a basic concept in chemistry, and molecular weights are generally consistent. For instance, the molecular weight of carbon dioxide is 44, no matter where it exists, because it contains one carbon and two oxygen atoms. (Sahu, Tr. 1804).

887. Polymers are not specifically defined molecules and a polyethylene product does not have the same number of repeating monomer units in each strain. (Sahu, Tr. 1805).
888. Because polymer chains have varying lengths within a product, the strains have different molecular weights, and that creates a molecular weight distribution. (Sahu, Tr. 1805).
889. There is no way to manufacture a polymer and ensure that all the lengths of the individual chains in the same polyethylene product melt have the same molecular weight. (Sahu, Tr. 1807-1808).
890. Molecular weight distribution will affect product characteristics such as tensile strength. (Sahu, Tr. 1808-1809).
891. The ECM Additive affects molecular weight as a system-wide MasterBatch additive that enters the structure of the plastic. (Sahu, Tr. 1809-1810, 1813).
892. When the ECM Additive is blended into plastic, it alters the plastic matrix, the polymer chains, and adds an attractant that permits microorganisms to take root at the surface and within the plastic. (Sahu, Tr. 1810).
893. To examine the threshold question of whether plastics or polymers are capable of biodegrading, Dr. Sahu performed an extensive literature search and memorialized his research in his expert report. (Sahu, Tr. 1848-1849; RX 855 (Sahu Expert Report at 24-40)).
894. Dr. Sahu based his opinion on a thorough review of peer-reviewed literature published since the 1950s, as well as between 30 to 40 different tests collected during this case. Dr. Sahu's report includes many of the citations to, and discussions of, the literature that he relied on. (Sahu, Tr. 1754-1756, 1791; RX 855 (Sahu Expert Report)).
895. Dr. Burnette's research revealed that peer-reviewed publications demonstrate that there are organisms that make an enzyme that can degrade plastics. (Burnette, Tr. 2426-2429; RX 854 (Burnette Expert Report at 16-22)).
896. Conventional plastics are those made from petroleum feedstocks or natural gas, as opposed to those manufactured from biological materials like starches. (Sahu, Tr. 1758).
897. Conventional plastics have only existed in modern manufacturing for about ninety to one hundred years. (Sahu, Tr. 1879-1880).
898. It is commonly accepted that conventional plastics last very long in the environment, perhaps 10,000 years. (Sahu, Tr. 1758-1759; CCX 891(McCarthy Expert Report at 7)).

899. Although conventional plastics biodegrade very slowly, they still biodegrade. (RX 855 (Sahu Expert Report at 40, 44)).
900. Dr. McCarthy does not provide support for the proposition in his expert report that there is “overwhelming scientific consensus that conventional plastics are not biodegradable after customary disposal,” and has acknowledged that there are peer-reviewed scientific publications that conclude that conventional plastics are biodegradable. (CCX 891 (McCarthy, Report at 13); McCarthy, Tr. 570-576; RX 841 (McCarthy, Dep. at 112-115)).
901. Conventional plastics like polyethylene have been proven to be biodegradable in peer-reviewed literature. (Sahu, Tr. 1848-1853).
902. Polyethylene can be considered a conventional plastic in the sense that it is ordinarily derived from feedstocks like petroleum or natural gas. (Sahu, Tr. 1784-1785).
903. There are many different grades of plastics in the commercial stream. Polyethylene has at least ten different commercial grades. (Sahu, Tr. 1785-1786).
904. In general, because the end-application of ECM Plastics is not demanding (*e.g.*, plastics made for carrying groceries vs. medical devices), the grade of polymer used in manufacturing ECM Plastics is not high. (Sahu, Tr. 1877-1878).
905. Plastics that are intended for garbage bags or packaging materials can be made of a lesser grade than plastics intended for more specific uses. (Sahu, Tr. 1878).
906. Lesser grade plastics are more likely to contain impurities and inconsistencies that promote biodegradation. (Sahu, Tr. 1878-1879).
907. Polyethylene is comprised of the monomer ethylene, which is a repeating unit in the polyethylene polymer. (Sahu, Tr. 1788).
908. Dr. Sahu evaluated different polymers, including polyethylene, polypropylene, and polystyrene. (Sahu, Tr. 1801).
909. Dr. Sahu focused on certain polymers because the vast majority of ECM Plastics manufactured by ECM’s Customers (about three quarters) are polyethylene-based products. (Sahu, Tr. 1801; RX 471).
910. The ECM Additive helps to set in motion the attraction/migration of microbes and biological agents to the plastic, and to the areas of the plastic where weaknesses or hydrophilic defects exist. (RX 855 (Sahu Expert Report at 27); Sahu, Tr. 1865-1867).
911. The formation of biofilms near the additive sites promotes the development and growth of bacteria, which spreads to other areas of the plastic. (RX 855 (Sahu Expert Report at 27)).

912. Depending on the linear chains and branches within a polymer, biological activity typically begins at the weak points and endings of a polymer chain, and works into the remaining portions of the polymer. (Sahu, Tr. 1866-1867).
913. Microbes secrete enzymes and chemicals that degrade plastic where the biofilms are present, beginning with the weak links in plastic. (RX 855 (Sahu Expert Report at 27)).
914. Dr. Sahu relied on peer-reviewed literature to demonstrate that plastic polymers biodegrade, including crystalline regions therein. (RX 855 (Sahu Expert Report at 24-40)).
915. Dr. Sahu reviewed hundreds of papers in preparation of his expert report, including the 11 that he quoted and relied upon in the text of his report. Those include: (1) Tokiwa, Y., et al., *Biodegradability of Plastics*, Int. J. Mol. Sci. 2009, 10, 3722-3742; (2) Tilstra, L., et al., *The biodegradation of blends of polycaprolactone and polyethylene exposed to a defined consortium of fungi*, *Journal of Environmental Polymer Degradation*, Vol. 1, No. 4, 1993; (3) Zheng, Y., et al., *A Review of Plastic Waste Biodegradation*, *Critical Reviews in Biotechnology*, 25:243-250, 2005; (4) Bhardwaj H, Gupta R, Tiwari A (2012) *Microbial Population Associated With Plastic Degradation*. 1: 272. doi:10.4172/scientificreports; (5) Arutchelvi, J., et. al., *Biodegradation of polyethylene and polypropylene*, *Indian Journal of Biotechnology*, Vol. 7, January 2008, p. 9-22; (6) Mueller, R-J., *Biological degradation of synthetic polyesters – Enzymes as potential catalysts for polyester recycling*, *Process Biochemistry*, Volume 41, Issue 10, October 2006, p. 2124-2128; (7) Van der Zee, M., *Analytical Methods for Monitoring Biodegradation Processes of Environmentally Degradable Polymers*, Section 11.4.2; (8) Shah, A.A., et. al., *Biological degradation of plastics: A comprehensive review*, *Biotechnology Advances* Vol. 26, 2008, p. 246-265; (9) Pramila, R., et. al., *Biodegradation of Low Density Polyethylene (LDPE) by Fungi Isolated from Municipal Landfill Area*, *J. Microbiol. Biotech. Res.*, 2011, 1 (4):131-136; (10) Albertsson, A-C., *Biodegradation of synthetic polymers. II. A limited microbial conversion of ¹⁴C in polyethylene to ¹⁴CO₂ by some soil fungi*, *Journal of Applied Polymer Science*, Volume 22, Issue 12, p. 3419-3433, December 1978; and (11) Albertsson, A-C., et. al., *Biodegradation of synthetic polymers. III. The liberation of ¹⁴CO₂ by molds like fusarium redolens from ¹⁴C labeled pulverized high-density polyethylene*, *Journal of Applied Polymer Science*, Volume 22, Issue 12, p. 3435-3447, December 1978. (RX 855 (Sahu Expert Report at 24-40)).
916. Based on his experience and research, Dr. Sahu determined that peer-reviewed literature demonstrated that beyond aerobic biodegradation, anaerobic processes are capable of biodegrading conventional plastics. (Sahu, Tr. 1858-1859).
917. Inclusion of the ECM Additive, a biodegradable substance and attractant for microbiological growth, contributes to an acceleration of biodegradation. (Sahu, Tr. 1853-1855).

918. The ECM Additive likely promotes biodegradation in two ways: first, by serving as an attractant for microbial growth on and within plastics; and second, by weakening or perturbing the carbon-carbon bonds through weaknesses in the chain or the addition of more weak points in the form of the additive. (Burnette, Tr. 2435-2436).
919. When the ECM Additive is added to the plastics mixture, it perturbs the plastics mixture. Enzymes look for points of weakness. If there is a way to take a bond that is already favorable for an enzyme and make it even more favorable, it would be to further reduce that bond strength. The ECM Additive could be perturbing those preferred carbon-carbon bonds, making the plastic more available as a food source. (Burnette, Tr. 2436).
920. The biodegradation of plastic polymers involves, *inter alia*, hydrolytic cleavage of polymer bonds. (Sahu, Tr. 1859-1860).
921. The hydroxyl radical is capable of facilitating hydrolytic reactions. (Sahu, Tr. 1860).
922. Oxidative reactions involve electron transfer. (Sahu, Tr. 1860-1861; Burnette, Tr. 2421).
923. Oxidative reactions need not occur in the presence of oxygen and occur in anaerobic systems. (Sahu, Tr. 1861-1862; Burnette, Tr. 2421-2422).
924. Oxidative reactions can play a role in anaerobic biodegradation of polymers. (Burnette, Tr. 2422).
925. Pro-oxidants can facilitate biodegradation, but they are not the only mechanisms that work to degrade polymers. (Sahu, Tr. 1871-1873).
926. Many forms of polymer biodegradation have been documented in the peer-reviewed literature. (Sahu, Tr. 1875).
927. Blending biodegradable and non-biodegradable polymers is one of the means documented in the peer-reviewed literature by which polymers can be rendered biodegradable. (Sahu, Tr. 1876; RX 925 at 647).
928. In "*Biodegradable Polymers - A Review on Recent Trends and Emerging Perspectives*," published in the *Journal of Polymers and the Environment* that Dr. McCarthy edits, the authors discussed the methods to create "biodegradable polymer blends," and one of the methods they cited was "blending a thermoplastic resin with a biodegradable one." The authors state: the insertion of weak links into polymers can cause biodegradation; compounding polymers with photosensitizers can cause biodegradation; and "[t]he most frequently adopted approach to degradability design of [Low Density Polyethylene] LDPE has been to introduce pro-degradant additives such as starch and cellulose into synthetic polymers." (McCarthy, Tr. 673-674; RX 925).

929. Dr. McCarthy did not inform the authors of “*A Review on Recent Trends and Emerging Perspectives*” that they had no basis for the claim that one can blend a biodegradable additive into an otherwise nonbiodegradable polymer and cause the nonbiodegradable polymer to become biodegradable. (McCarthy, Tr. 674).
930. In an article Dr. McCarthy authored titled, “*Biodegradable Blends of Bacterial Polyesters with Polyethylene and Polystyrene*,” Dr. McCarthy wrote that “binary blends of bacterial polyesters with polyethylene (PE) and polystyrene (PS)” can result in a biodegradable ‘blend.’” (McCarthy, Tr. 586; RX 945).
931. Dr. McCarthy based his opinion that microbes and enzymes cannot penetrate into PE crystalline phase inside plastics based on his experience with polycaprolactone generally. He did not perform specific experiments on plastics containing the ECM Additive. (McCarthy, Tr. 677-678).
932. The scientific literature shows that polymer chains with molecular weights as high as 10,000 can be biodegraded. (Sahu, Tr. 1872-1873).
933. As molecular weights decrease through microbial biodegradation, the susceptibility of polymers to further biodegradation increases. (Sahu, Tr. 1873).
934. Because the ECM Additive is uniformly dispersed throughout an ECM Plastic, the additive provides a continued food source for microbial growth through plastic degradation and the additive’s effect is not limited to a surface effect. (Sahu, Tr. 1863-1864).
935. The presence of the ECM Additive throughout the plastic provides for continued and complete biodegradation of the conventional plastic. (Sahu, Tr. 1865).
936. MSW landfills contain bacteria, fungi, and other microorganisms that secrete enzymes capable of completing the biodegrading processes that Dr. Sahu identified in his expert report. (Sahu, Tr. 1865-1866).
937. Those microorganisms have evolved over time, and can evolve quickly, to adapt for plastics biodegradation. (Sahu, Tr. 1880-1881).
938. Scientists in the field have published information concerning the types of bacteria and microorganisms that are found in nature (including MSW landfills), which have also been shown to biodegrade conventional plastics. (Sahu, Tr. 1868-1869; RX 855 (Sahu Expert Report at 34)).
939. Those microorganisms described in F. 938 are found in landfills, sewage treatment plants, digesters, and compost piles. (Sahu, Tr. 1869).

940. Plastic polymers can have amorphous and crystalline regions. Crystalline portions of the polymer can be biodegraded just as the amorphous regions can, but perhaps at a different rate. (Sahu, Tr. 1883-1885).
941. Crystalline portions of polymers are still fundamentally composed of the same chains. Those polymer regions are actually semi-crystalline. (Sahu, Tr. 1884).
942. Scientists have examined the biodegradability of crystalline portions of polymers and found that they do in fact biodegrade. (Sahu, Tr. 1885).
943. Peer-reviewed literature has discussed the loss of crystallinity or decreases in crystallinity, or loss of the lamellae that are the crystalline subcomponents as indicators that degradation has occurred in the crystalline portions of plastics. (Sahu, Tr. 1885).
944. In the article titled, *Biodegradation of polyethylene and polypropylene*, Arutchelvi, J., et. al., *Indian Journal of Biotechnology*, Vol. 7, January 2008, p. 9-22, the authors focused on polyethylene and polypropylene and discussed other literature wherein scientists have observed loss of crystallinity in conventional plastics. (Sahu, Tr. 1885-1886; RX 586; RX 855 (Sahu Expert Report at 35)).
945. While scientists have posited that biodegradation begins in amorphous regions of the polymers, the peer-reviewed literature also supports that crystalline regions will biodegrade. (RX 855 (Sahu Expert Report at 28, 41 n. 62); RX 586 at 13).
946. The amorphous regions of a polymer are more susceptible to degradation, but while the crystalline sections of a polymer are “more resistant than the amorphous region,” they will also degrade in kind. (RX 855 (Sahu Expert Report at 28 (quoting Tokiwa, Y., et al., *Biodegradability of Plastics*, Int. J. Mol. Sci. 2009, 10, 3722-3742; RX 582)).
947. Tokiwa, Y., et al. (RX 582) have explained that certain enzymes have been shown to biodegrade “both the amorphous and crystalline” portions of plastics. (RX 582 at 3732 (discussing the lipase enzymatic degradation of PCL)).
948. The degree of crystallinity is one of many factors that can influence the biodegradability of plastics. (RX 582 at 3722).
949. Plastics with high degrees of crystallinity can be more biodegradable than others with lesser degrees of crystallinity if other factors promote biodegradability, such as surface area, molecular weight distribution, and the melting point. (Sahu, Tr. 1886; RX 582 at 3722).
950. It is a scientific error to use the crystallinity of a polymer as the only factor or variable that governs whether a plastic will biodegrade. (Sahu, Tr. 1887).
951. Peer-reviewed literature support’s Dr. Sahu’s opinion that the ECM Additive contributes to an acceleration of biodegradation. Tokiwa, Y., et al. explained in the

International Journal of Molecular Sciences (2009) that “the adherence of microorganisms on the surface of plastics followed by the colonization of the exposed surface is the major mechanisms involved in the microbial degradation of plastics.” Tokiwa, et al., further explained that many factors, including the polymer morphology, chemical and physical properties of the plastics, the surface conditions (*e.g.*, surface area, hydrophilic and hydrophobic properties), the molecular weight and molecular weight distribution, glass transition temperature, melting temperature, and crystallinity are just some of the many factors that can affect the rate of biodegradability of plastics. (RX 855 (Sahu Expert Report at 28); RX 582).

952. The rate of biodegradation of plastic polymers depends on many variables, including the various properties of the base plastic, the presence and types of amounts of biological organisms in the vicinity of the plastic material, and the properties of the local physical environment. (RX 855 (Sahu Expert Report at 27)).
953. Many factors affect the ability of a plastic to biodegrade. (Sahu, Tr. 1828).
954. The inclusion of impurities and other additives in a plastic polymer can influence the ultimate biodegradability of the plastic. (Sahu, Tr. 1828).
955. Impurities are included in the final plastic product unintentionally. (Sahu, Tr. 1829-1830).

6. Types of Microbes that Biodegrade Plastics

956. Bacteria are the most proliferative, abundant form of life known. (Burnette, Tr. 2377).
957. Bacteria are very small, single-celled organisms that primarily live in colonies. (Burnette, Tr. 2378).
958. There are bacteria that are specifically anaerobic, called obligate anaerobes, which can only proliferate in an anaerobic environment. (Burnette, Tr. 2378-2379).
959. There is a broad class of bacteria, called facultative anaerobes, which possess the tools to live, proliferate, reproduce, and feed in both oxygen and non-oxygen containing environments. (Burnette, Tr. 2379).
960. The types of microorganisms relevant to biodegradation can be facultative anaerobes, obligate anaerobes, and methanogens, archaea bacteria. (Burnette, Tr. 2379-2380).
961. Archaea bacteria are within a subclass of bacteria that contain many types of anaerobic organisms. (Burnette, Tr. 2380).
962. Enzymes are proteins by definition. (Burnette, Tr. 2380).

963. Enzymes catalyze reactions or expedite reactions that may move slowly or may not move at all. (Burnette, Tr. 2380).
964. Enzymes have active sites which structurally favor the substrate in a manner such that the reaction can be facilitated. (Burnette, Tr. 2381).
965. Enzymes in landfills come primarily from microorganisms, bacteria and fungi. (Burnette, Tr. 2382).
966. Enzymes in nature are not made without the presence of an organism to make them. (Burnette, Tr. 2382).
967. In an MSW landfill, with respect to the degradation of food sources, the goal of enzymatic production is to obtain carbon for microbial metabolism. (Burnette, Tr. 2383-2384).
968. There are bacteria that secrete certain chemicals, *e.g.*, polysaccharide in nature, acidic or basic, that would result in chemical degradation of food sources. (Burnette, Tr. 2384).
969. Microbial succession is the lifecycle of microorganisms. (Burnette, Tr. 2385).
970. In the natural environment, it would be rare to find a singular species of bacteria; multiple species of bacteria coexist and each has a discrete function in the overall cycle of life. (Burnette, Tr. 2385).
971. Microbial succession involves the lifecycle of a population of bacteria from initiation through proliferation until death. (Burnette, Tr. 2385).
972. The process of biodegradation and bacterial metabolism can take several paths to access carbon in substrates, including, *e.g.*, hydrolysis reactions, oxidative reactions, and fermentation. (Burnette, Tr. 2396-2399).
973. Feedback inhibition is a common mechanism by which the product of a biochemical reaction itself will loop back and negatively impact further production of the product, like an accumulation event that prevents the reaction from going forward. (Burnette, Tr. 2403-2404; RX 854 (Burnette Expert Report at 14, Figure 5)).
974. During testing in a closed-system environment, the buildup of inhibitory byproducts begins to occupy binding sites of certain other enzymes and when that happens, the byproducts of the microbiological metabolic functions will compete adversely with the substrate for enzymatic binding sites. (Burnette, Tr. 2404-2405).
975. Virtually all microorganisms are susceptible to feedback inhibition effects. (Burnette, Tr. 2405).
976. A biofilm is the formation of microbial colonies in a somewhat concerted manner that develop into films. (Burnette, Tr. 2406).

977. Bacteria can adhere to plastics, in part, by secreting polysaccharides, which promote bonding to the food source. (Burnette, Tr. 2407-2408).
978. The process of adhering to potential food substrates has been described as “docking and locking.” (Burnette, Tr. 2408).
979. The surface area of a plastic has a substantial influence on the ability of a biofilm to form and adhere. (Burnette, Tr. 2409).
980. Biofilms can contain hundreds to thousands of bacterial species. (Burnette, Tr. 2410).
981. Enzymes can weaken or break carbon-carbon bonds in plastic polymers (and other long-chain polymers) by lowering the amount of energy required to break the bonds. (Burnette, Tr. 2414).
982. The increase in free chlorine ions in solution during the test marked RX 254 performed by Environ on polyvinyl chloride (“PVC”) substrate (“BioPVC test”) indicates that the carbon-carbon bonds were either broken or the bond breakage was imminent. (Sahu, Tr. 1912-13; RX 254; Burnette, Tr. 2414-2416).
983. When chlorine atoms are present in the solution of the BioPVC test (F. 982), it indicates that the HCl group was cleaved from the polymer through a nucleophilic attack on the PVC molecule. (Burnette, Tr. 2415-2417).
984. The resulting PVC molecule in the BioPVC test is substantially weakened in that area, and the carbon-carbon bonds will thus break because the remaining carbon-carbon bond is subject to a hydrolysis reaction that will, in fact, cause bond breakage. (Burnette, Tr. 2417; CCX 1081).
985. The fact that PVC molecule in the BioPVC test becomes unstable and degraded after losing the HCl group is a textbook analysis of a nucleophilic attack; it is documented in the peer-reviewed literature, and it is “a fundamental of biochemistry.” (Burnette, Tr. 2417-2418).
986. Nucleophilic attack means that the enzyme is looking for a positively charged substance to attack. (Burnette, Tr. 2418).
987. Depolymerases are a class of enzymes that reduce large polymers into smaller units. (Burnette, Tr. 2418-2419).
988. Depolymerases are also responsible for biodegradation of plastic polymers, and they are ubiquitous in the environment. (Burnette, Tr. 2418-2421).
989. Depolymerases use hydrolysis and nucleophilic attacks to break bonds, and they are involved in the reduction and oxidation reactions. (Burnette, Tr. 2419).

990. Dr. Burnette's expert report (RX 854) documented several microorganisms that have been identified for their ability to biodegrade plastic polymers. (Burnette, Tr. 2420-2421).
991. Anaerobic and aerobic metabolisms in microorganisms are different concepts, but they share many key similarities, including certain mechanisms of action used to achieve the breakdown of substrates. For example, the use of pyruvate dehydrogenase is a key ingredient and factor in both aerobic and anaerobic metabolism. (Burnette, Tr. 2424-2425).
992. One documented pathway to polyethylene biodegradation includes a common mechanism applicable to both aerobic and anaerobic systems, including the co-factor NAD (nicotinamide adenine dinucleotide, a coenzyme found in living cell) and the oxidative reactions that occur in both environments. (Burnette, Tr. 2426).
993. Dr. Burnette identified and testified to other mechanisms of enzymatic degradation of plastic polymers, including the degradation of polyethylene terephthalate, using the cutinase enzyme, a more difficult to digest polymer. (Burnette, Tr. 2427-2428).
994. Hydrolysis reactions are not limited to environments with high moisture contents. (Burnette, Tr. 2429).
995. Digestion of certain polymer chains may require just a few molecules of water. (Burnette, Tr. 2429).
996. Impurities may include byproducts from manufacturing. (Sahu, Tr. 1830).
997. Impurities affect the biodegradability of plastics by providing attack points in the polymer chains. (Sahu, Tr. 1830).
998. Impurities become spots where the plastic is weaker than it would be without the impurities, and those weaknesses facilitate microbial attack. (Sahu, Tr. 1830-1831).
999. Virtually all plastic articles have additives. (Sahu, Tr. 1836).
1000. Some plastic additives (*e.g.*, colorants) may include components that have an antimicrobial effect. (Sahu, Tr. 1827-1828).
1001. Additives to plastics create heterogeneity in the polymer, and create opportunities for biological attack. (Sahu, Tr. 1830-1831).
1002. Plastic additives may include articles like plasticizers, lubricants, impact modifiers, fillers, pigments, flame retardants, stabilizers, and antimicrobial agents. (Sahu, Tr. 1831-1833).

1003. There are plastic additives that can have antimicrobial properties but are not specifically introduced to the plastic for antimicrobial purposes. (Sahu, Tr. 1835).
1004. There are some catalysts, including copper-based, zinc-based or silver-based components that have antimicrobial properties but are not included intentionally as antimicrobials. (Sahu, Tr. 1835).
1005. An antimicrobial additive or impurity would likely reduce or negate biodegradation. (Sahu, Tr. 1836).

7. Dr. Barlaz's Analysis of Gas Evolution Data from ECM Tests

1006. In a gas evolution laboratory-scale reactor test, it is broadly accepted by the scientific community that biodegradation can be proven with data showing that the volume of methane produced in the test vessel is greater than the volume of gas produced in the inoculum. (Barlaz, Tr. 2246).
1007. Methane is only produced in a system that is strictly anaerobic. (Barlaz, Tr. 2188).
1008. Dr. Barlaz reviewed many of the gas evolution studies involving ECM Plastics. (Barlaz, Tr. 2247).
1009. Dr. McCarthy did not run any statistics for the gas evolution studies on ECM Plastics. (McCarthy, Tr. 654).
1010. Dr. Barlaz was surprised that Dr. McCarthy was dismissive of gas evolution testing involving ECM Plastics without having examined the data. (Barlaz, Tr. 2247).
1011. Dr. Barlaz examined the raw data produced from the gas evolution studies on ECM Plastics by certain laboratories, particularly the data concerning methane generation from the test substrate and methane generation from the inoculum that would be the background methane. (Barlaz, Tr. 2247-2248).
1012. For those gas evolution studies on ECM Plastics where Dr. Barlaz had raw data or triplicate data, he performed statistical analysis, including t-tests, to determine whether there were statistically significant differences between the methane generation in the reactor with the test substrate and the methane attributable to the inoculum alone. (Barlaz, Tr. 2248).
1013. The t-statistic is the most common statistical test after a calculation of the average. The t-test is a statistical procedure that allows one to determine the significant difference between two sets of data. (Barlaz, Tr. 2259-2260).
1014. Dr. Barlaz also calculated standard deviations for gas evolution studies on ECM Plastics where he had triplicate data; however, the t-test is superior in that it also takes into consideration the elements of standard deviation. (Barlaz, Tr. 2264).

1015. In many instances of the gas evolution studies on ECM Plastics, Dr. Barlaz determined from the data itself that the results were statistically significant, and that the data suggested that there was anaerobic biodegradability of the test plastic. Dr. Barlaz concluded for those studies, that ratios varied, but the ratios were generally significant even at the lower end. (Barlaz, Tr. 2248-2249).
1016. For other gas evolution studies on ECM Plastics where triplicate data was not available, Dr. Barlaz examined the ratios of methane generation in the test material plus inoculum to methane generation from the inoculum only. (Barlaz, Tr. 2248).
1017. From the ratios described in F. 1016, Dr. Barlaz determined that the methane generation in the test vessels could be attributable to the test substrate, which suggests that the substrate was undergoing anaerobic biodegradation and conversion to methane. (Barlaz, Tr. 2249, 2260-2262).
1018. Dr. Barlaz prepared a spreadsheet of his statistical calculations from the gas evolution studies on ECM Plastics. (Barlaz, Tr. 2250; RX 472).
1019. Dr. Barlaz also updated his spreadsheet to include additional calculations based on the data from the gas evolution studies on ECM Plastics. (Barlaz, Tr. 2251; RX 968).
1020. To address the question of whether only the ECM Additive had biodegraded, Dr. Barlaz estimated the amount of methane that could theoretically be produced by the ECM Additive alone. (Barlaz, Tr. 2251).
1021. Dr. Barlaz made certain conservative assumptions about the ECM Additive when he calculated the amount of potential methane. (Barlaz, Tr. 2252-2253).
1022. Dr. Barlaz's conservative calculation was that one gram of the ECM Additive would produce 933 mL of methane gas. (Barlaz, Tr. 2253).
1023. Based on his calculation that one gram of the ECM Additive would produce 933 mL of methane gas, Dr. Barlaz looked at the methane yields in the test vessels during biodegradation testing, and determined if the amount of biodegradation exceeded the amount that could potentially be sourced from the additive. (Barlaz, Tr. 2253-2254).
1024. Dr. Barlaz made an assumption for his calculations that the ECM Additive was 50% carbon because most items are about 50% carbon. (Barlaz, Tr. 2254).
1025. Polyethylene, by contrast, is almost 90% carbon. (Barlaz, Tr. 2254).
1026. Dr. Barlaz also calculated the methane yield of the ECM Additive based on the formula for the ECM Additive that Dr. McCarthy used in his expert report at page 24, footnote 17. (Barlaz, Tr. 2254-2255; CCX 891 (McCarthy Expert Report at 24 n.17)).

1027. Based on Dr. McCarthy's description of the ECM Additive that was based on reverse engineering of the ECM Additive, Dr. Barlaz calculated a methane yield for the ECM Additive of 838 mL per gram. (Barlaz, Tr. 2255; RX 968).
1028. Using Dr. McCarthy's assumptions, the data produced in the gas evolution tests suggests that even more of the substrate plastic (not the ECM Additive) biodegraded, because the ECM Additive would have had a lower potential methane yield. (Barlaz, Tr. 2255-2256).
1029. Using, as an example, the ASTM D5511 test on ECM Plastics performed by NE Labs on behalf of Minigrips ("NE Labs Minigrips test") (F. 1286-1312), Dr. Barlaz explained the arithmetic summarized in his spreadsheet. (Barlaz, Tr. 2256-2257; RX 968).
1030. Dr. Barlaz calculated the weight of the ECM Additive (in grams) by multiplying the percentage of the ECM Additive load rating (in the Minigrips test, 1.5%) by the starting weight of the entire test plastic. (Barlaz, Tr. 2256-2257).
1031. By calculating the amount of total methane potential from one gram of ECM Additive, Dr. Barlaz could determine the total amount of methane possible in the ECM Additive in each specific test by multiplying the actual weight of the ECM Additive by the conservative 933 mL calculation (F. 1022) (or 838 mL if using Dr. McCarthy's assumptions) (F. 1027). (Barlaz, Tr. 2256-2258; RX 968).
1032. Dr. Barlaz also calculated the net methane for each test vessel, which he did by subtracting the mean triplicate methane data from the inoculum blanks from the test vessels. (Barlaz, Tr. 2257-2258; RX 968 (summary sheet)).
1033. Dr. Barlaz looked for a 95% certainty in the statistics that he ran, which would mean that the researchers are 95% "certain that you got the right answer." (Barlaz, Tr. 2260).
1034. Dr. Barlaz's t-statistics were generally well below the .05 that indicates statistical significance at the 95% level. (Barlaz, Tr. 2257).
1035. Dr. Barlaz's mathematical process is explained in his testimony. (Barlaz, Tr. 2257-2259).
1036. Dr. Barlaz explained that where the methane is associated and produced from the test vessel is not attributable to the inoculum, and not attributable to the ECM Additive, then the biodegradation must come from the plastic substrate itself. (Barlaz, Tr. 2258).
1037. Dr. Barlaz also analyzed the ratios of methane to carbon dioxide in the lab tests. (Barlaz, Tr. 2261-2262).
1038. A ratio of methane to carbon dioxide that is greater than 1:1 is a good indication that the anaerobic environment was behaving properly. (Barlaz, Tr. 2262-2263).

1039. Gas evolution testing does not account for carbon that may have been cleaved from the substrate, but converted to cell mass instead of gas. (Barlaz, Tr. 2263-2264).
1040. The biodegradation numbers calculated by the laboratories in this case based on gas data alone are a lower limit of the carbon conversion that was actually realized. (Barlaz, Tr. 2263-2264).
1041. Based on his statistical analyses and the test data he reviewed concerning ECM Plastics, Dr. Barlaz testified that competent and reliable scientific evidence exists to show that plastics manufactured with the ECM Additive are anaerobically biodegradable. (Barlaz, Tr. 2264-2265).
1042. Dr. Barlaz testified that “there are certainly many tests where there’s good scientific evidence that the material -- that the material underwent anaerobic [biodegradation].” (Barlaz, Tr. 2265).

8. Testing Performed on the ECM Additive

1043. Dr. Barlaz reviewed the test materials in evidence in this case. Based on checking of the lab reports, Dr. Barlaz concluded that in numerous tests, plastics manufactured with the ECM Additive were shown to anaerobically biodegrade to methane. (Barlaz, Tr. 2175).
1044. There were some tests that did not conclusively show anaerobic biodegradation, but there were many more tests that did. In totality, there is evidence that plastics made with the ECM Additive is anaerobically biodegrading. (Barlaz, Tr. 2274).
1045. For purposes of determining biodegradability under landfill conditions, only anaerobic biodegradability is of relevance. (RX 853 (Barlaz Expert Report at 7); Barlaz, Tr. 2300).

a. Anaerobic testing by Eden Research Laboratories

1046. Eden Research Laboratories (“ERL”) is a laboratory in New Mexico, owned and operated by Mr. Thomas Poth. (Poth, Tr. 1440-1441).
1047. Mr. Poth completed the course requirements for an undergraduate degree from New Mexico Institute of Mining and Technology in chemistry and environmental engineering and has taken numerous courses on hazardous waste management and radioactive waste management at the graduate level, but did not receive a degree. (Poth, Tr. 1435-1436).
1048. ERL employs two full-time employees, and two part-time employees. In addition to Mr. Poth, ERL’s other full-time employee is Dr. Brian Esau. ERL’s tests are performed by Mr. Poth and Dr. Esau. (Poth, Tr. 1440-1441).

1049. Dr. Esau has a master's degree and a Ph.D. in biochemistry from the University of Illinois at Champaign-Urbana. Dr. Esau participates in the daily operation of the laboratory, including project design, and performs testing of products. (Poth, Tr. 1441).
1050. ERL has performed biodegradability testing of plastic products such as plastic bags and drink bottles since 2010. Approximately 50% of ERL's current business is biodegradability testing. (Poth, Tr. 1444-1445).
1051. ERL performs ASTM D5511 biodegradation testing for clients. (Poth, Tr. 1447-1448).
1052. ERL follows the D5511 protocol, but has made adjustments to that protocol to more closely simulate a landfill. (Poth, Tr. 1449-1450).
1053. ERL has increased the solids content in its D5511 test. (Poth, Tr. 1450).
1054. Other than the adjustment to solids content (or moisture content), ERL does not alter the D5511 test protocol in any substantial way. (Poth, Tr. 1450).
1055. ERL increased the solids content of its test so that its D5511 test would look more like a landfill as opposed to a digester. (Poth, Tr. 1450).
1056. ERL explained to its customers that ERL's testing is not performed at optimal moisture content and, as a consequence, the performance of test samples in biodegradation testing are not going to be optimal. (Poth, Tr. 1451-1452).
1057. ERL explained that the higher solid content involved in ERL D5511 testing would be more appropriate because the testing was more indicative of performance in a landfill. (Poth, Tr. 1452).
1058. ERL prepares its test inoculum with compost obtained from a local facility. (Poth, Tr. 1457-1458).
1059. ERL conditions its inoculum in an incubator to climatize it to temperature and promote selection of anaerobic microbes. (Poth, Tr. 1459-1460).
1060. ERL combines its compost with sewage sludge to form the final inoculum. (Poth, Tr. 1461).
1061. Sewage sludge, as used by ERL, consists of the solids that come from the digester in ERL's laboratory. (Poth, Tr. 1461).
1062. ERL determines the moisture content of its inoculum, and adjusts the liquid added to the inoculum before placing it in the incubator, which helps control the specific moisture content in the final, test-ready inoculum. (Poth, Tr. 1463).

1063. ERL reviews and controls for the carbon to nitrogen levels, the ammonia levels, and the pH. (Poth, Tr. 1463-1464).
1064. ERL runs all D5511 tests in triplicate, using three separate test vessels for each of the three controls in the D5511 standard, the two additional controls that ERL relies on, and the test vessels. (Poth, Tr. 1466).
1065. ERL uses a gas chromatograph to analyze the gas emissions produced during the D5511 test. (Poth, Tr. 1468-1469).
1066. ERL calibrates its gas chromatograph monthly and as appropriate. (Poth, Tr. 1469).
1067. ERL uses a graduated cylinder to record total gas volume and collect gas during the D5511 test. (Poth, Tr. 1468).
1068. ERL does not use Mylar or Kevlar bags for gas collection because ERL previously determined that those bags leaked methane, and because the bags made gas transfer difficult. (Poth, Tr. 1468).
1069. ERL calculates the percentage of biodegradation observed in a D5511 test by performing the necessary calculations of theoretical gas yields, and comparing those to the gas yield of the sample (excluding the gas produced by the inoculum blanks). (Poth, Tr. 1469-1471).
1070. ERL's method of calculating the percentage of biodegradation follows the ASTM D5511 standard. (*Compare F. 1069 with RX 356 at 4*).
1071. ERL has had difficulties in testing certain plastic polymers in laboratory reactor tests. (Poth, Tr. 1472-1473).
1072. With plastic foams, ERL found it was difficult to have decent surface area contact with the inoculum because foam products frequently consumed too much space in the test vessel. (Poth, Tr. 1473).
1073. ERL's testing protocols, which follow the D5511 test, are not suitable for plastics that have components inhibitory to microorganisms. (Poth, Tr. 1471).
1074. ERL does not refresh inoculum during D5511 tests that are run over a long duration. (Poth, Tr. 1474).
1075. ERL has seen plateaus in the biodegradation in long term tests, which last for a period of up to two months before biodegradation in the test system sometimes resumes. (Poth, Tr. 1474).
1076. ERL uses a standard format for reporting data in a D5511 test. (Poth, Tr. 1480-1481).

1077. Dr. Barlaz visited ERL in about December 2012. His visit predated and was unrelated to his participation as an expert witness in this case. (Barlaz, Tr. 2274-2275).
1078. Dr. Barlaz observed ERL's test reactors and reviewed ERL's testing process with ERL's owner, Thomas Poth. (Barlaz, Tr. 2275).
1079. Having reviewed ERL's biodegradation testing, Dr. Barlaz was comfortable that ERL's testing was strictly under anaerobic conditions and that ERL had the appropriate capability to monitor gas volume and composition. (RX 853 (Barlaz Expert Report at 14); Barlaz, Tr. 2275).

i. RX 248, ERL No. 092511B

1080. In September 2011, ERL reported test data from an anaerobic D5511 biodegradation test in laboratory reactors, ERL No. 092511B, marked RX 248. (RX 248).
1081. ERL performed the test on behalf of FP International, using test samples that were provided by FP International. (RX 248 at 1).
1082. The test marked RX 248 followed the ASTM D5511 protocol. The solid content of the test was 48.4%. (RX 248 at 1).
1083. In the test marked RX 248, the study authors recorded gas evolution data on a weekly basis and calculated pH volumes, volatile fatty acids, and ammonium nitrogen levels. (RX 248 at 1-4).
1084. The test marked RX 248 included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and two test samples, all of which were run in triplicate. (RX 248; Poth, Tr. 1466-1467).
1085. The test marked RX 248 included two "test" plastic samples, both amended with the ECM Additive at 1% by weight. (RX 248 at 1-2).
1086. The two test samples, marked "ERL #223" and "ERL #224" in RX 248, were polyethylene airbags. (RX 871 (Blood, Dep. at 166-169)).
1087. The test marked RX 248 involved a negative control that was an airbag control, a plastic that was not amended with the ECM Additive. (RX 248).
1088. The test marked RX 248 revealed biodegradation of the two ECM amended plastics in the amount of 11.5% for sample ERL #223 and 15.2% for sample ERL #224 after 120 days of anaerobic testing. (RX 248 at 5).

1089. In the test marked RX 248, the amount of methane recorded in sample ERL #223 was 3,884.2 mL. The amount of methane recorded from sample ERL #224 was 4,761.8 mL. (RX 248 at 5).
1090. In the test marked RX 248, the total mass of the sample ERL #223 was 20 grams. The ECM Additive, at 1% by weight, had a mass of 0.2 grams. (RX 248).
1091. Based on Dr. Barlaz's calculation from the data from the sample ERL #223 in the test marked RX 248, the total theoretical yield of methane from 0.2 grams of the ECM Additive is 186.6 mL of methane, calculated by multiplying the grams of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968).
1092. At 3,884.2 mL, the amount of methane recorded from test sample ERL #223 in RX 248 was nearly twenty times the biodegradation that could have been sourced from the ECM Additive alone. (RX 248 at 5; RX 968; Barlaz, Tr. 2252-2258).
1093. In the test marked RX 248, the total mass of the sample marked ERL #224 was 20 grams. The ECM Additive, at 1% by weight, had a mass of 0.2 grams. (RX 248).
1094. Based on Dr. Barlaz's calculation from the data from the sample ERL #224 in the test marked RX 248, the total theoretical yield of methane from the 0.2 grams of the ECM Additive is 186.6 mL of methane, calculated by multiplying the grams of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968).
1095. At 4,761.8 mL, the amount of methane recorded from the test sample ERL #224 in RX 248 is more than twenty five times the amount of biodegradation that could have been sourced from the ECM Additive alone. (RX 248 at 5; RX 968; Barlaz, Tr. 2252-2258).
1096. The cumulative amount of methane collected from the test marked RX 248 represented about fifty percent of the total gas emissions. (RX 248 at 5).
1097. The study author of the test marked RX 248 reported that it was "obvious that biodegradation has occurred on the treated sample." (RX 248 at 6).
1098. Based on the data collected in the test marked RX 248, the study author reported that, as of the date of the report, "the treated sample is continuing to biodegrade." (RX 248).

ii. RX 839, ERL No. 070312C

1099. In July 2012, ERL reported test data from an anaerobic D5511 biodegradation test in laboratory reactors, ERL No. 070312C, marked RX 839. (RX 839).
1100. ERL performed the test marked RX 839 on behalf of Shields Bag & Printing. (RX 839 at 113977).

1101. The test marked RX 839 followed the ASTM D5511 protocol. The solid content of the test was 48.4%. (RX 839 at 113977).
1102. In the test marked RX 839, the study authors recorded gas evolution data on a weekly basis and calculated pH volumes, volatile fatty acids, and ammonium nitrogen levels. (RX 839 at 113977-113980).
1103. The test marked RX 839 included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and one test sample, all of which were run in triplicate. (RX 839 at 113982; Poth, Tr. 1466-1467).
1104. The test marked RX 839 included a test plastic sample amended with the ECM Additive at 1% by weight. The test sample, "ERL #476A," was a clear film. (RX 839 at 113978, 113982).
1105. The test marked RX 839 involved a negative control that was a control film, a plastic that was not amended with the ECM Additive. (RX 839 at 113982).
1106. The test marked RX 839 revealed biodegradation of the ECM amended plastic in the amount of 7.9% after 22 weeks of anaerobic testing. (RX 839 at 113982).
1107. In the test marked RX 839, the amount of methane recorded in sample ERL #476A was 2,053.2 mL. (RX 839 at 113982).
1108. In the test marked RX 839, the total mass of the sample ERL #476A was 20 grams. The ECM Additive, at 1% by weight, had a mass of 0.2 grams. (RX 839 at 113982; Barlaz, Tr. 2252-2258).
1109. Based on Dr. Barlaz's calculation from the data from the test marked RX 839, the total theoretical yield of methane from 0.2 grams of the ECM Additive is 186.6 mL of methane, calculated by multiplying the grams of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968; Barlaz, Tr. 2252-2258).
1110. At 2,053.2 mL, the amount of methane recorded from test sample ERL #476A in RX 839 was eleven times the amount of biodegradation that could have been sourced from the ECM Additive alone. (RX 839 at 113982; RX 968; Barlaz, Tr. 2252-2258).
1111. The amount of methane recorded in the test marked RX 839 in the inoculum blanks was just 792.7 mL. (RX 839 at 113982).
1112. The study author of the test marked RX 839 reported that it was "obvious that biodegradation has occurred on the treated sample." (RX 839 at 113982).

1113. Based on the data collected in the test marked RX 839, the study author reported that, as of the date of the report, “the treated sample is continuing to biodegrade.” (RX 839 at 113982).

iii. RX 403, ERL Fellows

1114. In October 2012 through February 2013, ERL reported test data from an anaerobic D5511 biodegradation test in laboratory reactors, ERL Fellows Test, marked RX 403. (RX 403).

1115. ERL performed the test marked RX 403 on behalf of Fellows. (RX 403 at 001048).

1116. The test marked RX 403 followed the ASTM D5511 protocol. (RX 403 at 001048).

1117. The test marked RX 403 is an ERL “update.” (RX 403).

1118. ERL produces update reports to keep customers abreast of the status of testing. Update reports do not include all of the information relevant to the test, or all of the information included in a final report. (Poth, Tr. 1475-1477).

1119. The test marked RX 403 included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), two negative controls consisting of untreated plastics, and two test samples, all of which were run in triplicate. (RX 403 at 001048; Poth, Tr. 1466-1467).

1120. The test marked RX 403 included two test plastic samples amended with the ECM Additive at 1% by weight. (RX 403 at 001048).

1121. In the test marked RX 403, one test sample, designated “568-P1004,” included a “1% ECM BioFilm Resin” and the other test sample, designated “570-TPU,” included a “1% ECM BioFilm Resin Pink.” (RX 403 at 001048).

1122. The test marked RX 403 involved negative controls that were control resins, plastics that were not amended with the ECM Additive and contained “0% ECM.” (RX 403 at 001052).

1123. ERL recorded data for the test marked RX 403 through 197 days. (RX 403 at 001052).

1124. In the test marked RX 403, ERL recorded biodegradation of the ECM amended sample 568-P1004 in the amount of 71.8% after 197 days of anaerobic testing. (RX 403 at 001052).

1125. In the test marked RX 403, for the sample marked 568-P1004, Dr. Barlaz calculated a net methane yield of 7,548.9 mL, meaning that the test produced 7,548.9 mL more than the inoculum blanks. (RX 403; RX 968; Barlaz, Tr. 2252-2258).

1126. In the test marked RX 403, the total mass of the sample 568-P1004 was 20 grams. The ECM Additive, at 1% by weight, had a mass of 0.2 grams. (RX 403 at 001052; Barlaz, Tr. 2252-2258).
1127. Based on Dr. Barlaz's calculation from the data from the test marked RX 403, the total theoretical yield of methane from 0.2 grams of the ECM Additive is 186.6 mL of methane, calculated by multiplying the grams of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968; Barlaz, Tr. 2252-2258).
1128. At a net methane production of 7,548.9 mL, the amount of methane recorded from test sample 568-P1004 in the test marked RX 403 was more than forty times the amount that could have theoretically been sourced from the ECM Additive. (RX 403 at 113982; RX 968; Barlaz, Tr. 2252-2258).
1129. In the test marked RX 403, ERL recorded biodegradation of the ECM amended sample 570-TPU in the amount of 16.1% after 197 days of anaerobic testing. (RX 403 at 001052).
1130. In the test marked RX 403, for the sample marked 570-TPU, Dr. Barlaz calculated a net methane yield of 2,337.5 mL, meaning that the test produced 2,337.5 mL more than the inoculum blanks. (RX 403; RX 968; Barlaz, Tr. 2252-2258).
1131. In the test marked RX 403, the total mass of the sample 570-TPU was 20 grams. The ECM Additive, at 1% by weight, had a mass of 0.2 grams. (RX 403 at 001052; Barlaz, Tr. 2252-2258).
1132. Based on Dr. Barlaz's calculation from the data from the test marked RX 403, the total theoretical yield of methane from 0.2 grams of the ECM Additive is 186.6 mL of methane, calculated by multiplying the grams of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968; Barlaz, Tr. 2252-2258).
1133. At 2,337.5 mL, the amount of methane recorded from test sample 570-TPU in the test marked RX 403 was more than twelve times the amount of biodegradation that could have been sourced from the ECM Additive alone. (RX 403 at 113982; RX 968; Barlaz, Tr. 2252-2258).
1134. The ratio of mean substrate methane to mean inoculum methane in the test marked RX 403 was more than 5:1, indicating that the biodegradation observed in the test environment was confidently ascribed to the test article. (RX 968; Barlaz, Tr. 2247-2250).

iv. RX 402, ERL FP International

1135. In October 2013 through February 2014, ERL reported test data from an anaerobic biodegradation test in laboratory reactors, ERL FP International Testing, marked RX 402. (RX 402).
1136. ERL performed the test marked RX 402 on behalf of FP International, an ECM customer. (RX 402 at 001046; F. 53, 58).
1137. The test marked RX 402 followed a modernized and more recent ASTM protocol. (RX 402 at 001046).
1138. The test report is an ERL “update.” (RX 402). *See* F. 1118.
1139. The test marked RX 402 included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and two test samples, all of which were run in triplicate. (RX 402 at 001046; Poth, Tr. 1466-1467).
1140. The test marked RX 402 included two test plastic samples amended with the ECM Additive at 1% and 1.75% by weight. (RX 402 at 001046).
1141. One test sample in the test marked RX 402 designated “726” included a “Film with 1% ECM.” (RX 402 at 001046).
1142. One test sample in the test marked RX 402 designated “727” included a “Film with 1.75% ECM.” (RX 402 at 001046).
1143. The test marked RX 402 involved a negative control that was a control film containing “0% ECM.” (RX 402 at 001046).
1144. ERL recorded data for the test marked RX 402 through 290 days. (RX 402 at 001042).
1145. In the test marked RX 402, ERL recorded biodegradation of the ECM amended sample 726 in the amount of 11.5% after 290 days of anaerobic testing. (RX 402 at 1042).
1146. For the sample marked 727 in the test marked RX 402, Dr. Barlaz calculated a net methane yield of 1,352.2 mL, meaning that the test produced 1,352.2 mL more than the inoculum blanks. (RX 402; RX 968; Barlaz, Tr. 2252-2258).
1147. In the test marked RX 402, the total mass of the sample 727 was 20 grams. The ECM Additive, at 1% by weight, had a mass of 0.35 grams. (RX 402 at 001042; RX 968; Barlaz, Tr. 2252-2258).
1148. Based on Dr. Barlaz’s calculation from the data from the test marked RX 402, the total theoretical yield of methane from 0.35 grams of the ECM Additive is 326.55 mL of methane, calculated by multiplying the grams of ECM Additive by Dr. Barlaz’s

calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968; Barlaz, Tr. 2252-2258).

1149. At a net methane production of 1,352.2 mL, the amount of methane recorded from test sample 727 in RX 402 was more than four times the amount of biodegradation that could have theoretically been sourced from the ECM Additive alone. (RX 402 at 001042; RX 968; Barlaz, Tr. 2252-2258).

v. CCX 548, ERL FP International

1150. In October 2013 through February 2014, ERL reported test data from an anaerobic biodegradation test in laboratory reactors, ERL FP International Testing, marked CCX 548. (CCX 548).
1151. ERL performed the test marked CCX 548 on behalf of FP International. (CCX 548 at 1).
1152. The test marked CCX 548 followed a modernized and more recent ASTM protocol. (CCX 548 at 1).
1153. The test report is an ERL “update.” (CCX 548). *See* F. 1118.
1154. The test marked CCX 548 included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and a test sample, all of which were run in triplicate. (CCX 548 at 1; Poth, Tr. 1466-67).
1155. The test marked CCX 548 included a test plastic amended with the ECM Additive and labeled “723 – Biodegradable EPS FloPak” (“723”). (CCX 548 at 1).
1156. ERL recorded data for the test marked CCX 548 through 291 days. (CCX 548 at 1).
1157. In the test marked CCX 548, ERL recorded biodegradation of the ECM amended sample 723 in the amount of 30.4% after 291 days of anaerobic testing. (CCX 548 at 1).
1158. In the test marked CCX 548, for the sample marked 723, ERL reported 2,705.9 mL of total methane, compared to just 383.4 mL of methane in the inoculum blank. The net methane is 2322.5 mL in the 723 sample vessels. (CCX 548 at 1).
1159. In the test marked CCX 548, the sample mass of the 723 test sample was 7.5 grams. The amount of the ECM Additive is not provided in the report marked CCX 548. (CCX 548 at 1).

1160. Even assuming that the ECM Additive was introduced at 5% by weight, the weight of the ECM Additive in the 7.5 gram 723 sample tested in CCX 548 would have been 0.375 grams. (CCX 548; RX 968; Barlaz, Tr. 2252-2258).
1161. Based on Dr. Barlaz's calculations from the data from the test marked CCX 548, the total theoretical yield of methane from 0.375 grams of the ECM Additive is 349.875 mL of methane, calculated by multiplying the grams of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968; Barlaz, Tr. 2252-2258).
1162. At a net methane production of 2322.5 mL, the amount of methane recorded from test sample 723 in the test marked CCX 548 was more than 6.5 times the amount of biodegradation that could have theoretically been sourced from the ECM Additive alone. (CCX 548 at 1; RX 968; Barlaz, Tr. 2252-2258).

vi. CCX 546, ERL FP International

1163. In November 2013, ERL reported test data from an anaerobic D5511 biodegradation test in laboratory reactors, ERL FP International Testing, marked CCX 546. (CCX 546).
1164. ERL performed the test marked CCX 546 on behalf of FP International. (CCX 546 at 1).
1165. The test marked CCX 546 is an ERL "update." (CCX 546). *See* F. 1118.
1166. The test marked CCX 546 included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and two test samples, all of which were run in triplicate. (CCX 546 at 1; Poth, Tr. 1466-1467).
1167. The test marked CCX 546 included two test plastics containing the ECM Additive, labeled "223A-TKN Green" ("223A") and "224A-HOP Green" ("224A"). (CCX 546 at 1).
1168. Mr. James Blood, of FP International, explained that the primary difference between the test samples marked "TKN" and "HOP" in test CCX 546 was the location or factory where the samples were manufactured. (RX 871 (Blood, Dep. at 164-165)).
1169. The ERL test marked CCX 546 does not report the amount of ECM Additive included in the test samples. (CCX 546 at 1).
1170. Mr. Blood testified that the test marked CCX 564 would have involved a 1% ECM additive product. (RX 871 (Blood, Dep. at 164-165)).
1171. ERL recorded data for the test marked CCX 546 through 977 days. (CCX 546 at 1).

1172. In the test marked CCX 546, ERL recorded biodegradation of the ECM amended sample 223A in the amount of 36.7% after 977 days of anaerobic testing. (CCX 546 at 1).
1173. In the test marked CCX 546, ERL recorded biodegradation of the ECM amended sample 224A in the amount of 39.8% after 977 days of anaerobic testing. (CCX 546 at 1).
1174. For the sample marked 223A in the test marked CCX 546, ERL reported 9,268.8 mL of total methane, compared to just 1,805.9 mL of methane in the inoculum blank. (CCX 546 at 1).
1175. The net methane is 7,462.9 mL in the 223A sample vessels in the test marked CCX 546. (CCX 546 at 1; RX 968; Barlaz, Tr. 2252-2258).
1176. For the sample marked 224A in test CCX 546, ERL reported 9,970.8 mL of total methane, compared to just 1,805.9 mL of methane in the inoculum blank. (CCX 546 at 1; RX 968; Barlaz, Tr. 2252-2258).
1177. The net methane is 8,164.9 mL in the 224A sample vessels in the test marked CCX 546. (CCX 546 at 1; RX 968; Barlaz, Tr. 2252-2258).
1178. In the test marked CCX 546, the sample mass of the 223A test sample was 20 grams and the sample mass of the 224A sample was 20 grams. (CCX 546 at 1).
1179. At 1% by weight, the sample mass of the ECM Additive in the 223A and 224A samples in the test marked CCX 546 was 0.20 grams. (RX 968; Barlaz, Tr. 2252-2258).
1180. Based on Dr. Barlaz's calculations from the data from the test marked CCX 546, the total theoretical yield of methane from 0.2 grams of the ECM Additive is 186.6 mL of methane, calculated by multiplying the grams of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968; Barlaz, Tr. 2252-2258).
1181. At a net methane production of 7,462.9 mL, the amount of methane recorded from test sample 223A in the test marked CCX 546 was about forty times the amount that could have possibly been sourced from the ECM Additive. (CCX 546 at 1; RX 968; Barlaz, Tr. 2252-2258).
1182. At a net methane production of 8,164.9 mL, the amount of methane recorded from test sample 224A in the test marked CCX 546 was about forty-four times the amount of biodegradation that could have possibly been sourced from the ECM Additive. (CCX 546 at 1; RX 968; Barlaz, Tr. 2252-2258).

vii. CCX 534, ERL MicroTek

1183. In May 2012 through March 2013, ERL reported test data from an anaerobic D5511 biodegradation test in laboratory reactors, ERL MicroTek Testing, marked CCX 534. (CCX 534).
1184. The test marked CCX 534 was performed by ERL on a polyethylene film on behalf of MicroTek. (CCX 534 at 009017).
1185. The test marked CCX 534 is an ERL “update.” (CCX 534). *See* F. 1118.
1186. The test marked CCX 534 included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), a negative control consisting of an untreated plastic, and a test sample, all of which were run in triplicate. (CCX 534 at 009017; Poth, Tr. 1466-1467).
1187. The test marked CCX 534 included a test plastic amended with the ECM Additive, labeled “BIO10115 ECM FILM” (“BIO10115”). (CCX 534 at 009017).
1188. The ERL test marked CCX 534 does not report the amount of ECM Additive included in the test samples. (CCX 534 at 009017).
1189. ERL recorded data for the test marked CCX 534 through 485 days. (CCX 534 at 009017).
1190. In the test marked CCX 534, ERL recorded biodegradation of the ECM amended sample BIO10115 in the amount of 45.2% after 485 days of anaerobic testing. (CCX 534 at 009017).
1191. For the sample marked BIO10115 in the test marked CCX 534, ERL reported 7,588.2 mL of total methane, compared to just 1,781.7 mL of methane in the inoculum blank. (CCX 534 at 009017).
1192. The net methane for the sample marked BIO10115 in the test marked CCX 534 is 5,806.5 between the test vessels and the inoculum vessels. (CCX 534 at 009017; RX 968; Barlaz, Tr. 2252-2258).
1193. The sample mass of the BIO10115 test sample in the test marked CCX 534 was 13 grams. (CCX 534 at 009017).
1194. Even assuming that the ECM Additive was included at 5% by weight, the sample mass of the ECM Additive in the BIO10115 sample in the test marked CCX 534 would have been 0.65 grams. (CCX 534 at 009017; RX 968; Barlaz, Tr. 2252-2258).
1195. Based on Dr. Barlaz’s calculations from the data from the test marked CCX 534, the total theoretical yield of methane from 0.65 grams of the ECM Additive is 606.45 mL

of methane, calculated by multiplying the grams of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968; Barlaz, Tr. 2252-2258).

1196. At a net methane production of 5,806.5 mL, the amount of methane recorded from test sample BIO10115 in the test marked CCX 534 was about nine and one half times the amount of biodegradation could have possibly been sourced from the ECM Additive. (CCX 534 at 009017; RX 968; Barlaz, Tr. 2252-2258).

viii. CCX 547, ERL EcoLab

1197. In March 2013 through September 2013, ERL reported test data from an anaerobic D5511 biodegradation test in laboratory reactors, ERL EcoLab Testing, marked CCX 547. (CCX 547).

1198. ERL performed the test marked CCX 547 on behalf of EcoLab. (CCX 547 at 009008).

1199. The test marked CCX 547 is an ERL "update." (CCX 547). *See* F. 1118.

1200. The test marked CCX 547 included the use of an inoculum blank, a negative control (polyethylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (CCX 547 at 009017; Poth, Tr. 1466-1467).

1201. The test marked CCX 547 included two "test" plastics containing the ECM Additive, on sample labeled "538A BIO10115 ECM Film," ("538A") and another sample labeled "539A BIO10115 ECM Film" ("539A") (CCX 547 at 009008).

1202. ERL recorded data for the test marked CCX 547 through 452 days. (CCX 547 at 009004-009008).

1203. In the test marked CCX 547, ERL recorded biodegradation of the ECM amended sample 538A in the amount of 19.6% after 452 days of anaerobic testing. (CCX 547 at 009008).

1204. In the test marked CCX 547, ERL recorded biodegradation of the ECM amended sample 539A in the amount of 46.5% after 452 days of anaerobic testing. (CCX 547 at 009008).

1205. The ERL test marked CCX 547 does not report the amount of ECM Additive included in the test samples. (CCX 547 at 009008).

1206. For the sample marked 538A in the test marked CCX 547, ERL reported 5,356.4 mL of total methane, compared to just 1093.3 mL of methane in the inoculum blank. (CCX 547 at 009008).

1207. The net methane for sample 538A in the test marked CCX 547 is 4,263.1 mL between the test vessels and the inoculum vessels. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-2258).
1208. For the sample marked 539A, ERL reported 9,778.7 mL of total methane, compared to 1093.3 mL of methane in the inoculum blank. (CCX 547 at 009008).
1209. The net methane for sample 539A in the test marked CCX 547 is 8,685.4 mL between the test vessels and the inoculum vessels. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-2258).
1210. The sample masses of the 538A and 539A test samples were 20 grams each. (CCX 547 at 009008).
1211. Even assuming that the ECM Additive was included at 5% by weight in the 538A sample in the test marked CCX 547, the sample mass of the ECM Additive in the 538A sample would have been 1 gram. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-2258).
1212. Even assuming that the ECM Additive was included in the 539A sample in the test marked CCX 547 at 15%, the sample mass of the ECM Additive in the 539A sample would have been 3 grams. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-2258).
1213. Based on Dr. Barlaz's calculations from the data from the test marked CCX 547, the total theoretical yield of methane from 1 gram of the ECM Additive is 933 mL of methane, calculated by multiplying the grams of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968; Barlaz, Tr. 2252-2258).
1214. The total theoretical yield of methane from 3 grams of the ECM Additive is 2,799 mL, calculated by multiplying the grams of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive in the sample. (RX 968; Barlaz, Tr. 2252-2258).
1215. At a net methane production of 4,263.1 mL, the amount of methane recorded from test sample 538A in CCX 547 was more than four and one half times the amount of biodegradation (933 mL) that could have possibly been sourced from the ECM Additive assuming even a 5% load rate. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-2258).
1216. At a net methane production of 8,685.4 mL, the amount of methane recorded from test sample 539A in CCX 547 was more than three times the amount of biodegradation (2,799 mL) that could have possibly been sourced from the ECM Additive assuming even a 15% load rate. (CCX 547 at 009008; RX 968; Barlaz, Tr. 2252-2258).

b. Anaerobic testing by Northeast Laboratories

1217. Mr. Alan Johnson serves as the current laboratory director at Northeast Laboratories (“NE Labs”). (Johnson, Tr. 1554).
1218. Mr. Johnson has a bachelor’s degree with a major in biology and a minor in chemistry from the University of Connecticut and took graduate level coursework for a master’s degree in microbiology, but did not complete the program. (Johnson, Tr. 1554-1555).
1219. NE Labs has 14 employees, working in different disciplines, including biodegradation, wastewater, microbiology, and chemistry. (Johnson, Tr. 1556-1557).
1220. NE Labs is certified by the Environmental Protection Agency, Food and Drug Administration, United States Department of Agriculture, Centers for Disease Control, and the state of Connecticut. These certifications authorize the lab to do pharmaceutical, wastewater, food and environmental microbiology testing. (Johnson, Tr. 1558-1559).
1221. NE Labs’ biodegradation testing is a branch of NE Labs’ testing services; however, NE Labs relies on its other laboratory divisions, including its chemistry lab, which has passed audits, for portions of the biodegradation testing work. (Johnson, Tr. 1560-1561).
1222. NE Labs began performing biodegradation testing around 2005. (Johnson, Tr. 1560).
1223. NE Labs’ biodegradation testing business was initiated and operated by Dr. William Ullmann, who founded NE Labs in 1977. (Johnson, Tr. 1560-1562).
1224. Dr. Ullmann was the former director of the state of Connecticut’s Public Health Laboratory and had a Ph.D. in microbiology. (Johnson, Tr. 1562-1563).
1225. Dr. Ullmann was responsible for developing NE Labs’ biodegradation testing protocols, and he performed those studies until his death in 2011. (Johnson, Tr. 1563).
1226. NE Labs would begin biodegradation testing by obtaining test samples directly from customers, and then calculating the carbon content of those samples. (Johnson, Tr. 1564).
1227. NE Labs generally follows the ASTM D5511 protocol, but NE Labs uses metal canisters as reactor vessels instead of glass vessels. (Johnson, Tr. 1565).
1228. NE Labs’ metal canisters are specially manufactured for biodegradation testing. (Johnson, Tr. 1565).

1229. NE Labs drills into the metal canisters and threads a fitting into the can so that the test tubing is airtight and feeds directly from the reactor into the graduated cylinder, where gas volume is measured. (Johnson, Tr. 1565-1566).
1230. The ASTM D5511 method calls for the use of an inverted graduated cylinder to measure total gas volume. (RX 356, at 2 § 6.1).
1231. NE Labs uses lined paint cans to prevent corrosion. (Johnson, Tr. 1566).
1232. The issue of corrosion was never an issue in NE Labs' shorter-duration studies. (Johnson, Tr. 1565-1566).
1233. In longer duration studies during the early years when NE Labs used unlined canisters, corrosion may have been an issue to the extent that NE Labs observed rust forming on the can. (Johnson, Tr. 1566).
1234. NE Labs seals its canisters with silicone caulking and then seals each container with a resin. (Johnson, Tr. 1567).
1235. NE Labs pressure treats its containers by applying compressed air. (Johnson, Tr. 1567-1568).
1236. NE Labs never had any indications that its test systems leaked or were not gas tight. (Johnson, Tr. 1566-1567).
1237. A leaking canister would be quite obvious. (Johnson, Tr. 1567-1568).
1238. NE Labs could determine whether its test vessels leaked or were airtight because if the canisters had leaked, then the water level in the graduated cylinder (used for gas collection) would be lowered. (Johnson, Tr. 1566-1567).
1239. NE Labs could determine that the test environment was not aerobic (or gaining oxygen) because the test vessels were producing methane, and the D5511 tests used methane as a marker for biodegradation. (Johnson, Tr. 1566-1567).
1240. The presence of methane means that the test environment is anaerobic. (Johnson, Tr. 1566-1567, 1570).
1241. NE Labs extracted gas from the cylinder through an extraction valve in the test tubing. (Johnson, Tr. 1568-1569).
1242. NE Labs uses a Quantek analyzer to analyze carbon dioxide. (Johnson, Tr. 1569).
1243. NE Labs uses an infrared ("IR") spectrometer to measure methane content. (Johnson, Tr. 1569).

1244. The precision of the IR spectrometer varies depending on the amount of methane detected in the system. (Johnson, Tr. 1586-1587).
1245. The error rate for the IR spectrometer may be as low as 1% or less for higher amounts of methane, but may be as high as 20% for very low amounts of methane recorded. (Johnson, Tr. 1586-1587).
1246. Because NE Labs' test vessels have headspace at the top of the canisters, the canisters contain ambient gases that are not produced from the biological processes in the tests. (Johnson, Tr. 1591-1592).
1247. The ambient gases in the headspace at the top of the canisters are collected in a graduated cylinder so that the gas composition would include a percentage of ambient gas unassociated with the inoculum or biota. (Johnson, Tr. 1591-1592).
1248. The biodegradation process produces carbon dioxide and methane, the presence of the latter in relatively equal proportions to the carbon dioxide is an indication that the test environment is anaerobic (as opposed to aerobic). (Johnson, Tr. 1566-1567; Barlaz, Tr. 2188-2189).
1249. NE Labs uses a standard format for its biodegradation test reports. (Johnson, Tr. 1571). The reports in evidence from NE Labs are in the format of NE Labs' standard reports. (Johnson, Tr. 1571-1572).
1250. NE Labs has performed extension biodegradation testing, in other words, testing over the initial period of time, for certain customers. (Johnson, Tr. 1573).
1251. For longer-term extension testing over 45 days past the planned termination date, NE Labs would assess whether the activity in the triplicate vessels had leveled off. (Johnson, Tr. 1573-1574).
1252. If the activity in the test vessels had leveled off, and the positive control had already been digested, NE Labs would remove the test materials and negative controls from the stale testing environment, and place those materials into a new reactor canister with fresh inoculum. (Johnson, Tr. 1573-1574).
1253. To maintain anaerobic conditions during a long-term extension test, NE Labs would sparge (or flush) the new canisters with nitrogen to remove excess atmospheric gases. (Johnson, Tr. 1573-1574).
1254. When using fresh canisters with fresh inoculum to extend tests, NE Labs would always use fresh inoculum blanks, and often use fresh negative control vessels. (Johnson, Tr. 1574-1575).
1255. Nothing in the record indicates that NE Labs changed canisters during biodegradation testing of ECM Plastics. (Johnson, Tr. 1560-1596).

1256. Nothing in the record indicates that corrosion of canisters occurred in biodegradation testing of ECM Plastics. (Johnson, Tr. 1557-1596).
1257. Nothing in the record indicates that there was leakage in the metal canisters that NE Labs used in biodegradation testing of ECM Plastics. (Johnson, Tr. 1560-1596).
1258. Dr. Barlaz reviewed NE Labs' testing protocol. (Barlaz, Tr. 2276).
1259. NE Labs' use of metal canisters in D5511 testing would not affect the validity of NE Labs' test results. (Barlaz, Tr. 2276).
1260. With respect to NE Labs' use of metal canisters, Dr. Barlaz explained that "you either have a leak in your system or you don't have a leak in your system, and if you don't have a leak in your system, then a metal can should be fine." (Barlaz, Tr. 2276).
1261. The fact that NE Labs was getting methane generation from their positive controls indicates that NE Labs has the ability to make a gas-tight system out of a metal can. (Barlaz, Tr. 2276).
1262. The presence of methane in NE Labs testing proves that the test environment was anaerobic "because oxygen kills methanogens" responsible for producing methane. (Barlaz, Tr. 2277).
1263. NE Labs used weekly gas measurements and would report the data for individual days based on an average from the weekly readings. (RX 873 (Ullmann, Dep. at 61)).
1264. Dr. Sahu had no concerns with NE Labs' methodology or inoculum type or amount. (Sahu, Tr. 1932-1933; RX 855 (Sahu Expert Report at 45-47)).
1265. Dr. Sahu was not concerned with the process of reinoculating the test vessels in long-term D5511 studies. (Sahu, Tr. 1933-1934).
1266. Dr. Sahu was satisfied that the amount of biogas produced in the ECM tests that was in excess of that which could come from the inoculum was sufficient to show that the plastic itself had been rendered biodegradable. (Sahu, Tr. 1934-1935).

i. RX 836, NE Labs N1048340 (PPC Industries, Inc.)

1267. From September 2010 through November 2013, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors, NE Labs N1048340 (PPC Industries, Inc.), marked RX 836. (RX 836).
1268. NE Labs performed the test marked RX 836 on behalf of PPC Industries, Inc. (RX 836 at 1).

1269. The test marked RX 836 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 836; Johnson, Tr. 1571).
1270. The test marked RX 836 included the use of an inoculum blank, a negative control (untreated plastic), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 836 at 2; Johnson, Tr. 1575).
1271. The test marked RX 836 included a plastic amended with 1% ECM Additive. (RX 155; RX 156; RX 157).
1272. The plastic sample in the test marked RX 836 was labeled “EP Flex Renew Green Poly Bags Treated,” and the test involved an untreated “Clear Poly Bag” sample as a negative control. (RX 836 at 2).
1273. NE Labs recorded data for the test marked RX 836 through 900 days. (RX 836 at 126 (10/21/2013 Report)).
1274. In the test marked RX 836, NE Labs recorded biodegradation of the ECM amended sample “EP Flex Renew Green Poly Bags Treated” in the amount of 49.28% after 900 days of anaerobic testing. (RX 836 at 126 (10/21/2013 Report)).
1275. The negative control in the test marked RX 836 revealed just 0.1152% total biodegradation after 900 days of anaerobic biodegradation testing. (RX 836 at 126 (10/21/2013 Report)).
1276. Dr. Barlaz reviewed the raw data provided by NE Labs, including data pertaining to RX 836. (RX 836; RX 968; Barlaz, Tr. 2252-2258).
1277. For the sample “EP Flex Renew Green Poly Bags Treated,” NE Labs reported 4,716 mL of total methane, compared to just 1,854 mL of methane in the inoculum blank. (RX 836; RX 472; RX 968).
1278. The net methane yield between the inoculum and the test vessel in the test marked RX 836 was 2,862.4 mL. (RX 836; RX 472; RX 968).
1279. Dr. Barlaz calculated the mean substrate to inoculum ratio at 2.5 for the test marked RX 836, affirming that the methane content observed in the test vessels was from the test substrate (the plastic). (RX 836; RX 968; Barlaz, Tr. 2247-2249, 2260-2263).
1280. Dr. Barlaz calculated methane and carbon dioxide t-statistics, and determined that the results of the test marked RX 836 were statistically significant. (RX 968; Barlaz, Tr. 2259-2260).
1281. The mass of the test sample in the test marked RX 836 was 20 grams. At 1% by weight, the mass of the ECM Additive in the sample test was approximately 0.2 grams. (RX 836 at 1; RX 968; Barlaz, Tr. 2251-2254).

1282. Based on Dr. Barlaz's calculations from the data from the test marked RX 836, the total theoretical yield of methane from the 1% ECM Additive tested in the test marked RX 836 is 186.6 mL of methane, calculated by multiplying the weight of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive (933 mL). (RX 968; Barlaz, Tr. 2252-2258).
1283. At a net methane yield of 2,862.4 mL, the biodegradation of the test substrate in the test marked RX 836 was more than fifteen times the amount of biodegradation that could have possibly been sourced from the ECM Additive alone. (RX 836; RX 968; Barlaz, Tr. 2252-2258).
1284. Dr. Barlaz also calculated standard deviations for the test marked RX 836, which were within reasonable limits as expressed by the t-statistics. (RX 968; RX 472; Barlaz, Tr. 2264).
1285. Based in part on the test marked RX 836, Dr. Barlaz testified that the scientific evidence showed that plastic containing the ECM Additive anaerobically biodegraded. (RX 968; Barlaz, Tr. 2274).

ii. RX 838, NE Labs 1149980 (MINIGRIPS)

1286. From May 2011 through August 2012, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors, NE Labs 1149980 (MINIGRIPS) Testing, marked RX 838 ("NE Labs Minigrips test") (RX 838).
1287. NE Labs performed the test marked RX 838 on behalf of Minigrips in Kennesaw, GA. (RX 838 at 1).
1288. The test marked RX 838 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 838; Johnson, Tr. 1571).
1289. The test marked RX 838 included the use of an inoculum blank, a negative control (untreated plastic), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 838 at 2; Johnson, Tr. 1575).
1290. The test marked RX 838 included a plastic amended with 1.5% ECM Additive. (RX 838).
1291. The plastic sample in the test marked RX 838 was labeled "#1149980-01 Zip Bags, Green Line LDPE/LLDPE¹⁴ Treated, 1.5% ECM (25 Grams)," and the test involved an untreated control labeled "#1149980-02 Zip Bags, Red Line LDPE/LLDPE Untreated (25 Grams). (RX 838 at 1).

¹⁴ LDPE stands for low density polyethylene. LLDPE stands for linear low density polyethylene. (Sahu, Tr. 1808).

1292. NE Labs recorded data for the test marked RX 838 through 365 days. (RX 838 at 72 (6/4/2012 Report)).
1293. In the test marked RX 838, NE Labs recorded biodegradation of the ECM amended sample “#1149980-01” in the amount of 17.069% after 365 days of anaerobic testing. (RX 838 at 72 (6/4/2012 Report)).
1294. The negative control in the test marked RX 838 revealed just 0.1009% total biodegradation after 365 days of anaerobic biodegradation testing. (RX 838 at 72 (6/4/2012 Report)).
1295. Dr. Barlaz reviewed the raw data provided by NE Labs, including data pertaining to the test marked RX 838. (RX 838; RX 968; Barlaz, Tr. 2252-2258).
1296. For the sample #1149980-01, NE Labs reported 5,197 mL of total methane, compared to just 1,360 mL of methane in the inoculum blank. (RX 838; RX 472; RX 968).
1297. The net methane yield between the inoculum and the test vessel in the test marked RX 838 was 3,837.3 mL. (RX 838; RX 472; RX 968).
1298. Dr. Barlaz calculated the mean substrate to inoculum ratio at 3.8 for the test marked RX 838, affirming that the methane content observed in the test vessels was from the test substrate (the plastic). (RX 838; RX 968; Barlaz, Tr. 2247-2249, 2260-2263).
1299. Dr. Barlaz calculated methane and carbon dioxide t-statistics, and determined that the results of the test marked RX 838 were statistically significant. (RX 472; RX 968; Barlaz, Tr. 2259-2260).
1300. The mass of the test sample in the test marked RX 838 was 25 grams. At 1.5% by weight, the mass of the ECM Additive in the sample test was approximately 0.375 grams. (RX 838 at 1; RX 968; Barlaz, Tr. 2251-2254).
1301. Based on Dr. Barlaz’s calculations from the data from the test marked RX 838, the total theoretical yield of methane from the 1.5% ECM Additive tested in the test marked RX 838 is 349.875 mL of methane, calculated by multiplying the weight of ECM Additive by Dr. Barlaz’s calculation of the mL of methane per gram of ECM Additive (933 mL). (RX 968; Barlaz, Tr. 2252-2258).
1302. At a net methane yield of 3,837.3 mL, the biodegradation of the test plastic in the test marked RX 838 was about eleven times the amount of biodegradation that could have possibly been sourced from the ECM Additive alone. (RX 838; RX 968; Barlaz, Tr. 2252-2258).

1303. Dr. Barlaz also calculated standard deviations for the test marked RX 838, which were within reasonable limits as expressed by the t-statistics. (RX 968; RX 472; Barlaz, Tr. 2264).
1304. Based in part on the test marked RX 838, Dr. Barlaz testified that the scientific evidence showed that plastic containing the ECM Additive anaerobically biodegraded. (RX 968; Barlaz, Tr. 2274).
1305. Along with its RX 838 test, NE Labs also performed an Analytical Report under ASTM D6579 to determine the molecular weight averages and molecular weight distribution of the test sample after completion of the biodegradation test. (RX 838 at 73 (8/1/2012 Report)).
1306. In its August 1, 2012 Analytical Report (RX 838), NE Labs demonstrated that the plastic zip bags treated with the 1.5% ECM Additive had lost molecular weight after biodegradation testing. (RX 838 at 73 (8/1/2012 Report)).
1307. In the test marked RX 838, both the number average and the weight average molecular weights of the 1.5% ECM treated plastic had declined by about 16%, as measured using a different ASTM standard, ASTM D6579, which is a standard for calculating molecular weight averages and molecular weight distribution in the test sample vs. the negative control. (RX 838 at 73 (8/1/2012 Report)).
1308. For comparison, the biodegradation percentage recorded by NE Labs at the end of the RX 838 testing, measured by methane conversion, was listed at about 17%. (RX 838 at 72 (6/4/2012 Report)).
1309. In comments written on NE Labs' certificate of analysis, of the test marked RX 838, NE Labs explained that "change in molecular weight is a measure of bulk deterioration. As an analytical method it indicates that polymer chains are breaking down or cleaving during biodegradation." (RX 838 at 73 (8/1/2012 Report)).
1310. The NE Labs Minigrips test (RX 838) demonstrated about 6% biodegradation based on methane conversion after 30 days of testing, before ultimately continuing to biodegrade to more than 17% after 365 days of testing. (RX 838 at 6 (6/13/2011 Report)).
1311. The 17% biodegradation of the test substrate in the test marked RX 838 was confirmed through molecular weight testing, and far exceeded the amount of biodegradation that could have been sourced from the ECM Additive alone. (RX 838; RX 968; Barlaz, Tr. 2252-2258).
1312. Having reviewed the Minigrips data, Mr. Johnson testified that by the end of the test marked RX 838, there was virtually no activity of any kind occurring in any of the test vessels. (Johnson, Tr. 1589-1590).

iii. RX 398, NE Labs N0946510-01 (Masternet I)

1313. In December 2009, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors, NE Labs N0946510-01 (Masternet I), marked RX 398. (RX 398).
1314. NE Labs performed the test marked RX 398 on behalf of Masternet Ltd. in Mississauga, Ontario, Canada. (RX 398 at 1).
1315. The test marked RX 398 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 398; Johnson, Tr. 1571).
1316. The test marked RX 398 included the use of an inoculum blank, a negative control (untreated plastic, polyethylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 398 at 2; Johnson, Tr. 1575).
1317. The test marked RX 398 included a polyethylene plastic amended with 1% ECM Additive. (RX 398 at 1).
1318. The plastic test sample in the test marked RX 398 had an initial weight of 25 grams. (RX 398 at 2).
1319. NE Labs recorded data for the test marked RX 398 through 15 days. (RX 398 at 4).
1320. In the test marked RX 398, NE Labs recorded biodegradation of the ECM amended polyethylene in the amount of 4.91% after 15 days of anaerobic testing. (RX 398 at 4).
1321. The 4.91% biodegradation within 15 days of anaerobic testing, calculated based on methane conversion, in the test marked RX 398, is more than the 3.65% biodegradation observed in the first 15 days of testing in the NE Labs Minigrips test, marked RX 838. (RX 398 at 4; RX 838 at 6 (6/13/2011 Report)).
1322. Dr. Barlaz reviewed the raw data provided by NE Labs, including data pertaining to the test marked RX 398. (RX 398; RX 472; RX 968; Barlaz, Tr. 2252-2258).
1323. In the test marked RX 398, for the ECM amended plastic, NE Labs reported 2,628 mL of total methane, compared to 1,554 mL of methane in the inoculum blank. (RX 398; RX 472; RX 968).
1324. The net methane yield between the inoculum and the test vessel in the test marked RX 398 was 1,074.3 mL. (RX 398; RX 472; RX 968).
1325. Dr. Barlaz calculated methane and carbon dioxide t-statistics, and determined that the results of the test marked RX 398 were statistically significant. (RX 472; RX 968; Barlaz, Tr. 2259-2260).

1326. The mass of the 1% ECM amended polyethylene sample in the test marked RX 398 was 25 grams. At 1% by weight, the mass of the ECM Additive in the sample test was approximately 0.25 grams. (RX 398 at 1; RX 968; Barlaz, Tr. 2251-2254).
1327. Based on Dr. Barlaz's calculations from the data from the test marked RX 398, the total theoretical yield of methane from the 1% ECM Additive tested in the test marked RX 398 is 233.25 mL of methane, calculated by multiplying the weight of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive (933 mL). (RX 968; Barlaz, Tr. 2252-2258).
1328. At a net methane yield of 1,074.3 mL, the biodegradation of the test plastic in the test marked RX 398 was more than four and one half times the amount of biodegradation that could have possibly been sourced from the ECM Additive alone. (RX 398; RX 968; Barlaz, Tr. 2252-2258).

iv. RX 405, NE Labs 1048742-01 (Eco SmartPlastics I)

1329. In November 2010, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors, NE Labs 1048742-01 (Eco SmartPlastics I), marked RX 405. (RX 405).
1330. NE Labs performed the test marked RX 405 on behalf of Eco SmartPlastics in Bohemia, New York. (RX 405 at 1).
1331. The test marked RX 405 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 405; Johnson, Tr. 1571).
1332. The test marked RX 405 included the use of an inoculum blank, a negative control (untreated plastic, polypropylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 405 at 2; Johnson, Tr. 1575).
1333. The test marked RX 405 included a low-density polyethylene plastic ("LDPE") amended with 1.5% ECM Additive. (RX 405 at 1).
1334. The plastic test sample in the test marked RX 405 had an initial weight of 25 grams. (RX 405 at 1).
1335. NE Labs recorded data for the test marked RX 405 through 45 days. (RX 405 at 3).
1336. In the test marked RX 405, NE Labs recorded biodegradation of the ECM amended low-density polyethylene in the amount of 7.37% after 45 days of anaerobic testing. (RX 405 at 3).
1337. The 7.37% biodegradation within 45 days of anaerobic testing, calculated based on methane conversion, in the test marked RX 405, is roughly equal to the 7.53%

biodegradation observed in the first 45 days of testing in the NE Labs Minigrips test, marked RX 838. (RX 405 at 3; RX 838 at 9 (7/5/2011 Report)).

v. RX 396, NE Labs 1048819 (Eco SmartPlastics II)

1338. In December 2010, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors, NE Labs 1048819 (Eco SmartPlastics II), marked RX 396. (RX 396).
1339. NE Labs performed the test marked RX 396 on behalf of Eco SmartPlastics in Bohemia, New York. (RX 396 at 1).
1340. The test marked RX 396 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 396; Johnson, Tr. 1571).
1341. The test marked RX 396 included the use of an inoculum blank, a negative control (untreated plastic, polypropylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 396 at 1-2; Johnson, Tr. 1575).
1342. The test marked RX 396 included a polyethylene terephthalate (“PET”) plastic amended with the ECM Additive. (RX 396 at 1; CCX 413).
1343. In the test marked RX 396, the plastic test sample had an initial weight of 25 grams. (RX 396 at 1).
1344. The test report does not specify the amount of ECM Additive included in the test plastic in the test marked RX 396. (RX 396).
1345. Eco SmartPlastics used a 1.5% load rate for the ECM Additive in other plastic applications. (RX 405 at 1).
1346. NE Labs recorded data for the test marked RX 396 through 43 days. (RX 396 at 3).
1347. In the test marked RX 396, NE Labs recorded biodegradation of the ECM amended polyethylene in the amount of 7.01% after 45 days of anaerobic testing. (RX 396 at 4).
1348. The 7.01% biodegradation within 45 days of anaerobic testing, calculated based on methane conversion, in the test marked RX 396, is roughly equal to the 7.53% biodegradation observed in the first 45 days of testing in the NE Labs Minigrips test, marked RX 838. (RX 396 at 4; RX 838 at 9 (7/5/2011 Report)).
1349. For the ECM amended plastic in the test marked RX 396, NE Labs reported 3,496 mL of total methane, compared to 1,821 mL of methane in the inoculum blank. (RX 396 at 4).

1350. The net methane yield between the inoculum and the test vessel in the test marked RX 396 was 1,675 mL. (RX 396 at 4).
1351. In the test marked RX 396, even assuming Eco Smartplastics included the ECM Additive in the test PET plastic at an amount as high as 2%, a load rate higher than Eco SmartPlastics previously used, the mass of the sample would have been 0.5 grams. (Barlaz, Tr. 2251-2254).
1352. Based on Dr. Barlaz's calculations from the data from the test marked RX 396, the total theoretical yield of methane from a 2% ECM Additive (0.5 grams) tested in the test marked RX 396 is 466.5 mL of methane, calculated by multiplying the weight of the ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive (933 mL). (RX 968; Barlaz, Tr. 2252-2258).
1353. At a net methane yield of 1,675 mL, the biodegradation of the test plastic in the test marked RX 396 was more than three and one half times the amount of biodegradation that could have possibly been sourced from the ECM Additive alone. (RX 396; RX 968; Barlaz, Tr. 2252-2258).

vi. RX 395, NE Labs 1150851 (Sweet Tape Enterprise)

1354. In September 2011, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors, NE Labs 1150851 (Sweet Tape Enterprise, marked RX 395). (RX 395).
1355. NE Labs performed the test marked RX 395, on behalf of Sweet Tape Enterprise (M) Sdn. Bhd., in Malaysia. (RX 395 at 1).
1356. The test marked RX 395 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 395; Johnson, Tr. 1571).
1357. The test marked RX 395 included the use of an inoculum blank, a negative control (untreated plastic, polyethylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 395 at 1-2; Johnson, Tr. 1575).
1358. The test marked RX 395 included a polypropylene ("PP") clear tape plastic amended with the ECM Additive. (RX 395 at 1; CCX 413).
1359. In the test marked RX 395, the plastic test sample had an initial weight of 25 grams. (RX 395 at 1).
1360. The test report for the test marked RX 395 does not specify the amount of ECM Additive included in the test plastic. (RX 395).
1361. NE Labs recorded data for the test marked RX 395 through 45 days. (RX 395 at 3).

1362. In the test marked RX 395, NE Labs recorded biodegradation of the ECM amended PP sample in the amount of 4.54% after 45 days of anaerobic testing. (RX 395 at 3).

vii. RX 394, NE Labs 1150851 (Tycoplas Sdn. Bhd.)

1363. In October 2011, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors, NE Labs 1150851 (Tycoplas Sdn. Bhd.), marked RX 394. (RX 394).

1364. NE Labs performed the test marked RX 394 on behalf of Tycoplas Sdn. Bhd. (RX 394 at 1).

1365. The test marked RX 394 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 394; Johnson, Tr. 1571).

1366. The test marked RX 394 included the use of an inoculum blank, a negative control (untreated polyethylene), a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 394 at 1; Johnson, Tr. 1575).

1367. The test marked RX 394 included a plastic amended with the ECM Additive. (RX 394).

1368. In the test marked RX 394, the plastic sample was labeled PS Foam Lunch Boxes with ECM Additive. (RX 394 at 1).

1369. NE Labs recorded data for the test marked RX 394 through 15 days. (RX 394 at 3).

1370. In the test marked RX 394, NE Labs recorded biodegradation of the ECM amended polystyrene sample in the amount of 5.89% after 15 days of anaerobic testing. (RX 394 at 3).

1371. Dr. Barlaz reviewed the raw data provided by NE Labs, including data pertaining to the test marked RX 394. (RX 394; RX 968; Barlaz, Tr. 2252-2258).

1372. For the test PS sample in the test marked RX 394, NE Labs reported 1,962 mL of total methane, compared to just 621 mL of methane in the inoculum blank. (RX 394 at 3; RX 472; RX 968).

1373. The net methane yield between the inoculum and the test vessel in the test marked RX 394 was 1,340.6 mL. (RX 394; RX 472; RX 968).

1374. Dr. Barlaz calculated the mean substrate to inoculum ratio at 3.2 for the test marked RX 394, affirming that the methane content observed in the test vessels was from the test substrate (the plastic). (RX 394; RX 968; Barlaz, Tr. 2247-2249, 2260-2263).

1375. Dr. Barlaz calculated methane and carbon dioxide t-statistics, and determined that the results in the test marked RX 394 were statistically significant. (RX 472; RX 968; Barlaz, Tr. 2259-2260).
1376. The mass of the test sample in the test marked RX 394 was 25 grams. The test report (RX 394) does not specify the load rate of the ECM Additive in the test polystyrene product. (RX 394 at 1, 3).
1377. In the test marked RX 394, even assuming the ECM Additive was included at a 2% load rating, an amount higher than the 1.0-1.5% customers ordinarily use, the mass of the ECM Additive would be 0.5 grams. (RX 394 at 3; RX 968; Barlaz, Tr. 2251-2254).
1378. Based on Dr. Barlaz's calculations from the data from the test marked RX 394, the total theoretical yield of methane from 0.5 grams of the ECM Additive is 466.5 mL of methane, calculated by multiplying the weight of ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive (933 mL). (RX 968; Barlaz, Tr. 2252-2258).
1379. At a net methane yield of 1,340.6 mL, the biodegradation of the test plastic in the test marked RX 394 was about three times the amount of biodegradation that could have possibly been sourced from the ECM Additive alone. (RX 394; RX 968; Barlaz, Tr. 2252-2258).
1380. Dr. Barlaz also calculated standard deviations for the test marked RX 394, which were within reasonable limits as expressed by the t-statistics. (RX 968; RX 472; Barlaz, Tr. 2264).
1381. Based in part on the test marked RX 394, Dr. Barlaz testified that the scientific evidence showed that plastic containing the ECM Additive anaerobically biodegraded. (RX 968; Barlaz, Tr. 2274).
1382. Whereas the NE Labs Minigrips test, marked RX 838, demonstrated about 6% biodegradation based on methane conversion after 30 days of testing, before ultimately continuing to biodegrade to more than 17% after 365 days of testing, the NE Labs Tycoplas test, marked RX 394, exhibited nearly 6% biodegradation in roughly half the time. (RX 394). (RX 394; RX 838 at 6 (6/13/2011 Report)).

viii. RX 393, NE Labs 1253020 (National Tree Co.)

1383. In April 2012, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors, NE Labs 1253020 (National Tree Co.), marked RX 393. (RX 393).
1384. NE Labs performed the test marked RX 393 on behalf of National Tree Co. in Cranford, New Jersey. (RX 393 at 1).

1385. The test marked RX 393 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 393; Johnson, Tr. 1571).
1386. The test marked RX 393 included the use of inoculum blanks, negative controls (untreated plastic, PVC and PE), a positive control (cellulose), and two test samples, all of which were run in triplicate. (RX 393 at 1-2; Johnson, Tr. 1575).
1387. The test marked RX 393 included two test samples amended with the ECM Additive. (RX 393 at 1-2).
1388. In the test marked RX 393, one test sample was “PVC, Treated,” the other test sample was “PE, Treated.” (RX 393 at 2).
1389. Both test samples were 25 grams at the start of testing in the test marked RX 393. (RX 393 at 2).
1390. In the test marked RX 393, the negative controls involved untreated plastics, “PVC, Untreated” and “PE, Untreated.” (RX 393 at 2).
1391. NE Labs recorded data for the test marked RX 393 through 15 days of anaerobic testing. (RX 393 at 4).
1392. In the test marked RX 393, NE Labs recorded biodegradation of the ECM amended PVC sample in the amount of 9.89% after 15 days of anaerobic testing. (RX 393 at 4).
1393. In the test marked RX 393, NE Labs recorded biodegradation of the ECM amended PE sample in the amount of 5.75% after 15 days of anaerobic testing. (RX 393 at 4).
1394. For the ECM amended PVC sample in the test marked RX 393, NE Labs reported 1119 mL of total methane, compared to 254 mL of methane in the inoculum blank. (RX 393 at 4).
1395. The net methane yield between the inoculum and the treated PVC sample in the test marked RX 393 was 865 mL. (RX 393 at 4).
1396. For the amended PE sample in the test marked RX 393, NE Labs reported 1451 mL of total methane, compared to 254 mL of methane in the inoculum blank. (RX 393 at 4).
1397. The net methane production in the PE treated sample in the test marked RX 393 was 1,197 mL of methane gas. (RX 393 at 4).
1398. In the test marked RX 393, the negative controls for PVC and PE reported 238 mL and 219 mL of methane respectively, which is consistent with the 254 mL of methane produced in the inoculum blank. (RX 393 at 4).

1399. The test report (RX 393) does not specify the amount of ECM Additive included in the test plastic in the test marked RX 393. (RX 393).
1400. In the test marked RX 393, even assuming National Tree Co. included the ECM Additive in the test plastics at an amount as high as 2%, a load rate higher than ECM recommended and higher than other customers ordinarily used, the mass of the ECM Additive in the samples would have been 0.5 grams. (Barlaz, Tr. 2251-2254).
1401. Based on Dr. Barlaz's calculations from the data from the test marked RX 393, the total theoretical yield of methane from 0.5 grams of the ECM Additive is 466.5 mL of methane, calculated by multiplying the weight of the ECM Additive by Dr. Barlaz's calculation of the mL of methane per gram of ECM Additive (933 mL). (RX 968; Barlaz, Tr. 2252-2258).
1402. At a net methane yield of 865 mL, the biodegradation of the treated PVC plastic in the test marked RX 393 was almost twice the amount of biodegradation that could have possibly been sourced from the ECM Additive alone. (RX 393; RX 968; Barlaz, Tr. 2252-2258).
1403. Similarly, at a net methane yield of 1,197 mL, the biodegradation of the treated PE plastic sample in the test marked RX 393 was more than two and one half the amount of biodegradation that could have possibly been sourced from the ECM Additive alone. (RX 393; RX 968; Barlaz, Tr. 2252-2258).

ix. RX 392, NE Labs 1048036 (Transilwrap Co.)

1404. In April 2011, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors, NE Labs 1048036 (Transilwrap Co.), marked RX 392. (RX 392).
1405. NE Labs performed the test marked RX 392 on behalf of Transilwrap Co. in Richmond, Indiana. (RX 392 at 1).
1406. In the test marked RX 392 is an NE Labs analytical report of the type normally supplied by NE Labs. (RX 392; Johnson, Tr. 1571).
1407. The test marked RX 392 included the use of inoculum blanks, negative controls (polyethylene), a positive control (cellulose), and two test samples, all of which were run in triplicate. (RX 392 at 1-2; Johnson, Tr. 1575).
1408. The test marked RX 392 included two test samples amended with the ECM Additive. (RX 392 at 1-2).
1409. One test sample in the test marked RX 392 was a Thin HIPS ("High Impact Polystyrene") Based Sheet; the other test sample was a "Two Layer Laminating Film." Both test samples were 25 grams at the start of testing. (RX 392 at 1; CCX 273).

- 1410. Transilwrap described the samples in the test marked RX 392 as a “HIPS sheet allow with the ECM Additive, and a thin film PETG coated with EVA (also both having [the ECM] additive).” (CCX 273 at 3).
- 1411. NE Labs recorded data for the test marked RX 392 through 233 days of anaerobic testing. (RX 392 at 4).
- 1412. In the test marked RX 392, NE Labs recorded biodegradation of the ECM amended HIPS polystyrene sample in the amount of 7.85% after 233 days of anaerobic testing. (RX 392 at 4).
- 1413. In the test marked RX 392, NE Labs recorded biodegradation of the ECM amended Two Layer Laminating Film sample in the amount of 8.53% after 233 days of anaerobic testing. (RX 392 at 4).
- 1414. The test report (RX 392) does not specify the amount of ECM Additive included in the test plastic in the test marked RX 392. (RX 392).

x. RX 399, NE Labs N0843980 (Bio-Tec Environmental, LLC)

- 1415. In December 2008, NE Labs reported biodegradation test data from an anaerobic D5511 biodegradation test in laboratory reactors, NE Labs N0843980 (Bio-Tec Environmental), marked RX 399. (RX 399).
- 1416. NE Labs performed the test marked RX 399 on behalf of Bio-Tec Environmental, LLC in Albuquerque, New Mexico. (RX 399 at 1).
- 1417. The test marked RX 399 is an NE Labs analytical report similar to the type ordinarily supplied by NE Labs. (RX 399; Johnson, Tr. 1571).
- 1418. The test marked RX 399 included the use of an inoculum blank, a negative control, a positive control (cellulose), and a test sample, all of which were run in triplicate. (RX 399 at 1-2; Johnson, Tr. 1575).
- 1419. The test marked RX 399 included a polypropylene plastic sheet amended with the ECM Additive. (RX 399 at 1; CCX 413).
- 1420. In the test marked RX 399, the plastic test sample had an initial weight of 100 grams. (RX 399 at 1).
- 1421. The test report (RX 399) does not specify the amount of ECM Additive included in the test plastic in the test marked RX 399. (RX 399).
- 1422. In the test marked RX 399, NE Labs recorded data through 14 days. (RX 399 at 2).

1423. In the test marked RX 399, one of the earlier NE Labs biodegradation tests, NE Labs used two endpoints to assess biodegradation, methane gas conversion and gravimetric weight loss. (RX 399 at 2).
1424. Although gas data was not available, NE Labs concluded in the test marked RX 399 that, based on the average weight loss of the triplicate test samples and the methane gas conversion, the “results indicate[d] that the treated PP Sheets was biodegradable.” (RX 399 at 2).

c. Anaerobic testing by North Carolina State University

1425. In his research program at North Carolina State University, Dr. Barlaz has conducted numerous tests on the biodegradation of various components of MSW. (Barlaz, Tr. 2071).
1426. Dr. Barlaz performs commercial BMP testing (F. 750) in his lab for interested companies. (Barlaz, Tr. 2265).
1427. Dr. Barlaz’s experience with BMP testing is primarily with cellulosic material, which means that the majority of his testing has involved MSW testing, and cellulose is a major biodegradable component of same. (Barlaz, Tr. 2266).
1428. Dr. Barlaz’s BMP tests are performed in a completely liquid environment. (Barlaz, Tr. 2222-2223).
1429. Dr. Barlaz’s BMP tests are performed at 37 degrees Celsius. (RX 853 (Barlaz Expert Report at 8)).
1430. Dr. Barlaz’s BMP studies have been conducted mostly up to 60 days in duration. (Barlaz, Tr. 2267).
1431. With respect to slowly degrading materials, the BMP test that Dr. Barlaz runs is likely not representative of the total biodegradation expected from the material, and thus it is quite possible that the material would have continued to biodegrade after Dr. Barlaz terminated his test. (Barlaz, Tr. 2267-2268).
1432. If the experimental goal of the test is to capture the maximum methane yield of a test substrate, then a 60-day test is too short to accomplish that objective. (Barlaz, Tr. 2267-2268).
1433. Dr. Barlaz conducted four biodegradation tests of ECM Plastics using the BMP test in his laboratory at North Carolina State University. (CCX 946; CCX 951; CCX 952; CCX 954; Barlaz, Tr. 2306-2320).

1434. The results of Dr. Barlaz's BMP test of ECM Plastics, marked CCX 951, showed no methane production. (CCX 951).
1435. The results of Dr. Barlaz's BMP tests of ECM Plastics, marked CCX 946 and CCX 954, showed negligible amounts of methane production. (CCX 946; CCX 954).
1436. The results of Dr. Barlaz's BMP test of ECM Plastics, marked CCX 952, showed significant and continuing biodegradation. (Barlaz, Tr. 2269-2274). These results are discussed further in F. 1437-1447.

i. CCX 952, NC State 2010 StarchTech BMP

1437. In March 2010, Dr. Barlaz reported results from a BMP test that he performed on behalf of StarchTech involving recycled polystyrene loosefill peanuts with the ECM Additive, NC State 2010 StarchTech BMP Testing, marked CCX 952. (CCX 952).
1438. In the test marked CCX 952, Dr. Barlaz performed his BMP test as he did other BMP tests performed at his North Carolina State University laboratory. (Barlaz, Tr. 2220-2222, 2269-2272).
1439. In the test marked CCX 952, Dr. Barlaz tested two materials, a recycled polystyrene loosefill plastic with the ECM Additive, and a starch-based biodegradable loosefill product. (Barlaz, Tr. 2270).
1440. Dr. Barlaz's results in the test marked CCX 952 showed significant methane generation that was attributed to the test substrate, *i.e.*, the plastic. (Barlaz, Tr. 2270; CCX 952).
1441. In the test marked CCX 952, Dr. Barlaz calculated the percent that each material was converted to methane, subtracting the methane produced from the inoculum blanks. (Barlaz, Tr. 2270-2271; CCX 952).
1442. In the test marked CCX 952, Dr. Barlaz calculated the percentage of biodegradation by examining the percent loss of volatile solids, which was 7.4% of the ECM-amended polystyrene loosefill product in 60 days. (CCX 952; Barlaz, Tr. 2271).
1443. In the test marked CCX 952, although Dr. Barlaz terminated his BMP test on day 60, he observed that the short term, laboratory-scale biodegradation test was not an accurate representation of the biodegradation potential of the sample. (Barlaz, Tr. 2271-2274).
1444. Dr. Barlaz's test report of the test marked CCX 952 included methane production data at day 30 and day 60. Dr. Barlaz explained that "the methane generation on day 60 is double that of the methane generation on day 30, so there – the implication is that the measured methane is a lower limit and more methane would have been produced had we run the test for longer than 60 days." (CCX 952 at 2; Barlaz, Tr. 2271).

1445. In the test marked CCX 952, the fact that methane generated during days 31-60 was equal to or more than methane generated on days 1-30 was scientifically significant because it demonstrates that the test sample was likely to evidence more biodegradation than the 60-day BMP test would suggest. (Barlaz, Tr. 2271-2272).
1446. In the test marked CCX 952, according to Dr. Barlaz, there was “no evidence that methane generation is slowing down, whereas, if you look at the second material [starch-based product,] there’s considerable evidence that methane generation is slowing down.” (Barlaz, Tr. 2271-2272).
1447. Regarding the test marked CCX 952, Dr. Barlaz has concluded that this observed phenomena “speaks to the BMP as I’ve been using it with cutting it off at 60 days is perhaps imperfect or not appropriate if I have a slowly degradable substrate.” (Barlaz, Tr. 2272).

d. Other anaerobic gas evolution testing

i. RX 265, OWS Microtech Research Inc. (Feb. 1999)

1448. In February 1999, Organic Waste Systems Inc. (“OWS”) reported the results of anaerobic testing on the ECM additive pellets, OWS Microtech Research Inc. Anaerobic Testing, marked RX 265. (RX 265 at 6).
1449. In the test marked RX 265, OWS performed the test titled, “High Solids Anaerobic Digestion (HSAD) Test of ECM pellets,” on behalf of Patrick F. Riley of Microtech Research. (RX 265).
1450. The OWS test marked RX 265 was performed under the ASTM D5511-94 method. (RX 265).
1451. In the OWS test marked RX 265, the substance tested was the ECM pellets by themselves. (RX 265).
1452. At the time of the test marked RX 265, in 1999, the ECM pellets were comprised of approximately 50% active biodegradable components, and 50% of a traditionally non-biodegradable carrier resin. (CCX 818 (Sinclair, Dep. at 116)).
1453. ECM later changed its load rating to a 70% load of the actively biodegradable components. (CCX 818 (Sinclair, Dep. at 118-120)).
1454. In the test marked RX 265, OWS measured total gas volume using a graduated cylinder. (RX 265 at 8).
1455. The OWS test marked RX 265 was conducted at a 34.1% solids content (63.9% moisture). (RX 265 at 12).

1456. In the test marked RX 265, after 15 days, the ECM pellets anaerobically biodegraded 24%. (RX 265 at 17).

1457. The test marked RX 265 was terminated after 15 days. (RX 265).

ii. RX 268, OWS Covidien (May 2010)

1458. In May 2010, OWS reported the results of anaerobic testing on polypropylene (“PP”) product labeled “polypropylene plaques” in the OWS Covidien Anaerobic Testing, marked RX 268.¹⁵ (RX 268 at 6).

1459. In the OWS test, marked RX 268, OWS performed the test titled, “High Solids Anaerobic Digestion (HSAD) Test,” on behalf of Covidien in Mansfield, MA. (RX 268 at 1).

1460. The OWS test, marked RX 268, was performed under the ASTM D5511-02 method. (RX 268 at 3).

1461. In the OWS test, marked RX 268, the positive control, cellulose, reached a plateau at 69.5%. (RX 268 at 4).

1462. In the OWS test, marked RX 268, the failure to achieve 70% biodegradation in the positive control is an indication that the test environment was not suitable for biodegradation testing. (*See* RX 356 at 3 § 11.2.1.1).

1463. The OWS test, marked RX 268, revealed 3.9% biodegradation of the test sample in 15 days of anaerobic degradation. (RX 268 at 7).

1464. The test marked RX 268 indicated that the sample vessels plateaued around the same time as the cellulose vessels plateaued at 69.5%. (RX 268 at 5-7).

1465. In another OWS test performed for Microtech Research Inc. in 1999, the test marked RX 265, OWS wrote that cellulose should biodegrade at least to 85% through gas evolution, while at most 15% of the cellulose can be assimilated by microorganisms or left as other byproduct. (RX 265 at 16-17).

iii. CCX 164, Dr. Michel’s study

1466. Dr. Michel co-authored a study titled, “*Biodegradation of Conventional and Bio-Based Plastics and Natural Fiber Composites During Composting, Anaerobic Digestion and Long-Term Soil Incubation,*” *Journal of Polymer Degradation & Stability* 98 (2013) 2583-2591 (“Dr. Michel’s study”). (Michel, Tr. 2903-2904; CCX 164).

1467. Myers Industries (“Myers”) funded, in part, Dr. Michel’s study, marked CCX 164. (Michel, Tr. 2941).

¹⁵ The OWS Covidien Anaerobic Testing (May 2010) was entered into evidence as both CCX 157 and RX 268.

1468. In Dr. Michel's study, marked CCX 164, Dr. Michel assessed the anaerobic biodegradability of a wide range of commercially available materials used to manufacture plastic products. (Michel, Tr. 2904; CCX 164).
1469. In order to measure the anaerobic biodegradation of plastics infused with the ECM Additive, Dr. Michel's study, marked CCX 164, ran a soil test lasting over two years and a protocol similar to that described in ASTM D5511-02. (Michel, Tr. 2904-2905; CCX 164).
1470. In testing for anaerobic biodegradation of ECM Plastics in his peer-reviewed study, marked CCX 164, Dr. Michel did not use C-14 radiolabeling testing, *in situ* testing, or lysimeter testing. (Michel, Tr. 2906-2907; CCX 164).
1471. For Dr. Michel's study identified as CCX 164, Myers prepared the two sample materials said to contain the ECM Additive. (Michel, Tr. 2925; CCX 164).
1472. Dr. Michel does not have a certificate of ingredients regarding the samples provided to him by Myers for the study marked CCX 164. (Michel, Tr. 2933).
1473. Other than stating that the samples containing the ECM Additive were produced by injection molding, Dr. Michel's study, marked CCX 164, does not indicate the conditions for the injection molding and does not identify the particular processing conditions that were used in the injection molding of the blends containing the ECM Additive. (Michel, Tr. 2926-2927; CCX 164).
1474. Dr. Michel did not contact ECM directly and did no testing of the plastics to ensure that Myers had properly manufactured the plastics purportedly containing the ECM Additive for the study marked CCX 164. (Michel, Tr. 2935-2936).
1475. Dr. Michel performed no tests on the samples in the study marked CCX 164 to determine whether any ingredient in the plastic had an adverse effect on microbial life forms in the test environment. (Michel, Tr. 2938).
1476. Dr. Michel conducted no investigation of the inoculum used in the study marked CCX 164 to determine if the inoculum remained viable halfway through the test. (Michel, Tr. 2961-2962).
1477. Both Dr. Michel's study, marked CCX 164, and his expert rebuttal report fail to inform the reader as to the molecular weight or the level of crystallinity of the polypropylene or of the polystyrene employed in the study. (Michel, Tr. 2962-2963; CCX 164; CCX 895 (Michel Rebuttal Expert Report)).
1478. Dr. Michel's study, marked CCX 164, reveals no investigation to determine which kinds of bacteria were alive within the test environment at the conclusion of the study. (Michel, Tr. 2963).

1479. Myers first paid Dr. Michel to conduct a study in 2008 or 2009 and has paid Dr. Michel approximately \$40,000 to \$50,000 for his work. (Michel, Tr. 2928-2929).
1480. Dr. Michel is aware, and has been aware since he first started doing work for Myers, that Myers sells nursery pots made out of natural fibers, and that Myers probably markets those pots as compostable or biodegradable. (Michel, Tr. 2931-2932).
1481. The composting industry generally, and compostable plastics specifically, directly compete with ECM and other companies within the biodegradable plastics industry. (Sullivan, Tr. 696-697; Sinclair, Tr. 775-777).
1482. Dr. Michel is aware of the ethical standards that apply to peer-reviewed journal publications in his field. (Michel, Tr. 2939).
1483. Dr. Michel submitted his article, marked CCX 164, to Elsevier, Inc. (“Elsevier”) for peer-review publication. When he did so, Dr. Michel submitted only the article itself, and no other documentation such as the underlying data upon which the study was based. Dr. Michel’s article does not report the methane levels, the percentages of total gas composition, or triplicate data. (Michel, Tr. 2940; CCX 164).
1484. Elsevier based its decision to publish Dr. Michel’s study solely on the text of the article and no underlying data. The data underlying this study, marked CCX 164, was not the subject of peer review. (Michel, Tr. 2940).
1485. Dr. Michel did not disclose to Elsevier that Myers funded his study, marked CCX 164. (Michel, Tr. 2942).
1486. Dr. Michel did not disclose the fact that Mr. Eddie Gomez, a co-author of Dr. Michel’s article, marked CCX 164, was financially supported mostly by Myers’ contributions to Ohio State University. (Michel, Tr. 2942; CCX 164).
1487. Under an agreement between Dr. Michel, Mr. Gomez, and Myers, Dr. Michel could disseminate data obtained and used in CCX 164 only after revision by Myers. (Michel, Tr. 2943-2944; RX 223 at 15).
1488. Dr. Michel did not disclose to Elsevier the fact that dissemination of the data (described in F. 1487), which was funded by Myers, could only occur after revision by Myers. (Michel, Tr. 2944).
1489. Although Dr. Michel testified that Myers did not approve his article later marked CCX 164 before Dr. Michel sent it to Elsevier, Mr. Gomez sent Dr. Michel’s article directly to Myers for approval before sending it to Elsevier. (Michel, Tr. 2945-2947; RX 244).

1490. Dr. Michel did not disclose the fact that Myers approved the article, marked CCX 164, before submitting it for peer review to either Elsevier or in the article itself. (Michel, Tr. 2947).
1491. Mr. Tarang Shah was an employee for Myers at the time Dr. Michel conducted his studies for his article marked CCX 164. (Michel, Tr. 2946-2948).
1492. Mr. Gomez asked Mr. Shah whether he had any suggestions for conducting the research for Dr. Michel's article marked CCX 164. (Michel, Tr. 2948).
1493. Dr. Michel did not disclose to Elsevier, or in the article itself, the fact that Mr. Gomez asked an employee of Myers for suggestions regarding the article marked CCX 164. (Michel, Tr. 2948).
1494. Dr. Michel did not disclose to Elsevier, or in the article itself, the fact that an employee of Myers worked with Mr. Gomez and Dr. Michel on the article marked CCX 164. (Michel, Tr. 2948).
1495. Elsevier's conflicts of interest policy requires that all funding sources be declared. (Michel, Tr. 2951-2952).
1496. Dr. Michel is aware that reputable peer-review publishers, like Elsevier, require disclosures of conflicts of interest. (Michel, Tr. 2950).

F. MATERIALITY

1497. ECM's claims that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years and that that tests prove such claim, were material to ECM Customers, and customers of ECM's Customers. (F. 1498-1502, 1510, 1512; *see also* F. 245-247, 280, 286, 292-293, 300).
1498. ECM's claim that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years was expressly made. (CCX 3; *see also* CCX 5; CCX 6; CCX 7 at 6; CCX 10, CCX 11; CCX 19 at 5; CCX 24 at 6; CCX 25 at 104, 117, 203, 208; CCX 259A; *see also* CCX 809 (Flexible, Dep. at 20); *see also* CCX 822 (ANS, Dep. at 13); CCX 812 (Kappus, Dep. at 14); F. 245-247).
1499. ECM's claim that tests prove ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years, while not an express statement, was clear and conspicuous based on the overall net impression of the marketing materials upon which the claim appeared. (CCX 5; CCX 6; CCX 10; CCX 11; *see* F. 265).
1500. ECM's claims that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years, and that tests prove such claim, pertain to the central characteristics of the ECM Additive. (F. 245-246, 265, 1498)

1501. ECM reiterated its claim that independent tests proved its additive caused ECM Plastics to fully biodegrade in 9 months to 5 years in a landfill in its communications with Customers. (CCX 266; CCX 270 at 2; CCX 277 at 4; CCX 281; CCX 296 at 2; CCX 298; CCX 300; CCX 302; CCX 303; CCX 332; CCX 333; CCX 334; CCX 335; CCX 336; CCX 337; CCX 338; CCX 404 at 2).
1502. ECM Customers asked questions about the claim that ECM Plastics would biodegrade in 9 months to 5 years. (CCX 423 at 9 (customer wanting to know if complete biodegradation can be stated to happen by 5 years); CCX 300 at 1 (“Does ECM test, or recommend testing, the end-users’ products to ensure that they biodegrade in less than 5 years?”); CCX 269 at 1 (“What determines 9 months vs 5 years as it is such a variance?”); CCX 400 at 4 (asking ECM precisely how much additive it needed to use in its products “to meet your stated degradation timeline of 9 months to 5 years”).
1503. ECM’s Customers are motivated to produce biodegradable plastics to meet what they perceived to be their customers’ demand for such products. (CCX 809 (Flexible, Dep. at 72) (“There is a lot of backlash against plastic bags. A lot of people don’t like plastic bags.”); CCX 800 (BER, Dep. at 18) (“[Customers] were looking for a product they could mark as degradable to say that they were being, you know, environmentally sensitive. It’s very important in their packaging, that they could . . . print it right on the package, you know, biodegradable.”); CCX 822 (ANS, Dep. at 13) (“People . . . don’t want to pollute the environment and this [biodegradable plastics] is what they choose to buy.”)).
1504. ANS Plastics (“ANS”), an ECM Customer, believes its customers, such as health stores, are interested in purchasing biodegradable plastics because they want to be “green,” and that people do not want to pollute the environment. (CCX 822 (ANS, Dep. at 13)).
1505. Flexible Plastics, an ECM Customer, became interested in the ECM Additive because its customers wanted environmentally friendly alternative for plastic bags that were feasible economically, and corn-based bags were too expensive for its customers to sell. (CCX 809 (Flexible, Dep. at 14-16)).
1506. Quest Plastics (“Quest”), an ECM Customer, purchased the ECM Additive to serve its customer, Technical Sourcing Solutions, which wanted to manufacture biodegradable golf tees. Quest found that other additives were not appropriate for the reprocessed styrene the customer wanted, and, also, because other additives were cost prohibitive. (CCX 817 (Quest, Dep. at 19, 22, 25-26)).
1507. In response to Question 2 of the Stewart survey, 71% of the respondents answered yes to the question, “is the fact that a product or package is biodegradable important to you.” Although a sizable minority of respondents, 29%, responded that the fact that a product or package is biodegradable is not important to them. (RX 856 (Stewart Expert Report at 24)).
1508. ANS received ECM’s literature and certificate, including a flyer, which included the statement “fully biodegrade in 9 months to five years . . . in a landfill.” ANS believed

that ECM Plastics would biodegrade “[a]nywhere between nine months to five years that they claim it is.” (CCX 822 (ANS, Dep. at 13, 19)).

1509. Flexible Plastics believed that ECM Plastics would biodegrade in 9 months to 5 years. Flexible Plastics believed that the change in ECM’s rate language to “some period greater than a year” was due to changes in the FTC’s advertising guidelines, not to changes in the ECM Additive. (CCX 809 (Flexible Plastics, Dep. at 28-29); *see also* CCX 800 (BER, Dep. at 33 (“Q. During that time [approximately 2009 to the beginning of 2014], BER understood that plastic treated with the ECM additive should biodegrade in nine months to five years? A. Yes.”))).
1510. Down-to-Earth Organic and Natural (“DTE”), a customer of Island Plastic Bags (“IPB”), an ECM Customer, chose to include the 9 Months to 5 Years Claim and related information, as reflected in CCX 44 and 45, on its grocery bags (F. 293, 297-299) because the technology was new and DTE’s customers are well informed. DTE wanted to explain why it could make the claim that the bag was biodegradable. DTE also wanted to demonstrate that DTE was doing its part to help the environment. (CCX 803 (DTE, Dep. at 41-43)).
1511. When discussing biodegradation of plastic containing the ECM Additive with Eagle Film Extruders (“Eagle Film”), an ECM Customer, Mr. Sinclair did not discuss any specific time frame regarding how long it takes ECM amended plastics to biodegrade, although Eagle was aware of a claim of biodegradation in 9 months to 5 years in ECM’s information. (CCX 804 (Eagle Film, Dep. at 17-18)).
1512. Free-Flow Packaging (“FP”), an ECM Customer, conveyed to its potential customers that its “CELL-O air cushions will decompose completely within 9 to 60 months in the presence of microorganisms whether they are sent to a landfill or end up as litter in the soil” because “[i]t was important to convey a message of biodegradability. . . .” (CCX 810 (FP, Dep. at 24-25); *see also* CCX 565 (FP International advertisement stating “We care about the environment” and that FP’s Super 8 brand polystyrene loosefill was, among other things, “biodegradable within 9 to 60 months in the presence of microorganisms when present in a landfill or in soil.”))).
1513. ANS does not have anyone on staff that is a materials scientist or environmental scientist, or that is an expert on biodegradability, landfills, or disposal conditions for plastics. ANS does not have an in-house laboratory and did not hire any laboratory to test the biodegradability of ECM Plastics. (CCX 822 (ANS, Dep. at 14-16)).
1514. Mr. Ringley and Mr. Ewasko of BER Plastics (“BER”), an ECM Customer, were the BER employees involved in the decision whether to buy the ECM Additive. Neither of these individuals, or others on the staff of BER, is a polymer, material, or environmental scientist. Neither of these individuals, or others on the staff of BER, is an expert in biodegradability of plastics, disposal conditions for plastics, or landfills. (CCX 800 (BER Dep. at 21-22)).

1515. BER does not have laboratory facilities capable of conducting biodegradability testing, and does not perform any such testing in-house. BER did not hire any outside laboratory to do any testing on the ECM Additive. (CCX 800 (BER Dep. at 23)).
1516. BER reviewed the testing reports provided by ECM, but did not conduct any analysis of the testing or hire anyone else to conduct such analysis. (CCX 800 (BER Dep. at 23-24)).
1517. BER does not have in-house legal counsel, or outside legal counsel, that reviews advertising claims. (CCX 800 (BER Dep. at 25-26)).
1518. IPB, an ECM Customer, has no employees with education or expertise in polymer science, material science, environmental engineering or science, municipal solid waste management, the biodegradability of plastic, and has not engaged outside consultants with expertise in such areas. (CCX 811 (IPB, Dep. at 34-38)).
1519. DTE has never employed anyone with education or expertise in polymer science, material science, environmental engineering or science, municipal solid waste management, the biodegradability of plastic, or engaged outside consultants with expertise in such areas. (CCX 803 (DTE, Dep. at 13-19)).
1520. Flexible Plastics does not employ any polymer scientists, materials scientists, environmental scientists, or any experts in the biodegradability of plastics, disposal conditions for plastics, or landfills, nor has Flexible Plastics consulted with anyone on such matters. Flexible Plastics does not consider itself to have expertise on the biodegradability of plastics, disposal conditions for plastic or landfills. (CCX 809 (Flexible, Dep. at 35-37)).
1521. Flexible Plastics did not conduct any testing regarding the biodegradability of plastics made with the ECM Additive. Flexible Plastics does not have the equipment to conduct such testing, and would have had to outsource such testing. (CCX 809 (Flexible, Dep. at 37)).
1522. Kappus Plastic (“Kappus”), an ECM Customer, did not have any one involved in the decision to buy the ECM Additive that was a polymer scientist, material scientist, or environmental scientist, or an expert in the biodegradability of plastics, disposal conditions for plastic, or landfills. During the period that Kappus purchased the ECM Additive, Kappus did not have on staff any polymer scientists, material scientists, environmental scientists, or any experts on the biodegradability of plastics, disposal conditions for plastic, or landfills, and Kappus did not consult with anyone on these topics. (CCX 812 (Kappus, Dep. at 18-21)).
1523. Kappus does not have in-house legal counsel or outside counsel that reviews advertising claims. (CCX 812 (Kappus, Dep. at 43)).

1524. Kappus has a limited laboratory that does not do any testing related to the biodegradability of plastics. (CCX 812 (Kappus, Dep. at 43-44)).
1525. No one on Kappus' staff evaluated the testing that ECM provided with respect to the biodegradability of ECM Plastics because Kappus did not have the expertise to determine whether it was accurate or not. (CCX 812 (Kappus, Dep. 21-22)).
1526. Quest, an ECM Customer, does not employ any scientists, researchers, or engineers. Mr. James Bean, president and owner of Quest (*see* F. 77) handles all sales. He has a degree in biology and has no formal education in plastics. Mr. Bean's knowledge comes from his experience working in the plastic molding business. (CCX 817 (Quest, Dep. at 14-17)).
1527. Eagle Film, an ECM Customer, has no in-house expertise regarding the scientific assessment of biodegradability of plastics containing the ECM Additive. From the time Eagle Film began purchasing the ECM Additive to the present, Eagle Film has not employed any polymer scientists, material scientists, environmental scientists, or any experts on the biodegradability of plastics, disposal conditions for plastic, or landfills. (CCX 804 (Eagle, Dep. at 31-32)).
1528. Eagle Film did not have any in-house testing equipment. Eagle Film perceived itself as too small to manage biodegradability testing. (CCX 804 (Eagle, Dep. at 25)).
1529. Quest did not test for biodegradability. Quest did not have staff to conduct such a test. Quest was not aware that there are tests for biodegradability of plastic products. (CCX 817 (Quest, Dep. at 34)).
1530. BioPVC, an ECM Customer, had biodegradability and ecotoxicology testing done on its product. (RX 120; RX 121).
1531. ERL has performed biodegradability testing for ECM Customers. (Poth, Tr. 1481).
1532. NE Labs has conducted testing on plastics infused with the ECM Additive for ECM Customers. (Johnson, Tr. 1576-1577).
1533. 3M Company ("3M"), an ECM Customer, conducted in-house biodegradability testing of plastic manufactured with the ECM Additive. 3M does not necessarily rely on third party information with respect to claims regarding biodegradation of a polymer. (CCX 821 (3M, Dep. at 60, 113)).
1534. 3M was interested in the ECM Additive because 3M sells plastics and, therefore, wanted to research whether the ECM Additive can help reduce the impact of 3M's products on the environment following disposal. (CCX 821 (3M, Dep. at 42)).

1535. Organic Waste Systems (“OWS”) performed biodegradability testing of plastic with the ECM Additive for Covidien, an ECM Customer. (CCX 254; CCX 256).
1536. FP engaged Stevens Ecology to test the biodegradability of their products with the ECM Additive, including testing pursuant to ASTM D5511. (CCX 810 (FP, Dep. at 57-60)).
1537. D&W Fine Pack (“D&W”), an ECM Customer, believed that ECM’s former 9 months to 5 years claim was true because of the totality of the information provided by ECM. (CCX 802 (D&W, Dep. at 33)).
1538. D&W has a product development group. (CCX 802 (D&W, Dep. at 155)).
1539. D&W engaged Dr. Timothy Barber and Environ to test the biodegradability of ECM Plastics. (CCX 802 (D&W, Dep. at 95-99)).

III. ANALYSIS

A. BURDEN OF PROOF

The parties’ burdens of proof are governed by Rule 3.43(a) of the Federal Trade Commission’s (“FTC” or “Commission”) Rules of Practice for Adjudicative Proceedings (“Rules”), Section 556(d) of the Administrative Procedure Act (“APA”), and case law. Pursuant to Commission Rule 3.43(a), “[c]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.” 16 C.F.R. § 3.43(a). Under the APA, “[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof.” 5 U.S.C. § 556(d).

It is well established that the preponderance of the evidence standard governs Federal Trade Commission enforcement actions. *In re POM Wonderful LLC*, No. 9344, 2012 FTC LEXIS 106, at *464-65 (May 17, 2012) (Initial Decision); *In re Automotive Breakthrough Sciences, Inc.*, No. 9275, 125 F.T.C. 138, 1998 FTC LEXIS 112, at *38 n.45 (Sept. 9, 1998) (holding that each finding must be “supported by a preponderance of the evidence in the record”); *In re Adventist Health System/West*, No. 9234, 117 F.T.C. 224, 1994 FTC LEXIS 54, at *28 (Apr. 1, 1994) (“[e]ach element of the case must be established by a preponderance of the evidence”); *In re Bristol-Myers Co.*, No. 8917, 102 F.T.C. 21, 1983 FTC LEXIS 64, at *143 (July 5, 1983) (Initial Decision) (stating that complaint counsel has “the burden of

proving by a preponderance of credible evidence that the challenged advertising claims have not been established or did not have a reasonable basis”). *See also Steadman v. SEC*, 450 U.S. 91, 102, 101 S. Ct. 999, 67 L. Ed. 2d 69 (1981) (holding that the APA establishes preponderance of the evidence standard of proof for formal administrative adjudicatory proceedings). Accordingly, FTC Complaint Counsel (“Complaint Counsel”) has the burden of proving each factual issue supporting its claims against Respondent in this case by a preponderance of credible evidence. *Bristol-Myers*, 1983 FTC LEXIS 64, at *143-44. *See also FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006), *aff’d*, 512 F.3d 858 (7th Cir. 2008).

As a preliminary matter, Respondent asserts that Complaint Counsel has failed to meet its initial burden of production in this case because Complaint Counsel relied on deposition testimony from 19 fact witnesses, rather than calling such fact witnesses live. *See* RB at 1, 36-37. Complaint Counsel replies that it was not required to call live witnesses and that the introduction of sworn deposition testimony constitutes valid evidence. CCRB at 6. In support of the contention that only live testimony can meet Complaint Counsel’s burden of production, Respondent cites *FTC v. Tashman*, 318 F.3d 1273, 1283 (11th Cir. 2003). This is not authority for the proposition that Complaint Counsel was legally required to call live fact witnesses. The portion of the *Tashman* case upon which Respondent relies is a dissenting opinion, and therefore not precedential. Further, the cited portion addresses the persuasive value of certain admitted testimony, and does not address the proposition urged by Respondent. For all these reasons, the cited authority is legally and factually inapposite.

Moreover, the FTC’s Rules expressly authorize introduction of deposition testimony as substantive evidence. 16 C.F.R. § 3.43(b) (“If otherwise meeting the standards for admissibility described in this paragraph, depositions, . . . shall be admissible . . .”). While live testimony does provide a better means to determine the credibility of a witness and is typically more meaningful and persuasive evidence than a deposition transcript, relevant deposition testimony nevertheless constitutes admissible evidence in Commission proceedings. For all these reasons, Respondent’s argument that Complaint Counsel failed to meet its burden of production in this case because Complaint Counsel relied upon deposition testimony instead of calling live fact witnesses is rejected.

B. JURISDICTION

Section 5 of the Federal Trade Commission Act (“FTC Act”) grants the Federal Trade Commission the authority to prevent “unfair or deceptive acts or practices in or affecting commerce” by “persons, partnerships, or corporations” 15 U.S.C. § 45(a)(1)-(2) (2012). Section 4 of the FTC Act defines “corporation,” in part, as “any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, which is organized to carry on business for its own profit or that of its members, and has shares of capital or capital stock or certificates of interest” 15 U.S.C. § 44.

Respondent ECM BioFilms, Inc. (“ECM”) is an Ohio-based corporation, with a principal place of business listed as: Victoria Place, Suite 225, 100 South Park Place, Painesville, Ohio. F. 152. Thus, ECM is a corporation over which the FTC has jurisdiction. In addition, the acts and practices alleged in the Complaint are “in or affecting commerce.” Respondent is in the business of manufacturing, advertising, offering for sale, selling, and distributing, additives for plastics, including the ECM additive, known as “MasterBatch Pellets” (the “ECM Additive”). F. 156-158. ECM sells the ECM Additive to plastic manufacturers and distributors of plastics (“ECM Customers”). F. 164-166. ECM’s Customers, which total approximately 300, are located in various areas around the United States. F. 4, 9, 14, 23, 37, 46, 53, 64, 68, 78, 167. Accordingly, the acts and practices of Respondent, as alleged in the Complaint, are and have been “in or affecting commerce,” within the meaning of Section 4 of the FTC Act. Therefore, the FTC has jurisdiction over the conduct challenged in the Complaint, pursuant to Sections 4 and 5 of the FTC Act. 15 U.S.C. §§ 44, 45.

C. OVERVIEW

The Complaint alleges that Respondent engaged in deceptive trade practices in violation of Section 5(a) the FTC Act. 15 U.S.C. § 45(a). Complaint Counsel charges that Respondent made, and provided others with the “means and instrumentalities” to make, false or unsubstantiated representations to: (1) purchasers of the ECM Additive (“ECM Customers”); (2) “downstream” customers of ECM’s Customers, sellers or distributors of plastics made with

the ECM Additive (“ECM Plastics”); and (3) “end-use” consumers (hereafter, “consumers”).¹⁶ Specifically, Complaint Counsel charges that Respondent made the following false or unsubstantiated claims, “expressly or by implication”:

1. ECM Plastics are “biodegradable, *i.e.*, will completely break down and decompose into elements found in nature within a reasonably short period of time after customary disposal,” which time period Complaint Counsel asserts is less than one year after disposal in a landfill;¹⁷
2. ECM Plastics are “biodegradable” in a “landfill”;
3. ECM Plastics are “biodegradable in a stated qualified timeframe”; which according to Complaint Counsel was “9 months to 5 years”;¹⁸ and
4. Tests prove that ECM Plastics have the characteristics identified in 1, 2, or 3 above pursuant to “various scientific tests including, but not limited to ASTM D5511.”¹⁹

Complaint ¶ 9A-D; CCB at 5-9, 28-30 (collectively the “Challenged Claims”).

Section 5(a) of the FTC Act makes it unlawful to engage in a deceptive trade practice in or affecting commerce. 15 U.S.C. § 45(a)(1). “An advertisement is deceptive if it contains a representation or omission of fact that is likely to mislead a consumer acting reasonably under

¹⁶ The FTC Act does not define “consumer.” 15 U.S.C. § 41 *et seq.* In addition, in its Post-Trial Brief, Complaint Counsel did not offer any definition of “consumer” from the trial record. At oral argument, not as evidence, Complaint Counsel stated that, as Complaint Counsel uses the term in this case, the “end-use” consumer is anyone “who could walk into a store and purchase a plastic product containing the ECM additive, for instance, a water bottle that has the logo ‘ECM Biodegradable.’ That would be the end-use consumer that I’m referring to in this action, because they are receiving the claim from ECM through the means and [instrumentalities] of the logo that ECM provided to its customers to pass the claim down to consumers.” Transcript of Closing Arguments, Oct. 22, 2014 at 16-17.

¹⁷ Complaint Counsel’s position as to what period of time is “reasonably short” has vacillated, with Complaint Counsel asserting such alternative time periods as within 1 year, 2 years, 3 years, and/or “at least within 5 years.” *See* Complaint Counsel’s Pre-Trial Brief at 22-27. It is appropriate, however, that Complaint Counsel be held to the position taken in its Post-Trial Brief, which contends that the claim “biodegradable” implies complete biodegradation in less than one year. *See* CCB at 29-34.

¹⁸ As noted in Section III.D.3.b., *infra*, the evidence shows that ECM changed its stated biodegradation rate in 2013 to “some period greater than a year,” *see* F. 252-253, 256, and it is unclear whether Complaint Counsel challenges this rate claim as false or unsubstantiated.

¹⁹ ASTM International, formerly known as the American Society for Testing and Materials (“ASTM”). F. 650. The ASTM D5511 test is discussed in Section III.E.6., *infra*.

the circumstances, and that representation or omission is material to a consumer's purchasing decision." *In re POM Wonderful LLC*, No. 9344, 2013 FTC LEXIS 6, at *17-18 (Jan. 10, 2013) (citations omitted). The determination of whether Respondent violated the FTC Act as alleged in this case requires a three part inquiry: (1) whether Respondent disseminated advertisements conveying the claims alleged in the Complaint and challenged in this case; (2) whether those Challenged Claims are false or misleading; and (3) whether the Challenged Claims found to be false or misleading are material to prospective consumers. *See Id.* at *18-19, citing *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992); *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D. Mass. 2008), *aff'd*, 684 F.3d 1 (1st Cir. 2010); *see also In re Telebrands Corp.*, 140 F.T.C. 278, 290-92 (2005), 2005 FTC LEXIS 178, at *19-24, *aff'd*, 457 F.3d 354 (4th Cir. 2006).

Moreover, liability can accrue for misrepresentations made by others, under the doctrine of "means and instrumentalities." This doctrine holds that "[t]hose who put into the hands of others the means by which they may mislead the public, are themselves guilty of a violation of Section 5 of the Federal Trade Commission Act." *Waltham Watch Co. v. FTC*, 318 F.2d 28, 32 (7th Cir. 1963) (quoted in *FTC v. Five-Star Auto Club*, 97 F. Supp. 2d 502, 530 (S.D.N.Y. 2000)). *See also Regina Corp. v. FTC*, 322 F.2d 765, 768 (3d Cir. 1963); *In re Litton Indus., Inc.*, 97 F.T.C. 1, 1981 FTC LEXIS 94, at *105 (1981) (stating that it is "well established that one who puts into the hands of others the means by which such others may deceive the public is equally as responsible for the resulting deception"), *aff'd*, 676 F.2d 364 (9th Cir. 1982). Thus, the "means and instrumentalities" doctrine ensures that "[t]he author of false, misleading and deceptive advertising may not furnish customers with the means of misleading the public and thereby insulate himself against responsibility for its deception." *Irwin v. FTC*, 143 F.2d 316, 325 (8th Cir. 1944).

Accordingly, this Initial Decision proceeds to analyze whether Respondent made any of the Challenged Claims, including the extent to which any of the Challenged Claims found to have been made were "passed down" the supply chain, including to consumers. Thereafter, the analysis turns to the scientific evidence in the case to determine whether any of the Challenged Claims found to have been made by Respondent are false or unsubstantiated, and if so, whether

any such claim is material. Then, whether Respondent can be held liable for any deceptive claims passed “downstream,” under the “means and instrumentalities” doctrine, is addressed.

D. CLAIMS

1. General Legal Principles

An advertisement²⁰ is deemed to “convey a claim if consumers, acting reasonably under the circumstances, would interpret the advertisement to contain that message.” *In re Kraft, Inc.*, 114 F.T.C. 40, 1991 FTC LEXIS 38, at *10 (1991); *In re Thompson Medical Co.*, 104 F.T.C. 648, 788 (1984), *aff’d*, 791 F.2d 189 (D.C. Cir. 1986); *In re Cliffdale Associates, Inc.*, 103 F.T.C. 110, 164-66 (1984); Federal Trade Commission Policy Statement on Deception, appended to *Cliffdale*, 103 F.T.C. 110, 1984 FTC LEXIS 71, at *176-77 (1984) (the “Deception Statement”). Advertising claims may be conveyed either expressly or impliedly. Express claims directly state the representation at issue. *Kraft*, 970 F.2d at 319 n.4; *Thompson Medical*, 104 F.T.C. 648, 1984 FTC LEXIS 6, at *311; *Cliffdale*, 1984 FTC LEXIS 71, at *108. Because an express claim is stated unequivocally, the statement itself establishes its meaning. *Thompson Medical*, 1984 FTC LEXIS 6, at *311-12. When claims at issue are express, it is appropriate to infer that reasonable consumers interpret the statements to mean what they say. *FTC v. USA Bevs., Inc.*, 2005 U.S. Dist. LEXIS 39075, at *16-17 (S.D. Fla. Dec. 5, 2005). Implied claims are communicated in an oblique or indirect way. *Kraft*, 970 F.2d at 319 n.4.

An interpretation of an advertisement may be reasonable even though it is not shared by a majority of consumers. *Kraft*, 1991 FTC LEXIS 38, at *14; *Deception Statement*, 1984 FTC LEXIS 71, at *177 n.20. It is sufficient that a “significant minority” of reasonable consumers are likely to interpret the advertisement to be making the allegedly misleading claim. *Telebrands*, 140 F.T.C. at 291 (*quoted in POM*, 2013 FTC LEXIS at 6, at *20). The

²⁰ Respondent argues that its various promotional materials do not constitute “advertisements” because they were not “widely disseminated” to the public at large. RB at 40-41. This assertion – even if true – is not determinative. The reach of Section 5 is not limited to “advertisements,” but reaches deceptive commercial speech generally. *POM*, 2013 FTC LEXIS 6, at *146-48. Commercial speech is determined, *inter alia*, by whether the speech promotes a product, includes information about the product, and is motivated by the speaker’s economic or commercial interests. *Id.* at *147. Judged by these standards, it cannot reasonably be disputed that the claims at issue in this case constitute commercial speech within the scope of Section 5. Moreover, the standard for determining deception is the same for “advertisements” as for other commercial speech. *Id.* at *19 n.5.

requirement that an interpretation be shared by a “significant minority” of reasonable consumers reflects the principle that “[a]n advertiser cannot be charged with liability with respect to every conceivable misconception, however outlandish, to which his representations might be subject among the foolish or feeble-minded. Some people, because of ignorance or incomprehension, may be misled by even a scrupulously honest claim. . . . A representation does not become ‘false and deceptive’ merely because it will be unreasonably misunderstood by an insignificant and unrepresentative segment of the class of persons to whom the representation is addressed.” *Deception Statement*, 1984 FTC LEXIS 71, at *178. Moreover, the allegedly misleading interpretation need not be the only one that can be drawn from an advertisement. *Id.* at *178. “Where an ad conveys more than one meaning, only one of which is misleading, a seller is liable for the misleading interpretation even if non-misleading interpretations are possible. *See, e.g., In re Bristol-Myers Co.*, 102 F.T.C. 21, 320 (1983), *aff’d*, 738 F.2d 554 (2d Cir. 1984); *Nat’l Comm’n on Egg Nutrition v. FTC*, 570 F.2d 157, 161 n.4 (7th Cir. 1977).” *POM*, 2013 FTC LEXIS 6, at *21.

The primary evidence of the representations that an advertisement conveys to reasonable consumers is the advertisement itself. *POM*, 2013 FTC LEXIS 6, at *21. Thus, to determine whether an advertisement conveys an alleged claim, the first step is to examine the advertisement (a “facial analysis”). *Thompson Medical*, 1984 FTC LEXIS 6, at *313; *Cliffdale*, 1984 FTC LEXIS 71, at *108. “If, after examining the interaction of all the different elements in the ad, the Commission can conclude with confidence that an ad can reasonably be read to contain a particular claim, a facial analysis is sufficient basis to conclude that the ad conveys the claim. *See Kraft*, 114 F.T.C. at 121; *Thompson Medical*, 104 F.T.C. at 789.” *In re Stouffer Foods Corp*, 118 F.T.C. 746, 1994 FTC LEXIS 196, at *9 (Sept. 26, 1994). If, after a facial analysis, it cannot be concluded with confidence that a particular advertisement can reasonably be read to contain a particular implied message, the Commission “will not find the ad to have made the claim unless extrinsic evidence allows [the conclusion] that such a reading of the ad is reasonable. *Kraft*, 114 F.T.C. at 121; *Thompson Medical*, 104 F.T.C. at 789.” *Stouffer*, 1994 FTC LEXIS 196, at *10. Extrinsic evidence includes, but is not limited to, “reliable results from methodologically sound consumer surveys.” *Kraft*, 1991 FTC LEXIS 38, at *13; *Cliffdale*, 1984 FTC LEXIS 71, at *108-09.

Whether examining the advertisement itself, extrinsic evidence, or both, the Commission considers the overall, common-sense, net impression made by the advertisement in determining whether the alleged claim may reasonably be ascribed to it. *FTC v. Tashman*, 318 F.3d at 1283; *Kraft*, 114 F.T.C. at 122; *Thompson Medical*, 104 F.T.C. at 790; *Stouffer*, 1994 FTC LEXIS 196, at *11. Ultimately, “[t]he meaning of an advertisement, the claims or net impressions communicated to reasonable consumers, is fundamentally a question of fact. . . . This question of fact may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey.” *FTC v. Nat’l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008); *QT, Inc.*, 448 F. Supp. 2d at 957-58, *aff’d*, 512 F.3d 858 (7th Cir. 2008); *see also Removatron Int’l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir. 1989) (holding that findings with respect to what representations are made in advertisements are factual).

Applying the foregoing principles, and as more fully explained below, the greater weight of the evidence demonstrates that Respondent claimed that the ECM Additive rendered plastics “biodegradable,” including in a “landfill,” and that independent testing proved that ECM Plastics are “biodegradable.” In addition, prior to October 2012 and ending in 2013, Respondent claimed that ECM Plastics will fully biodegrade in a landfill within a time period of 9 months to 5 years, and that independent testing proved such claim. Further, the evidence shows that, in 2013, Respondent began discontinuing the “9 months to 5 years” claim, and instead claimed that ECM Plastics would fully biodegrade in “most” landfills, “in some period greater than a year.” However, the greater weight of the evidence fails to demonstrate that, by representing ECM Plastics are (1) “biodegradable” or (2) “biodegradable in some period greater than a year,” Respondent impliedly claimed that ECM Plastics would completely biodegrade in a landfill within one year.

Prior to analyzing the evidence in detail, some background on ECM’s business, its Customers, and the supply chain for ECM Plastics, is appropriate for context.

2. ECM's Customers and Supply Chain for ECM Plastics

Respondent sells an additive for plastic manufacturing called "MasterBatch Pellets." F. 156-158 (the "ECM Additive"). The ECM Additive is an industrial product that ECM sells exclusively to companies that manufacture plastic, or companies that have plastic manufactured for them, and to some distributors who sell the ECM Additive to plastic manufacturers ("ECM Customers"). F. 164-165, 168. The ECM Additive is sold in either sixty-five kilogram (65kg) drums or five hundred kilogram (500kg) pallet boxes, and is used only by companies that manufacture plastic. F. 166. It is undisputed that ECM has sold its product to approximately 300 Customers. F. 167. ECM does not advertise or sell the ECM Additive to "consumers." *See* F. 164-165, 168, 172. Hereafter, unless the context dictates otherwise, the terms "consumers" and "end-use" consumers, as used in this Initial Decision, shall mean members of the general public who would be exposed to ECM claims in the marketplace. *See* Section III.C., *supra*, n.16.

Plastics manufactured with the ECM Additive ("ECM Plastics") are sold by plastics manufacturers "downstream," through a multi-level supply chain of distributors or other "middlemen," before eventually reaching consumers. F. 165. Some of ECM's plastic manufacturer customers use the ECM Additive to make products for purchase by retailers that sell consumer products, such as grocery stores and restaurants. F. 171. For example, all products sold by ECM Customer D&W Fine Pack, a manufacturer of plastic dinnerware, are sold to distributors. The distributors then sell the plastic products to retail businesses, such as restaurants. F. 31. Customers frequently buy the ECM Additive to make plastic "films" that are used to make grocery "t-shirt" bags and packaging cushions. F. 11, 54, 193. As an example, ECM Customer Island Plastics Bags, Inc. ("IPB") manufactures and sells high density and low density polyethylene bags to distributors, that in turn sell to businesses such as restaurants, bars, and grocery stores and grocery chains. F. 62, 66. It can be difficult to determine who is the "end-user" of plastics made with the ECM Additive. For instance, when a company such as Amazon ships a product in a box containing an air-cushioned pillow made with ECM Additive-infused plastic, it is unclear whether the "end-user" of the ECM Plastic is Amazon or the recipient of the shipping box containing the product ordered from Amazon. F. 170.

Respondent markets the ECM Additive to potential Customers through its website, flyers, brochures, and sales presentations (hereafter, “Marketing Materials”). F. 206. ECM’s website, which is its principal advertising tool, is geared toward plastics manufacturers and people in the plastics industry. F. 207. ECM does not advertise to consumers. F. 172, 207, 210. The process by which a prospective customer becomes an actual customer commonly begins with website inquiries submitted by plastics manufacturers (or companies that subcontract the manufacturing to others). F. 213. The ECM website provides a standard web inquiry form that is automatically emailed to ECM. F. 213. A potential customer contact is generally first handled by Mr. Tom Nealis, ECM’s director of sales, and he will provide the potential customer with basic information, such as pricing and sales literature, and address other initial issues. F. 212, 214. As the sales process comes to involve the technical issues, the potential customer is directed to Mr. Robert Sinclair, ECM’s president. F. 214.

The ECM Additive cannot be purchased over the Internet. F. 208. Customers place orders directly with ECM, by telephone, with a follow-up email or fax, and the product is shipped directly to the Customer from ECM’s manufacturing site in Carpentersville, Illinois. F. 223-224. ECM Customers are normally long-term accounts, as opposed to one-time purchasers, and purchase again from ECM, as needed to meet demand from the Customers’ customers for biodegradable plastics. F. 231.

3. ECM’S Claims

a. Claims that ECM Plastics are “biodegradable” and “biodegradable in a landfill” and that “tests prove” the claims

i. “Biodegradable in a landfill”

Respondent has stipulated that it claims that the ECM Additive causes plastics to be “biodegradable” and that plastics treated with the ECM Additive are “biodegradable” in a “landfill.” *See* JX 3 at 3. Moreover, the evidence demonstrates that Respondent claims in its Marketing Materials that the ECM Additive renders plastics “biodegradable,” and that ECM Plastics will biodegrade in a “landfill.” For example, ECM’s website states that ECM’s

additive technology “renders . . . plastic products biodegradable . . .” F. 234; *see also* F. 237, citing, *inter alia*, CCX 6 (stating “where will it biodegrade? . . . Landfills”). Similarly, the ECM logo expressly represents that ECM Plastics are “biodegradable,” as shown below:



F. 239, 256.

It is not clear that the Complaint challenges ECM’s claim of “biodegradable” as false or unsubstantiated, except to the extent the term “biodegradable” implies complete biodegradation within one year, and Complaint Counsel’s position is that any claim by Respondent that ECM Plastics are “biodegradable” necessarily implies a time period for complete biodegradation; specifically, within one year. *See* CCB at 27-29. Whether ECM’s biodegradable claim implies to consumers that ECM Plastics will completely biodegrade into elements found in nature, in a landfill, within one year, is addressed in Section III.D.4., below. Whether “biodegradable” is properly defined, as a scientific matter, as the complete breakdown into elements found in nature, in a landfill, within one year, is addressed in Section III.E.3., *infra*.

Respondent’s claims that ECM Plastics are “biodegradable” and biodegradable “in a landfill” were made to its Customers, F. 232-235, 237, and also communicated to customers of ECM’s Customers. F. 280, 284, 287, 291. The representation that ECM Plastics are biodegradable, was also conveyed to consumers through ECM’s logo, which the evidence shows was placed on plastic bags and other plastic products to which consumers would potentially be exposed. F. 285, 289.

ii. Certificate of biodegradability

Complaint Counsel argues that Respondent’s “Certificate of Biodegradability” claims that ECM Plastics are “biodegradable” and that independent testing proves such claim. The evidence shows that ECM issues, and has issued, a Certificate of Biodegradability, to every

Customer who confirms that it will manufacture its ECM Additive-infused plastic in accordance with ECM’s manufacturing specifications. F. 266. The Certificate certifies that “numerous plastic samples, submitted by ECM Biofilms, Inc., have been tested by independent laboratories in accordance with standard test methods approved by ASTM, ISO [International Organisation for Standardization] and other such standardization bodies . . .”; that these tests “certif[y] that plastic products manufactured with ECM additives can be marketed as biodegradable”; and the certificate itself can be “used by [the Customer] to validate its claims to the biodegradability” of ECM Plastic. F. 269, 272-273. Based on the language and images of ECM’s Certificate of Biodegradability, the overall net impression is that ECM Plastics are biodegradable and that testing by independent laboratories proves that ECM Plastics are biodegradable. F. 274.²¹

The Certificate that ECM provided to its Customers, and/or the claims therein, were passed on to customers of ECM’s Customers, and at least one such downstream customer posted the ECM Certificate on its website. F. 305-307. However, the evidence fails to show that any consumer saw ECM’s Certificate of Biodegradability.

b. Challenged claims that ECM Plastic will fully biodegrade in a landfill in a “stated qualified timeframe” and that tests prove such claims

i. “9 Months to 5 Years”

The evidence demonstrates that Respondent, including through its website, flyers, and brochures, claimed that plastics manufactured with the ECM Additive would fully biodegrade in a landfill within 9 months to 5 years (the “9 Months to 5 Years Claim”). F. 245-247. This conclusion is based upon the express language used in these materials, as well as the overall net impression of each of the advertisements as a whole. F. 246. For example, ECM’s Marketing Materials included the following express representations:

²¹ While not denying that the Certificate represents that ECM Plastics are “biodegradable,” and that tests prove this claim, Respondent argues that the Certificate defines biodegradability in accordance with the ASTM standard, which does not mirror the “within one year” definition used by Complaint Counsel in this case. *See* RRB at 6-7.

Plastic products made with ECM additives

- **Fully biodegrade in 9 months to 5 years.**
- **Fully biodegrade wherever they are disposed of where other things are biodegrading (anaerobically and aerobically):**
 - In Landfills,
 - In Compost (backyard as well as commercial facilities),
 - Buried in the ground or littered,
 - Agricultural and erosion-control settings.
- **Are recyclable.**
- **Can be made with recycled resins.**
- **Do not use heat, light or mechanical stress to break them down.**
- **Do not require special handling (unlike PLA and oxo-degradable products).**
- **Do not contain heavy metals (unlike most oxo-degradable products).**

F. 245.

Respondent contends that it “qualified” its 9 Months to 5 Years Claim, both in its Marketing Materials and in ECM’s communications with prospective customers over the course of the sales cycle, to communicate that the rate of biodegradation was dependent on factors such as where the plastic was disposed, the environmental conditions at such disposal site, and the extent to which other biodegrading matter was present. RB at 35-36. At least some of ECM’s Marketing Materials included language advising that the rate of biodegradation was dependent on various factors such as soil conditions and the availability of microbes in the soil. F. 248. ECM’s website “Technology Page,” for example, immediately after claiming that ECM Plastics “break down in approximately 9 month[s] to 5 years in nearly all landfills . . . ,” states: “All sorts of factors determine the amount of microbes available in the soil and the soil conditions determine the rate of degradation. The plastic products made with ECM technology basically rely on the microbes in the soil” F. 248. The overall net impression, considering the language in context, is that various factors affect the point at which full biodegradation will occur *within* the time range of 9 months to 5 years, and not that such factors will result in a biodegradation rate beyond that time range. F. 249. Thus, such language does not alter the overall net impression conveyed by Respondent that ECM Plastics will fully biodegrade, including in a landfill, within 9 months to 5 years. F. 249.

Further, based on express language and the overall net impression of ECM's Marketing Materials, ECM claimed that independent testing proved that the ECM Additive caused ECM Plastics to fully biodegrade in a landfill in a time period of 9 months to 5 years. F. 265. For example, CCX 6, titled, "Our Technology for the Biodegradation of Plastic Products," refers to specific ASTM testing and further includes the following language: "ECM engaged several renowned testing laboratories to independently establish the biodegradability of plastics made with ECM's additives. The tests concluded that the products were fully biodegradable under both aerobic and anaerobic conditions. . . . The plastic products made with our additives will break down in approximately 9 month[s] to 5 years in nearly all landfills . . ." *See also* CCX 5 (referring to "9 months to 5 years" biodegradation rate and further stating: "[W]e certify the full biodegradation of most all plastic products manufactured with at least a one percent load of our additives. We can certify this situation due to the internal and external studies that have cost us hundreds of thousands of dollars. . . . We have had the various test data analyzed by independent scientists and their conclusions and some of the data have been sent to you in the presentation package and are what we base our certification on."). F. 265.

Based on the foregoing, Complaint Counsel has proven the Challenged Claim that ECM Plastics would fully biodegrade in a landfill "in a stated qualified timeframe," of 9 months to 5 years, and that tests proved such claim.

The claims that ECM Plastics would fully biodegrade in a landfill within 9 months to 5 years and that testing proved such claim were made directly to ECM Customers, including through ECM's Marketing Materials. F. 206, 245, 265, 1508. These claims were also passed downstream to customers of ECM's Customers. F. 280, 286. There is also evidence that at least some consumers visited Respondent's website for information on biodegradable products, and were, or may have been, exposed to the claims on the website about the ECM Additive, including that ECM Plastics would fully biodegrade in a landfill within 9 months to 5 years and that testing proved such claim. F. 279.

Regardless of whether consumers were in fact exposed to claims on ECM's website, the evidence shows that the 9 Months to 5 Years Claim appeared on grocery bags sold by IPB, an ECM Customer, including on bags sold to Down-to-Earth Grocery ("DTE"), a Hawaii grocery

store chain and a downstream customer of IPB. F. 32-36, 292-293, 297. IPB manufactured ECM Plastic bags reflecting the 9 Months to 5 Years Claim for 50 to 100 different customers. F. 300. In total, IPB alone manufactured about 10 million such bags. F. 300. DTE purchased about 700,000 plastic bags reflecting the 9 Months to 5 Years Claim, each year for approximately 5 years, for a total of 3.5 million bags. F. 301. Based on the foregoing, it is reasonable to infer that consumers were exposed to the 9 Months to 5 Years Claim. F. 302.

ii. “Some period greater than a year”

As of late 2013, ECM discontinued the 9 Months to 5 Years Claim, in response to the FTC’s issuance, in October 2012, of revised Guides For The Use Of Environmental Marketing Claims (“Green Guides”). F. 251-252, 259-261. The Green Guides are not law, but reflect the “Federal Trade Commission’s current views about environmental claims They do not . . . bind the FTC or the public. The Commission, however, can take action under the FTC Act if a marketer makes an environmental claim inconsistent with the guides. In any such enforcement action, the Commission must prove that the challenged act or practice is unfair or deceptive in violation of Section 5 of the FTC Act.” 16 C.F.R. § 260.1. The October 2012 revision to the FTC’s Green Guides added, *inter alia*, the following provision:

(c) It is deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal. Unqualified degradable claims for items that are customarily disposed in landfills, incinerators, and recycling facilities are deceptive because these locations do not present conditions in which complete decomposition will occur within one year.

16. C.F.R. § 260.8(c).

In response to the 2012 revision to the FTC’s Green Guides, ECM undertook to revise its biodegradability claims in an effort to meet the guidelines in the revised Green Guides. F. 251-252. ECM’s revised Marketing Materials placed an asterisk next to the word, “biodegradable,” which provided the following text: “Plastic products manufactured with [the ECM Additive] will biodegrade in any biologically-active environment (including most landfills) in some period greater than a year.” F. 253. In addition, Respondent revised its Marketing Materials to omit references to biodegradation within a period of “9 months to 5 years.” F. 252. ECM completed the process of revising its website in late 2013. F. 259.

Also in response to the revised Green Guides, Respondent similarly revised its logo, a green tree with the ECM name and the word “biodegradable” printed underneath, by adding the text: “Plastic products manufactured with [the ECM Additive] will biodegrade in any biologically-active environment (including most landfills) in some period greater than a year.” The revised logo appears as follows:



F. 256.

Although the evidence shows that Respondent claimed that ECM Plastics would fully biodegrade in a landfill “in a stated qualified timeframe” of “some period greater than a year,” Complaint ¶ 9C, it is not clear that Complaint Counsel in fact challenges this particular claim as false or unsubstantiated. *See* CCB at 8-9, 27-29. Similarly, although it is not entirely clear, Complaint Counsel does not appear to argue that Respondent deceptively claimed that “tests prove” ECM Plastics would fully biodegrade in a landfill in “some period greater than a year,” *see* CCB at 27-29, nor does Complaint Counsel propose a finding of fact on the issue. Thus, these issues are not properly presented, and accordingly, will not be, and are not, decided.

Complaint Counsel’s contention that Respondent’s claim that ECM Plastics will biodegrade in a landfill in “some period greater than a year,” implied to consumers that ECM Plastics would completely break down into elements found in nature within one year, CCB at 29-30, is addressed in Section III.D.4., *infra*.

c. Summary

In summary, as set forth above, the evidence demonstrates that Respondent’s Marketing Materials claimed that ECM Plastics are “biodegradable,” including in a “landfill”; that ECM

Plastics would completely biodegrade, including in a landfill, in a time period ranging from 9 months to 5 years; and that tests proved such claims. These claims were made to ECM's Customers, and passed down to customers of ECM's Customers. To the extent consumers could visit, and did visit, ECM's website, these claims would also have been passed on to consumers. Respondent's "biodegradable" claim and claim of complete biodegradation in a landfill within 9 months to 5 years were also passed on to consumers via plastic bags printed with the ECM logo, or printed with the ECM logo and the 9 Months to 5 Years Claim. The evidence further shows that, as of late 2013, Respondent revised its Marketing Materials and its logo to state that ECM Plastics were biodegradable within "some period greater than a year."

The following section of the Initial Decision evaluates Complaint Counsel's assertion that, in representing that ECM Plastics are "biodegradable" or "biodegradable in some period greater than a year," Respondent impliedly claimed that ECM Plastics would completely biodegrade, in a landfill, within one year. As shown below, the greater weight of the evidence fails to sustain this proposition.

4. Alleged Implied Claim of Biodegradation Rate of "Within One Year"

a. Introduction

Complaint Counsel argues that Respondent's claims that ECM Plastics are "biodegradable" – what Complaint Counsel refers to as Respondent's "unqualified" biodegradability claim²² – and "biodegradable" in "some period greater than a year" impliedly claimed to consumers that ECM Plastics will completely biodegrade into elements found in nature, in a landfill, within one year. CCB at 9-12, 30 ("Implied One Year Claim"). Complaint Counsel argues that Respondent communicated this message to consumers because "consumers understood ECM's 'biodegradable' and 'biodegradable in some period greater than a year' claims to mean ECM Plastics will completely biodegrade in a landfill within a year." CCB at

²² Although it is not entirely clear, Complaint Counsel at times refers to "biodegradable" claims as ECM's "unqualified" biodegradability claims. Complaint Counsel does not assign any legal definition, or other special definition, to the word "unqualified."

30.²³ Respondent replies that for the vast majority of products that eventually reach end-use consumers, consumers are exposed only to a generalized “biodegradable” claim in the form of a logo or a small stamp on the packaging, and that the evidence fails to show that consumers would take away the message that ECM Plastics will completely biodegrade in a landfill within a year. RB at 39-43.

To prove the Implied One Year Claim, Complaint Counsel bears the burden of proving that a significant minority of reasonable consumers would interpret ECM’s claims of (1) “biodegradable,” or (2) “biodegradable” in “some period greater than a year,” to be conveying the message that ECM Plastics will completely biodegrade in a landfill within one year. *See POM*, 2013 FTC LEXIS 6, at *44 (finding implied claim where net impression of advertisement “conveyed to at least a significant minority of reasonable consumers” the message that the advertiser had “clinical proof” for disease claims); *Telebrands*, 140 F.T.C. at 291 (holding that an implied claim is demonstrated where “at least a significant minority of reasonable consumers are likely to take away” the alleged claim).

In *POM*, the Commission reiterated the well-established rule that whether an advertisement conveys an implied claim “is a question of fact.” 2013 FTC LEXIS 6, at *44 (citing *Removatron Int’l*, 884 F.2d at 1496; *Nat’l Urological Grp.*, 645 F. Supp. 2d at 1189). The process for determining this factual issue was addressed by the Commission in *POM*, as follows:

To determine whether a particular implied claim has been made, the Commission starts with a facial analysis of the advertisement. A facial analysis of an ad considers “an evaluation of such factors as the entire document, the juxtaposition of various phrases in the document, the nature of the claim, and the nature of the transaction.” *Deception Statement*, 103 F.T.C. at 176. “If, after examining the interaction of all the different elements in the ad, the Commission can conclude with confidence that an advertisement can reasonably be read to contain a particular claim, a facial analysis is sufficient basis to conclude that the

²³ Complaint Counsel, in its briefing and proposed findings of fact, has vacillated regarding whether it is asserting that ECM impliedly claimed a biodegradation rate of “within one year,” “less than one year,” and “one year of less.” To this extent, Complaint Counsel should be bound by the definition of the claim that it provided to its proffered expert Dr. McCarthy, for the purpose of Dr. McCarthy’s evaluation of scientific support for Respondent’s claims, which was “that the unqualified marketing claim ‘biodegradable’ means that the entire treated plastic will completely break down . . . *within one year*.” F. 633; CCX 891(McCarthy Expert Report at 5 n.1) (emphasis added).

advertisement conveys the claim.” *Stouffer Foods Corp.*, 118 F.T.C. at 798; *accord Novartis Corp.*, 127 F.T.C. at 680; *Kraft, Inc.*, 114 F.T.C. at 121.

2013 FTC LEXIS 6, at *24-25. However, if, after a facial analysis, it cannot be concluded with confidence that a particular advertisement can reasonably be read to contain a particular implied message, the Commission “will not find the ad to have made the claim unless extrinsic evidence allows [the conclusion] that such a reading of the ad is reasonable. *Kraft*, 114 F.T.C. at 121; *Thompson Medical*, 104 F.T.C. at 789.” *Stouffer*, 1994 FTC LEXIS 196, at *10.

Having conducted a facial analysis of the ECM Marketing Materials, Certificate of Biodegradability, and logos at issue, including consideration of associated images, context and other elements, an implied claim that ECM Plastics will completely biodegrade into elements found in nature, in a landfill, within one year is not reasonably clear or conspicuous. F. 241, 242, 275. The word, “biodegradable,” on its face, does not state any time period for complete biodegradation, or refer to any disposal conditions or disposal results. The evidence shows that, to the extent that ECM stated any time period for complete biodegradation in its promotional materials prior to ECM’s revisions in 2013, that time period was 9 months to 5 years. F. 245-246. ECM’s revised stated time period of “some period greater than a year,” on its face, is clearly and directly contrary to any message that complete biodegradation would occur “within one year.” *See* F. 253, 256. Further, nothing in the images or context surrounding ECM’s use of the phrases “biodegradable” or “biodegradable in some period greater than a year” suggests that ECM Plastics would completely biodegrade into elements found in nature, in a landfill, within one year. F. 253, 256. Accordingly, a facial analysis of the ECM Marketing Materials, Certificate of Biodegradability, and logos at issue, including consideration of all their respective elements, does not lead to a confident conclusion that a significant minority of reasonable ECM Customers, downstream customers, or Consumers would view ECM’s claim of “biodegradable” or “biodegradable” in “some period greater than a year,” as communicating the message that ECM Plastics completely biodegrade within one year. F. 241, 242, 275. For all the foregoing reasons, it is appropriate in this case to look to extrinsic evidence to determine whether Complaint Counsel has proven an Implied One Year Claim. *See Thompson Medical*, 1984 FTC LEXIS 6, at *357-59.

Regardless of whether extrinsic evidence is necessary as a matter of law, when extrinsic evidence has been introduced, that evidence “must be considered by the Commission in reaching its conclusion” about the meaning of the advertisement. *POM*, 2013 FTC LEXIS 6, at *27 (quoting *Bristol-Myers*, 102 F.T.C. at 319); *see also Thompson Medical*, 104 F.T.C. at 794 (finding that the Commission was “obliged to consider” extrinsic evidence offered by the parties). The Commission will carefully consider any extrinsic evidence that is introduced, taking into account the quality and reliability of the evidence. *See Kraft*, 114 F.T.C. at 122, 1991 FTC LEXIS 38, at *14; *Stouffer*, 1994 FTC LEXIS 196, at *10. Finally, in all cases, evaluating whether an implied claim was made must be guided by the cautionary principle that “the Commission may not inject novel meanings into ads and then strike them down as unsupported; ads must be judged by the impression they make on reasonable members of the public.” *Bristol-Myers*, 1983 FTC LEXIS 64, at *249.

Thus, the analysis now turns to the extrinsic evidence on the issue of whether a significant minority of reasonable consumers would interpret ECM’s claim of (1) “biodegradable” or (2) “biodegradable in some period greater than a year,” to be conveying the message that ECM Plastics will completely biodegrade into elements found in nature, in a landfill, within one year, as argued by Complaint Counsel. In general, extrinsic evidence “might include common usage of terms, expert opinion as to how an advertisement might reasonably be interpreted, copy tests, generally accepted principles of consumer behavior, surveys, or ‘any other reliable evidence of consumer interpretation.’” *Telebrands*, 140 F.T.C. at 291 (quoting *Cliffdale*, 103 F.T.C. at 166).

b. Extrinsic evidence

i. Common usage of words

Respondent’s claims included express representations that ECM Plastics are (1) “biodegradable” or (2) “biodegradable” in “some period greater than a year.” It is appropriate to infer that consumers interpreted the words to mean what they say. *USA Bevs., Inc.*, 2005 U.S. Dist. LEXIS 39075, at *16-17; *see also In re Southwest Sunsites, Inc.*, 106 F.T.C. 39, 1985 FTC LEXIS 38, at *324 (1985). It is also appropriate to refer to the dictionary definition of a word as an aid in interpreting the common meanings of words. *Thompson Medical*, 1984

FTC LEXIS 6, at *359 (referring to dictionary definition in determining what reasonable consumers understand the word “aspirin” to mean). Because dictionary definitions are derived from the ordinary usage of words, such definitions are an indication of how reasonable consumers would understand these words. *Id.* Dictionary definitions are particularly useful in this case, where Complaint Counsel appears to base the Implied One Year Claim solely on the how consumers allegedly interpret the words, without reliance on any context surrounding the words that affect their meaning.²⁴

In this instance, according to the Merriam-Webster dictionary, “biodegradable” means “capable of being slowly destroyed and broken down into very small parts by natural processes, bacteria, etc.” or “capable of being broken down especially into innocuous products by the action of living things (as microorganisms).” *Merriam-Webster.com*. Merriam-Webster, n.d. Web. 22 July 2014, *available at* <http://www.merriam-webster.com/dictionary/biodegradable>); *see also Collins English Dictionary*, 10th Ed. 2009 (July 22, 2014), *available at* <http://dictionary.reference.com/browse/biodegradation>) (defining “biodegradable” to mean “capable of being decomposed by bacteria or other biological means”). The plain meaning of the word “biodegradable,” therefore, does not include any particular time frame for complete decomposition, much less complete decomposition, into elements found in nature, in a landfill, within one year. The foregoing dictionary definitions constitute extrinsic evidence that reasonable consumers would *not* interpret the words “biodegradable” or “biodegradable” in “some period greater than a year” to have the meaning urged by Complaint Counsel. *See Thompson Medical*, 1984 FTC LEXIS 6, at *359 (relying on dictionary definition of “aspirin” as containing acetylated salicylate to hold that consumers would not interpret the word “aspirin” to mean a generic pain reliever).

ii. Survey evidence – arguments of the parties

Complaint Counsel argues that, according to consumer survey evidence introduced through Complaint Counsel’s proffered expert, Dr. Shane Frederick, the percentage of

²⁴ In *Thompson Medical*, the Commission noted that dictionary definitions may be less reliable than survey research as an indicator of how consumers understand advertisements where the specific meanings of the words in a particular context in an advertisement “communicate a meaning at variance with the word’s dictionary definitions, such as when it is used as slang. (‘You can drive this lovely, late model car home for just two thousand five hundred bananas.’)” *Id.* at *360 n.35. Such usage variance has not been shown in this case.

consumers “who believe that ‘biodegradable’ products will biodegrade within one year or less generally ranges from 25% to 60%,” and that Dr. Frederick estimated that, overall, 35% of consumers hold this belief. CCB at 31-32. Complaint Counsel contends that such percentages demonstrate that a substantial minority of consumers “believe that ‘biodegradable’ means ‘biodegradable within one year or less.’” CCB at 30. Therefore, Complaint Counsel concludes, it has met its burden of proving that ECM made the Implied One Year Claim. CCB at 30-31.

In support of the foregoing, Complaint Counsel relies on three surveys addressed by Dr. Frederick: (1) a 2006 survey commissioned by the American Plastics Council (the “APCO” survey); (2) a survey conducted in December 2010 by the research company Synovate (the “Synovate” survey); and (3) a Google Consumer Survey commissioned by Dr. Frederick for purposes of this litigation (the “Google” survey). Specifically, Complaint Counsel relies on the following survey results, as addressed by Dr. Frederick:

- (1) based on APCO question 4, 60% of respondents “believe” that a package labeled “biodegradable” “should” biodegrade within one year;
- (2) based on Synovate question 19, 25% of respondents “believe” that “less than one year” is a “reasonable amount of time” for a “biodegradable” plastic package to decompose in a landfill; and
- (3) based on several questions in the Google survey, between 25% and 52% of respondents believe that a plastic product that is labeled “biodegradable,” including with the ECM logo, will take less than one year to decompose.

See CCB at 32 (citing CCFF 194-200); CCX 860 (Frederick Expert Report at 9-11, 15, ¶ 34).²⁵

Dr. Frederick opined that the APCO survey, the Synovate survey, and the Google survey were each “reasonably reliable and valid.” Frederick, Tr. 1180-1181. He concluded, based on the foregoing surveys, that “at least a substantial minority of end-use consumers understand that a ‘biodegradable’ product” will completely biodegrade in a landfill, into

²⁵ Complaint Counsel further asserts that certain results from Dr. Stewart’s survey support the Implied One Year Claim. That argument is addressed in Section III.D.4.b.vii., below.

elements found in nature, “within one year.” CCX 860 (Frederick Expert Report at 20, ¶ 47c). In his trial testimony, but not in his expert report, Dr. Frederick further estimated, based on his “research and expertise,” that 35% of American consumers believe that a plastic product labeled “biodegradable” will biodegrade completely within one year. Frederick, Tr. 1180-1181; *compare* CCX 860 (Frederick Expert Report at 20). Dr. Frederick also opined, based on responses to questions in the APCO survey, the Synovate survey, and the Google survey, that most consumers believe plastic products labeled “biodegradable” will biodegrade in landfills. Frederick, Tr. 1172; CCX 860 (Frederick Expert Report at 13). In addition, Dr. Frederick opined, based on his Google survey, that at least a substantial minority of respondents believe that a product bearing a “biodegradable” label, including the ECM logo, will “completely break down into elements found in nature.” CCX 860 (Frederick Expert Report at 16).

Respondent retained Dr. David Stewart to review and comment on the APCO, Synovate, and Google surveys, and to respond to the opinions of Dr. Frederick on those matters. Respondent relies on Dr. Stewart’s opinions that the APCO and Synovate surveys suffer from serious flaws that severely limit the conclusions that may be drawn from them with respect to the issues presented by this case, and that the Google survey is so seriously flawed that it cannot be relied on to demonstrate perceptions of representative consumers on the meaning of the term “biodegradable.” In addition, on behalf of Respondent, Dr. Stewart designed and implemented a consumer survey regarding consumers’ perceptions related to biodegradability. Based on Dr. Stewart’s survey and Dr. Stewart’s associated opinions, Respondent asserts that consumers have no common understanding of the term “biodegradable,” and that the vast majority of consumers understand that the process of biodegradability is “highly varied” and not always, or even often, a rapid process. RB at 43; RX 856 (Stewart Expert Report at 25-26). Specifically, Respondent notes that in Dr. Stewart’s survey, when asked how long a degradable item would take to decompose or decay, 39% of survey respondents stated that it depends on the type of product, and a total of 68% of survey respondents’ answers indicated recognition that there are differences in the rate of decomposition. RB at 47-48; RX 856 (Stewart Expert Report at 25). Further, Respondent states, when survey respondents were asked if they think that there are differences in the

amount of time it takes for different types of products to biodegrade, 98% of survey respondents answered, “yes.” RB at 48; RX 856 (Stewart Expert Report at 26).

iii. Expert qualifications

In determining what weight, if any, to assign the survey evidence, for the reasons explained below, greater weight is given to the opinions of Respondent’s expert, Dr. Stewart. F. 323-324.

Respondent’s expert witness, Dr. Stewart, is highly qualified in the field of consumer surveys. F. 322. Dr. Stewart is currently the president’s professor of marketing and business law at Loyola Marymount University, where he teaches advertising and promotion management, marketing strategy, and introductory MBA marketing. F. 145. Dr. Stewart has taught extensively in the field of conduct and methodology of surveys, teaching marketing research at the undergraduate, graduate, and doctoral levels, and has taught courses on research methodology, psychometrics, and experimental design. F. 146. Dr. Stewart has served as the editor of the *Journal of Marketing* and the *Journal of the Academy of Marketing Science* and is currently serving as the editor of the *Journal of Public Policy and Marketing*. F. 148. In this capacity, Dr. Stewart has reviewed papers submitted to those journals and the survey methodology used in those papers. Approximately half of the papers submitted to those three journals use survey methodology as a basis for empirical presentation. F. 148. Dr. Stewart’s work has been published in more than 200 peer-reviewed journals, proceedings volumes, and book chapters, over half of which contained survey research. F. 149.

Dr. Stewart has served as an expert witness for the FTC multiple times, in cases including *Kraft* (Docket No. 9298), *Novartis* (Docket No. 9279), and *POM* (Docket No. 9344). F. 316. Dr. Stewart was retained as an expert by the FTC in matters against *QVC* (Docket No. C-3955), and *John Beck* (FTC Matter No. 072 3138). F. 316. Dr. Stewart has also been retained by various respondents in consumer protection cases brought by the FTC, including *Pantron* (U.S. District Court Case No. CV88-6696 (C.D. Cal.)), *Schering* (Docket No. 9232), and *Guaranty Life* (FTC Matter No. 092 3169). F. 316. In most of the foregoing cases involving the FTC, Dr. Stewart has opined on surveys. F. 317. In approximately half of the cases, Dr. Stewart designed a survey, and in many of the cases, Dr. Stewart gave rebuttal

testimony concerning the opposing party's surveys. F. 317. Dr. Stewart is unaware of a single instance in which his testimony or survey was not accepted by either the Administrative Law Judge ("ALJ") or the Commission. F. 319. Indeed, in the *Kraft* decision, Dr. Stewart's survey was accepted by the ALJ and cited by the Commission as supportive of its decision. F. 320; *see Kraft*, 1991 FTC LEXIS 38, at *24-30 nn.13-15. More recently, in the *POM* decision, the Commission agreed with the conclusion of the ALJ that a consumer survey proffered by the respondents was entitled to little weight, based on the opinions of Dr. Stewart. *POM*, 2013 FTC LEXIS 6, at *49-50; *see POM*, 2012 FTC LEXIS 106, at *506 (Initial Decision). Dr. Stewart has also served as a survey expert in federal court "a couple of dozen times" and in none of those cases has his survey been deemed to be unreliable or been rejected by the court. F. 321.

Complaint Counsel's expert witness, Dr. Frederick, is a professor at Yale University's School of Management, where he has taught courses in consumer behavior, behavioral economics, and marketing. F. 113. Dr. Frederick has studied and published extensively concerning judgment and decision-making, with a focus on the role of cognitive abilities on preferences, preference measurements, and cognitive biases. F. 114. Dr. Frederick's work involves conducting and evaluating survey research, including internet-based research tools, such as Google Consumer Surveys. F. 115. Dr. Frederick has conducted hundreds of studies using both paper and pencil and web-based survey tools. F. 115. Dr. Frederick is affiliated with Yale's Center for Consumer Insights, which partners with corporations and academics to help understand the evolving dynamics of consumer behavior, and has advised corporations including Pepsico, Kimberly Clark, and AMC Networks on incorporating insights from consumer psychology. F. 116.

Having considered and weighed the qualifications of both proffered experts, Dr. Stewart is highly qualified in the field of designing, implementing, reviewing, and evaluating consumer surveys, and is more qualified than Dr. Frederick in these relevant areas. F. 323. In addition, Dr. Stewart's opinions are well supported and are more well reasoned, credible, and persuasive than the opposing opinions of Dr. Frederick. F. 324. Accordingly, Dr. Stewart's opinions in this case are entitled to, and are given, greater weight than the opposing opinions of Dr. Frederick.

iv. Google survey

(a) Introduction

Complaint Counsel argues that Dr. Frederick’s Google survey, “standing alone,”²⁶ “establishes” that “substantial numbers of consumers understand ‘biodegradable’ claims to imply within one year.” CCB at 32. Complaint Counsel asserts that it is not necessary for the Google survey to be perfect, “as long as it is ‘reasonably reliable and probative.’” CCB at 33. To the extent Complaint Counsel is asserting that its survey evidence need only be “reasonably reliable and probative” to meet its burden of proof on the Implied One Year Claim, Complaint Counsel’s position demonstrates a fundamental misunderstanding of the difference between the standards for the admissibility of evidence, and the standards for assigning it weight.

In *Bristol-Myers*, 1975 FTC LEXIS 218, at *127, the Commission held that consumer surveys need only be “reasonably reliable and probative” in order to be admissible in evidence. The Commission explained:

[We] must dismiss any contention that the F.T.C. is bound to reject these consumer surveys as inadmissible hearsay. The Commission has on numerous occasions considered the question of the admissibility of surveys which are obviously hearsay, and it is well settled that such surveys will be admitted for the truth of the matters asserted when it is demonstrated that they are reasonably reliable and probative. Upon thorough and independent examination of the record in this proceeding, we find that the surveys in question readily meet these standards; thus, they were properly admitted by the administrative law judge.

Id. at *127-28. To demonstrate that the survey possesses any probative value, and is therefore admissible, the proponent of the survey must prove the survey is “methodologically sound,” which requires proving that the survey draws valid samples from the appropriate population, asks appropriate questions in ways that minimize bias, and analyzes results correctly. *POM*, 2013 FTC LEXIS 6, at *49, citing *Thompson Medical*, 1984 FTC LEXIS 6, at *315. *See also Telebrands*, 140 F.T.C. at 323 (quoting *Thompson Medical*, in part, and stating that “[t]he standard that the Commission applies in determining whether a copy test is methodologically sound is whether it ‘draw[s] valid samples from the appropriate population, ask[s] appropriate

²⁶ Complaint Counsel’s argument that the Google survey, in combination with other surveys, proves the Implied One Year Claim under the theory of “convergent validity,” is addressed in Section III.D.4.b.vi., below.

questions in ways that minimize bias, and analyze[s] results correctly”).²⁷ “[I]f the methodology of a consumer survey is fundamentally unsound, then that survey cannot assist the Commission in deciding whether an advertisement communicates a particular claim to consumers. . . . The Commission’s practice is, in this regard, consistent with that of most federal courts when evaluating surveys purporting to assess the meaning that consumers take from ads.” *Stouffer*, 1994 FTC LEXIS 196, at *29.

Of course it is not necessary to prove that a survey is “perfect” in order for the survey to have any probative value. “No survey is perfect.” *Stouffer*, 1994 FTC LEXIS 196, at *29 n.27. However, the flaws in a survey’s methodology directly affect the evidentiary weight to be given the survey’s results. *See POM*, 2013 FTC LEXIS 6, at *49; *Stouffer*, 1994 FTC LEXIS 196, at *29 (“The nature and seriousness of any deficiencies will affect the weight that the Commission assigns to that piece of evidence.”). Accordingly, while Complaint Counsel clearly has the burden of demonstrating, at the outset, that the Google survey is “reasonably reliable and probative,” this alone does not “establish” any fact in issue, or satisfy Complaint Counsel’s burden of proof on any material fact.

As more fully explained below, Complaint Counsel has failed to prove that Dr. Frederick’s Google survey drew valid samples from the appropriate population, asked appropriate questions in ways that minimized bias, and analyzed results correctly, or that the Google survey should be given any meaningful weight on the issue of whether a significant minority of reasonable consumers would interpret Respondent’s biodegradable claims to be communicating a message that ECM Plastics will completely break down into elements found in nature, in a landfill, within one year. The greater weight of the evidence supports Dr. Stewart’s opinions that the Google survey conducted for this litigation is not reliable or valid to draw any conclusions about consumer interpretation of “biodegradable” claims, or the validity of other surveys, and cannot even be characterized as a “survey,” but rather was the asking of a

²⁷ The Commission’s standards are substantially the same as those that Dr. Stewart identified as broadly accepted standards, derived from the Manual for Complex Litigation, which require that: “1) the population was properly chosen and defined; 2) the sample chosen was representative of that population; 3) the data gathered were accurately reported; 4) the data were analyzed in accordance with accepted statistical principles; 5) the questions asked were clear and not leading; 6) the survey was conducted by qualified persons following proper interview procedures; and 7) the process was conducted so as to ensure objectivity (the study was double blind).” *See* F. 326.

single question to unidentified individuals who happened to have visited particular websites. F. 431, 434. To the extent that the Google survey can be deemed sufficiently reliable or valid to be admissible, the evidentiary weight to which the Google survey is entitled, given its methodological flaws, is minimal at best.

(b) Analysis of Google survey

Google Consumer Surveys markets its survey product as a new approach to “market research” and as a tool for those who “need to pre-test a marketing campaign, prioritize new product initiatives, or even gauge a reaction about a recent event. . . . Now, with Google Consumer Surveys, you can easily conduct market research or even automatically track your brand to inform important business decisions.” F. 356. Google has contracts with internet content providers to present survey questions to internet users who would otherwise need to pay to access content on the providers’ websites. F. 360. In a Google survey, an internet user will encounter a “pop-up” survey question when attempting to access desired content on a website. F. 357. The user is blocked from access to the desired content unless the user answers the survey question or pays for access to the desired content without answering the survey question. F. 357, 359.

In Dr. Frederick’s Google survey, each respondent was presented with only a single question. F. 371. A single question survey, such as the Google survey in this case, is called a “micro-survey.” F. 358. Dr. Frederick’s assertion that 20% to 52% of consumers “infer” that plastic products labeled “biodegradable” “will biodegrade within a year . . .” is based on the responses to 12 open-ended questions that Dr. Frederick crafted for the Google survey, designated as questions 3A–3K.²⁸ F. 435. These questions asked, in varying ways, that the respondent provide their opinions, beliefs, and/or estimates as to “how long,” or “how much time” such a “biodegradable” plastic product “would” or “will” take to decompose. F. 437.

The many, and significant, ways in which Dr. Frederick’s Google survey failed to draw valid samples from the appropriate population, ask appropriate questions in ways that

²⁸ There appear to be two questions labeled 3G in Dr. Frederick’s Google survey. See CCX 860 (Frederick Expert Report at 31). The first question 3G will be referred to herein as question 3G(1). The second question 3G will be referred to herein as question 3G(2).

minimized bias, and analyze results correctly, are set forth in detail in the Findings of Fact, at Section II.D.3., *supra*. The most significant and persuasive of these failures are discussed below.

- **The “pop-up” survey question design, in exchange for obtaining desired content, is inappropriate because it creates a disinterest bias**

Because questions in the Google survey are answered by respondents in exchange for access to internet-based content in which they may be interested, the questions are a distraction, at best, and a barrier to respondents whose objective is to access information, not to complete a survey. This type of disruptive questioning creates a “disinterest bias.” F. 382. Disinterest bias refers to the fact that if people are uninterested in a survey, if they are disengaged, or, even worse, if the survey serves as an interruption of an activity in which they are more interested, those people will be likely to give insincere, random, and often nonsensical responses simply to get past what is essentially an interruption in what they were doing before being confronted by the survey. F. 383. Dr. Frederick agreed that a person who does not take a survey question seriously is more likely to answer that question insincerely, whimsically, or with just a guess. F. 385. Incorporating such “protest” or “bypass” responses into a data set affects the integrity of the data analysis. F. 386; *see also* F. 506 (contrasting a telephone survey “protest” response of hanging up, which is not incorporated into the data set).

Complaint Counsel argues that disinterest bias has not been studied in academic literature and that Dr. Stewart’s opinion on the existence of such a bias is based on a “blog post from a [Google Consumer Surveys] competitor.” CCB at 46. However, Dr. Stewart testified, without contradiction, that the Greenbook Blog, which Dr. Stewart references on the phenomenon of disinterest bias, is a publication that is well known in the practicing market research community and among well-read researchers. F. 384. Complaint Counsel further contends that the average time that a respondent took to answer the Google survey question was “generally” above 20 seconds, which, according to Complaint Counsel, is evidence that respondents were thinking about the question, rather than merely clicking a random response. *See* CCB at 46. It cannot be assumed that the 20 second response time indicates that the resulting response was serious, sincere, or not a protest response. Dr. Frederick acknowledged

that numerous factors may cause survey respondents to take, on average, 20 seconds to answer their “pop-up” question, including performing other computer work in another window or on another screen, or taking a telephone call. F. 389. Dr. Frederick cannot know what caused his survey respondents to wait 20 seconds before keying in a response to his survey questions. F. 389.

Lastly, Complaint Counsel contends that, according to Dr. Frederick, the amount of “protest” responses was very small. CCB at 46. In fact, however, there is no way to know how many responses to Dr. Frederick’s Google survey questions were “protest” or “bypass” responses, because all the questions required a response before the respondent could access the desired internet content. F. 388. Dr. Frederick opined that there is “no reason to believe people who [give protest responses] actually have different views about biodegradation times” than the people who gave specific time estimates. CCX 865 (Frederick Expert Rebuttal Report at 6). But it also cannot be assumed that their views would have been the same. Dr. Frederick’s opinion on this issue is unsupported and unpersuasive, and is, thus, rejected.

- **The “single question” design was inappropriate and the questions were not asked in a way that would minimize bias in favor of an implied rate claim**

Each Google survey respondent was asked only one question. F. 371. How consumers interpret the term “biodegradable,” which is what Complaint Counsel undertook to prove, cannot be addressed and determined with a single question. *See* F. 372-374. A good open-ended question might provide some dimension of consumer perception of the term “biodegradable,” but it will not provide other dimensions, such as nuances, dependencies, or context effects. F. 374. Moreover, when there is only one question asked of a survey respondent, a researcher cannot really know what the response means or indicates. F. 373. The researcher cannot know whether it is a sincere response, and/or whether it is a response that would be subject to qualification if there had been a follow-up question. F. 375.

Furthermore, none of the Google survey questions actually asked the survey respondent how the respondent interpreted the word “biodegradable,” which is the material issue for purposes of the Implied One Year Claim. F. 381. The Google survey questions 3A-3K, upon

which Complaint Counsel relies, did not, for example, present a bag with the ECM “biodegradable” logo and ask whether the “biodegradable” logo communicated any message concerning the rate for complete biodegradation, and if so, what that specific rate message was. F. 436. Instead, the Google survey questions assumed that the representation of “biodegradable” communicates a biodegradation rate, and asked only for the respondents’ “best estimate of the amount of time,” or for the respondents to report “how long,” or “how much time,” they think that a plastic product that is labeled “biodegradable” “would” or “will take” to decompose or biodegrade. F. 437. *See generally*, F. 438-447. In this regard, the questions were not asked in a way to minimize bias. *Compare Kraft*, 1991 FTC LEXIS 38, at *24, n.13, in which the Commission found probative a survey by Dr. Stewart that, in order to assess whether certain ads for Kraft Singles implied that one slice of the cheese product contains the same amount of calcium in five ounces of milk, showed the advertisement to respondents and asked, “Does this ad say or suggest anything about the amount of calcium in a slice of Kraft Singles compared to the amount of calcium in five ounces of milk?” *See In re Kraft, Inc.*, 114 F.T.C 40, 1989 FTC LEXIS 131, at *42-43 (April 3, 1989) (Initial Decision). *Compare also Stouffer*, 1994 FTC LEXIS 196, at *23 n.21, *30 (finding probative, on issue of whether Stouffer’s advertisements for Lean Cuisine implied that the entrées were low in sodium, answers to questions about “what point” the advertisement was making and “what reason” the advertisement gives for buying Lean Cuisine).

- **Dr. Frederick did not analyze the results properly**

The process by which survey responses are classified into response categories for the purpose of analysis is referred to as “coding.” F. 390. In the Google survey, open-ended questions asking for the respondents’ estimated biodegradation times required coding into a time interval, and responses such as “3 months,” “6 months,” “between 5 and 9 months,” “a little less than a year,” and “1 year” would be coded as a response falling into the time interval category of “one year or less.” F. 390. Dr. Frederick used a “bright-line” coding rule, however, that included only responses that provided a time interval, and only if the time interval reported included both a numeric specification and an accompanying temporal unit. All other responses, including “it depends,” or “I don’t know,” were not coded, and were thereby eliminated from the survey results. F. 392-393. In this way, Dr. Frederick effectively

turned open-ended questions into closed-ended questions, by limiting the range of acceptable responses to those that fit Dr. Frederick’s pre-determined format, or “bright-line” rule. *See* F. 327-335, 399.²⁹ Overall, out of 29,000 total responses provided in response to Dr. Frederick’s Google survey, only approximately 21,000 (approximately 72%) were coded. F. 395.

By way of illustration of Dr. Frederick’s coding methodology described above, question 3K showed the image of a plastic bag, which was digitally edited or altered (“photoshopped”) to superimpose the image of a large ECM logo, as shown below:



F. 447. The question asked, “What is your best estimate of the amount of time it would take for this plastic bag (which bears the symbol ‘ECM biodegradable’) to biodegrade?” F. 447. While Dr. Frederick calculated that 38% of respondents estimated less than one year, the evidence shows that only 176 responses were coded, while 66 responses were not coded. F. 447; *see* CCX 860 (Frederick Expert Report at 33). Thus, out of the 242 actual responses, approximately 27% were eliminated from Dr. Frederick’s data analysis.

It is not appropriate for a researcher not to code a response because that response does not fit into the researcher’s desired structure, or to “force-fit” responses into a pre-existing structure of biodegradation time categories. F. 396-397. Such methodology is also improper because it limits the range of responses considered, and by definition creates greater homogeneity of responses than would be the case if the respondents were allowed more latitude in responding. F. 399. Dr. Frederick’s coding methodology is particularly egregious because it reduces the denominator of the percentage results reported by Dr. Frederick, which has the

²⁹ Closed-ended questions are questions where a list of possible responses to a question are provided to the respondent, and where the respondent must choose from one of the responses that were provided in order to give an answer to the question. F. 333-334. By contrast, open-ended questions allow consumers to offer responses in their own words, and are far more informative than closed-ended questions. F. 328-331.

effect of inflating the reported percentages. F. 398. In summary, the Google survey data was not analyzed in accordance with accepted statistical principles. F. 396-404.³⁰

Complaint Counsel argues that the responses excluded by Dr. Frederick's coding are not material because, according to Dr. Frederick, there is no reason to believe that non-coded responses would be different than the responses that were coded. For example, Dr. Frederick opined, it does not matter that he omitted responses of "I don't know" to questions asking how long a biodegradable item will take to decompose, because "there is no reason to believe" that those responding, "I don't know," hold a view about biodegradation times that differs from the rest of the population. CCB at 43. This opinion is unsupported and unpersuasive. It defies logic to assert that, as a group, those asserting no knowledge of how long a "biodegradable" item will take to biodegrade have the same views as those expressing a specific time. Moreover, Dr. Stewart persuasively opined that the distribution of responses "would be different because some of those people actually don't know, and so the fact they don't know will change the overall distribution even if there are a few people who say 'don't know' because they are less certain. But the overall distribution would be quite different." F. 400. Dr. Stewart's opinion on this issue, which is more credible and sensible, is given greater weight than that of Dr. Frederick.

Complaint Counsel further argues that Dr. Frederick's flawed coding methodology is not material because, according to an analysis of the data by Dr. Frederick, the distribution of numeric responses unaccompanied by a "temporal unit," such as "1," or "one," which were excluded from the data, were "very similar to the distribution of numeric responses which did have an accompanying unit." CCB at 43-44. Therefore, according to Dr. Frederick, excluding responses not meeting his "bright-line" rule had no effect on the data. (Frederick, Tr. 1127-

³⁰ It is also significant that the responses to the Google survey were coded primarily by Dr. Frederick himself, and his assistant, Mr. Meyer, both of whom were aware of the sponsor of the research and its purpose. F. 405-406. Blinding of coders is very important when coding open-ended questions because the coders are, in effect, transforming the data into categories of responses. This is the essence of data analysis. F. 349. To the degree that the coders have a prior understanding of what the researcher is looking for, that prior understanding can influence what codes the coders arrive at and how they code the data. F. 350, 509. Dr. Frederick's failure to use blind coders for his Google survey deviates from customary practice, may infect the survey with coder bias, and further calls into question the validity of the survey. F. 347, 407-408.

1128). However, Dr. Frederick's analysis assumes that those who entered, "1" or "one" intended to convey a temporal unit that was comparable to those that did provide a temporal unit – a fact which cannot be known, and will not be assumed.

- **The evidence fails to demonstrate that the Google survey sample was representative of the relevant population**

According to Dr. Frederick, his Google survey was directed at "end-use consumers," CCX 860 (Frederick Expert Report at 5), which are defined for purposes of this proceeding as members of the general public who would be exposed to ECM claims in the marketplace. *See* Section III.C., *supra*, n.16. Thus, Complaint Counsel did not undertake to prove that ECM Customers, or ECM's Customers' customers, interpreted ECM's representations that ECM Plastics are "biodegradable," or "biodegradable in some period greater than a year," to mean completely biodegrade into elements found in nature, in a landfill, within one year, even though this population is arguably the most relevant population for ECM's claims. *See* F. 164-165, 168, 172, 207, 210. In fact, there is evidence that ECM Customers did not interpret Respondent's biodegradable claims in this manner. F. 240; *see also* F. 12-13, 50, 1508-1509 (ECM Customer testimony that they believed biodegradation would occur within 9 months to 5 years).

To the extent that end-use consumers are a relevant population, Complaint Counsel has failed to demonstrate that the Google sample was representative of this population. Dr. Frederick opined in his report that Google provides respondents for its surveys that are "demographically representative of U.S. adults, and tend to yield similar results to other internet panels."³¹ CCX 860 (Frederick Expert Report at 12). As discussed below, Dr. Frederick's opinions in this regard are not adequately supported, and are outweighed by the more credible and persuasive opinion of Dr. Stewart that there is no way to know whether or not Dr. Frederick's Google survey population was representative of any identifiable population. F. 426-427.

³¹ In an internet panel survey, individuals will receive an email requesting participation in a survey, and a link to the survey site. The participants are compensated for their participation. F. 367.

Google provides only indirect information on a survey respondent's demographics. F. 409. Google draws inferences about demographics, such as gender and age, based on the respondent's Internet Protocol ("IP") address and "cookies," as well as other information indicating the respondent's website visits. F. 411. Google infers the respondent's location based on the computer's IP address, and then uses this information to further infer the respondent's income and urban density "by mapping the location to census tracts and using the census data to infer income and urban density." F. 410.

The methodology of "inferred" demographics is subject to numerous flaws, including many readily acknowledged by Dr. Frederick. F. 412-424. Accordingly, Dr. Frederick's Google survey failed to properly choose and define a population, because it is not clear what the population was that he was analyzing. Rather, the population is defined in terms of who participated in the survey, which is not an appropriate way to define a population. F. 425. Google's inferred demographics can be wrong, for example, when multiple members of a household visit websites from a single computer. F. 416. If a question is answered from that computer address, neither Google nor the surveyor can know which of those household members answered the survey question. F. 418. In addition, cookies can be deleted and website history may be insufficient to draw demographic conclusions. F. 416-417. Dr. Frederick was unaware of what percentage of internet users use websites, software, or Google Chrome's features that allow one to browse privately or to mask one's IP address. F. 423-424. A valid IP address of a survey respondent can only tell Google the location, but not the age, nationality, or gender of the person who answered the survey question. F. 419. In addition, Dr. Frederick did not choose the websites, or the number of websites, on which his questions were posted. F. 413. Dr. Frederick also does not know which websites among Google's contracted internet content providers featured his survey questions. F. 412.

Dr. Frederick's opinions about the sampling accuracy of Google Consumer Surveys, set forth on page 12 of his expert report, reference as support an article authored in part and published by Google itself, and also rely on an article from the New York Times *FiveThirtyEight* blog, authored by Nate Silver. F. 428. Both references, however, were provided to Dr. Frederick by Complaint Counsel. F. 428-430. Dr. Frederick was not even aware of Mr. Silver's blog post or the cited Google reference materials when he drafted his

expert report. F. 428. Complaint Counsel also drafted Dr. Frederick's "opinion" on page 12 of Dr. Frederick's expert report that, in predicting the results of the 2012 Presidential election, Google Consumer Surveys "best[ed] better-known rivals such Gallup, CNN, and Rasmussen." F. 430. In addition, Complaint Counsel drafted the "see" reference to Nate Silver's blog on page 13 of Dr. Frederick's expert report: "See N. Silver, *FiveThirtyEight*, The New York Times (Nov. 10, 2012) ('Perhaps it won't be long before Google, not Gallup, is the most trusted name in polling.')." F. 430.³²

Moreover, even if, according to Nate Silver, a Google survey was accurate as a polling mechanism for the 2012 presidential election, this is not persuasive evidence that the Google survey conducted for this case is sufficiently reliable and valid to determine how consumers would interpret Respondent's "biodegradable" claim. There is no evidence or opinion that the presidential poll performed using Google Consumer Surveys and the Google survey at issue in this proceeding were similar in any material way, other than that they were both conducted through Google. It is also logical that a binary question on a matter of public debate, such as a presidential candidate preference, is not comparable to the type of open-ended questions that are appropriate to determine consumers' interpretation of the term "biodegradable." See F. 328-331.

Complaint Counsel also relies on findings of a Pew Research Center ("Pew") study which, according to Dr. Frederick, found that, with respect to a certain series of questions administered by telephone to a Google Consumer Surveys sample and to Pew's own internet panel, "the Google Consumer Surveys sample appears to conform closely to the demographic composition of the overall internet population." See Frederick, Tr. 1069-1070; CCF 227, 228 (citing CCX 874 at 2). This general conclusion carries little, if any, weight on the question of whether the Google survey at issue in this proceeding drew valid samples from a representative population. The Pew study did not analyze the Google survey performed for this case. In addition, as noted above, Dr. Frederick did not choose the websites, or the number of websites, on which his questions were posted. F. 413. Dr. Frederick does not even know which websites

³² To be sure, one does not expect a retained expert witness to be objective and independent. However, one does expect the expert's opinions and support for those opinions to be the work of the expert witness.

among Google’s contracted internet content providers featured his survey questions. F. 412. Furthermore, notwithstanding the conclusion cited by Complaint Counsel, Pew also reached a number of conclusions that weigh against a finding that the Google survey at issue in this proceeding drew a valid sample from a representative population, including that: (1) the “sampling frame” used by Google Consumer Surveys is not “the general public”; (2) “[i]t is unknown whether visitors to the network of publisher sites are fully representative of all internet users or what proportion of internet users are covered by the publisher network”; (3) “[f]or approximately 30-40% of [Google Consumer Surveys] users, demographic information is not available – either because their cookies are turned off but more often because the [Google Consumer Surveys] algorithm cannot determine a trend from the websites visited as recorded in their DoubleClick advertising cookie that would suggest what gender or age they are”; and (4) “there can be substantial errors in how individual people are classified using Google’s inferred demographics.” CCX 874 at 2-5.

Complaint Counsel also contends that Google’s own studies of its sampling concluded that its sampling compared well to internet panels. However, there is reason to discount the weight given to Google’s own studies of its own surveys, given Google’s obvious economic interest in the results. Finally, Complaint Counsel argues, based on the opinion of Dr. Frederick, that Google has “high incentives” to get its demographic information “reasonably accurate.” According to Dr. Frederick, “[a]dvertisers value online advertising only to the extent that it works, which gives Google strong incentives to accurately ascertain the demographic characteristics of respondents advertisers target.” CCB at 37-38; Frederick, Tr. 1398; CCX 865 (Frederick Rebuttal Expert Report at 3). Dr. Frederick has no personal knowledge in this regard, and he is not an expert in either economic incentives in general or Google’s incentives in particular. Accordingly, his opinions on these issues are given little weight.

(c) Summary and conclusion as to Google survey

In addition to the many, significant, methodological flaws shown by the evidence, there are other reasons to reject the Google survey as evidence supporting the Implied One Year

Claim. First, there is no legal precedent for relying on results of a Google Consumer Survey to establish a fact in litigation. Complaint Counsel does not point to any litigation – FTC or otherwise – in which a Google Consumer Survey was accepted as evidence and/or given any significant weight. In addition, the evidence fails to show that Google Consumer Surveys have been become generally accepted as a reliable research tool by market research professionals. F. 361-363. As of the date of Dr. Frederick’s deposition in this case, Dr. Frederick had never actually seen a Google Consumer Survey question live on a website. F. 370. When choosing to use a Google Consumer Survey for his research in this case, Dr. Frederick was unaware of any administrative litigation in which the FTC had relied upon Google Consumer Survey data as a basis for decision. F. 369. Moreover, the evidence readily supports a conclusion that Dr. Frederick was motivated to use a Google survey for this litigation, at least in part because it was inexpensive to conduct (\$2,000). F. 364-368. Dr. Frederick was paid a flat fee for his work on this case (\$40,000) and the less Dr. Frederick had to pay for a survey, on assistants, and on costs, the more money he would net as compensation for his work in this case. F. 364-366.

In summary, Dr. Frederick’s Google survey fails to comport with generally accepted standards for survey research, as well as the legal standards used by the Commission, and is insufficiently reliable or valid to draw any material conclusions. F. 431-434. Even if the Google survey is sufficiently reliable or valid to be admissible evidence, the Google survey is so seriously flawed that it is entitled to little, if any, evidentiary weight on the issue of whether a significant minority of reasonable consumers would interpret ECM’s biodegradable claims to be conveying the message that the item will completely biodegrade into elements found in nature within one year. A Google Consumer Survey may well provide helpful information to those who need “to pre-test a marketing campaign, prioritize new product initiatives, or even gauge a reaction about a recent event [or] . . . track your brand to inform important business decisions,” as claimed in Google’s marketing materials. F. 356. However, the Google survey is not of sufficient methodological quality to constitute probative evidence in litigation, under

the Commission’s standards or the standards applicable to federal courts in general. Rather, for purposes of this adjudication, the Google survey is weak, at best.³³

v. APCO and Synovate surveys

(a) Pertinent survey questions and results

As evidentiary support for the Implied One Year Claim, Complaint Counsel relies on a 2006 survey by the American Plastics Council (“APCO” survey). APCO commissioned the APCO survey to investigate consumer perceptions about the terms “biodegradable” and “compostable.” F. 455. Complaint Counsel relies on the responses to question 4 from the APCO survey and asserts, based on those responses, that 60% of consumers “believe” that packages labeled “biodegradable” “should” biodegrade within one year. *See* CCB at 32, citing RX 597 at 2; *see also* CCX 860 (Frederick Expert Report at 9); *see* F. 458-459 (noting Dr. Frederick’s reliance on question 4 as the most pertinent question in the APCO survey). That question and the distribution of answers are as follows:

If a package is labeled “biodegradable,” what should be the maximum amount of time that it should take for that package to decompose?

One month or less	19.2%
Three months	6.6%
Six months	8.3%
One year	26.1%
Two to four years	4.7%
Five years or more	16.5%
Other	0.5%
Unsure (not read)	17.4%
Refused (not read)	0.7%

F. 459, 463.

³³ Complaint Counsel points to questions from the Google survey purporting to show that consumers believe biodegradable items will decompose in various periods other than 1 year, including 2 years and 5 years, *see, e.g.*, CCF 212-213, and that the claim of decomposition in “some period greater than a year” may result in biodegradation time estimates that are faster than 9 months to 5 years. *See* CCF 308-309. As set forth in detail above, the Google survey is not sufficiently reliable to provide valid conclusions and the cited evidence does not support the Implied One Year Claim.

Complaint Counsel also relies on a survey, commissioned by the company EcoLogic and conducted by Synovate (“Synovate” survey). The Synovate survey was a 2000-respondent internet panel survey conducted in 2010. F. 480. EcoLogic procured the Synovate survey in connection with the public comment period for the FTC’s proposed revisions to the Green Guides. F. 481. EcoLogic wanted to conduct consumer research into consumer comprehension of packaging that biodegrades in a landfill and/or composting environment, so that it could report findings and recommendations to the FTC. F. 481. Complaint Counsel relies on question 19 of the Synovate survey to assert that 25% of consumers “believe” that less than one year is “a reasonable amount of time” for a biodegradable plastic package to decompose in a landfill. CCB at 32; *see also* F. 483 (citing Dr. Frederick’s statement that Synovate question 19 is the “most pertinent” to the issues upon which he was asked to opine). That question and its responses are as follows:

What do you believe is a reasonable amount of time for a “biodegradable” plastic package to decompose in a landfill?

Please select one:

Less than 1 year	25%
Less than 5 years	45%
Less than 10 years	17%
Less than 20 years	6%
Less than 40 years	3%
40 years or greater	4%

F. 485-486.

In his expert report, Dr. Frederick cites the responses to APCO question 2 and Synovate question 5 as demonstrating that “at least a significant minority of consumers understand that a ‘biodegradable’ product will biodegrade in a landfill.” CCX 860 (Frederick Expert Report at 13). APCO question 2 and its responses are as follows:

From what you know, if something is labeled “biodegradable,” does that mean it will decompose in:

	Yes	No	Unsure
The natural environment	86%	8%	6%
A landfill	83%	11%	6%

Your backyard 80% 15% 5%

F. 464-465. Synovate question 5 and its responses are as follows:

If something is labeled “biodegradable,” where will it decompose? If you are not sure, please take your best guess. (Select all that apply.)

In the open environment (land or water) as litter	51%
In a landfill	72%
When buried in our backyard	43%
In a home composting device	46%
In a commercial composting facility	51%
None of these	2%

F. 490.

(b) Analysis of APCO and Synovate survey results

APCO question 4 and Synovate question 19 ask for consumer beliefs and/or opinions as to what is a “maximum amount of time” or “reasonable amount of time” for a biodegradable product to decompose. F. 460, 485-487. The material factual issue in this case is what message was implied by Respondent’s use of the term “biodegradable.” This necessarily includes a determination of *whether* the term “biodegradable” communicates to the consumer *any* message as to a rate for complete biodegradation in the first instance, and then, if so, what that rate message is. Evidence of consumer beliefs and/or opinions as to a “maximum amount of time” or “reasonable amount of time” for biodegradable products to decompose sheds little, if any, light on that issue. Therefore, such survey evidence has little probative value regarding whether Respondent, in using the term “biodegradable”– for example on its logo – communicated the message to a significant minority of reasonable consumers that plastics made with the ECM Additive would completely biodegrade in a landfill within one year.

Notwithstanding the foregoing, the evidence fails to prove that either the APCO survey or the Synovate survey is valid for the purpose of drawing conclusions about consumers’ beliefs and/or opinions regarding the time a “biodegradable” product will take to decompose. Both Dr. Frederick and Dr. Stewart agree that the APCO and Synovate surveys are flawed because they ask closed-ended questions. F. 489, 492-493. As noted above, closed-ended questions limit the range of acceptable responses, while open-ended questions allow consumers

to offer responses in their own words. F. 327-335. The subject of public perception of biodegradation and biodegradation of plastics as a field of consumer survey research has not been researched extensively. F. 327. Given the current understanding and state of knowledge with respect to consumer perception of biodegradation, open-ended questions are much more suitable, appropriate, and informative than closed-ended questions. F. 328, 456. Indeed, when beginning consumer perception work in a new area, open-ended questions are essential. F. 329. Use of open-ended questions and interviews early in the exploration of a topic, such as biodegradability, helps surveyors be sure that, when they do finally design closed-ended questions, they give people the full array of response options. F. 332. As the Commission noted in *Telebrands*, “[o]pen-ended questions allow survey participants themselves to articulate the central claim or claims in the ad” 140 F.T.C. at 318. “Marketing experts have found that credible evidence comes in response to open-ended questions, just as in trials where the unbiased testimony comes after direct, non-leading questions.” *Stouffer*, 1994 FTC LEXIS 196, at *59.

Closed-ended questions, because they limit the choices for response, can result in a misleading homogeneity of responses. F. 334-335. Misleading homogeneity adversely affects the validity of the answers to both APCO question 4 and Synovate question 19. F. 467-468, 474, 491. By way of illustration, four of the six time period response options to APCO question 4 state a period of one year or less, while only two response options are longer than two years. F. 467-468. APCO survey question 4 is invalid as inherently biased because it offers many more opportunities to select an answer that reflects one year or less than an answer that reflects a longer time period. F. 467, 471. Because two-thirds of the time period response options were one year or less, the response options predisposed people to select a short time frame, rather than a longer time frame. F. 467, 472. Both experts agreed that the allocation of response options for APCO survey question 4 is a significant problem and renders the question inherently biased. F. 467-470. Even random responses to APCO question 4 would result in 66% (two-thirds) of the responses falling into one of the four choices of one year or less. F. 473. Against this background, the fact that 60% of respondents selected one of those options is not entitled to significant weight. Indeed, the evidence supports Dr. Stewart’s opinion that the APCO survey is invalid for the purpose of drawing conclusions about people’s perceptions

about how long biodegradation takes, because it fails to provide adequate opportunity for consumers to offer their perceptions, yet at the same time provides response options that are biased in favor of the “one year” time period. F. 477.

In addition, Dr. Frederick also found fault with the use of the word “should” in APCO question 4 (“what should be the maximum amount of time that it should take” for a package to decompose). F. 476. Use of the word “should” in APCO question 4 could be interpreted by survey respondents “as referring to what would be desirable, as in, ‘*Wouldn’t it be nice* if packages decomposed this quickly,’ rather than assessing their judgment of how long such decomposition would, in fact, take.” F. 476. Dr. Frederick ultimately agreed that the validity of the APCO survey could not be determined, notwithstanding his apparently contrary opinion in his expert report. F. 478. For all the foregoing reasons, the APCO survey is entitled to, and is given, little weight. F. 479.

Complaint Counsel’s expert, Dr. Frederick, pointed out that Synovate question 19 is also flawed because it asks the respondents what they believe is a “reasonable” amount of time for biodegradation, which creates a potential problem because the word “reasonable” could be interpreted to be asking the respondent what he or she “would like to happen, what kind of product should be produced,” or what is “a goal” to which “we should aspire.” F. 488. Dr. Frederick and Dr. Stewart agreed that misleading homogeneity also adversely affects the validity of the answers to Synovate question 19, although the response options are biased toward a longer time period for degradation, rather than a shorter time period, as was the case with APCO question 4. F. 491.

It should be noted that the FTC was critical of both the APCO and the Synovate surveys, which it reviewed in connection with its adoption of the “one-year” guideline for “unqualified” biodegradable claims in the revised Green Guides. *See* F. 238, 481, 495-496. Specifically, in connection with the proposition that consumers expect products labeled “biodegradable” to completely biodegrade in a landfill in less than one year, the Commission stated that both the APCO and Synovate surveys “may be faulted for lacking control groups and presenting the timeframe questions with close-ended, rather than open-ended, answers, but they nevertheless are the only studies in the record.” F. 496 (citing Statement of Basis and

Purpose, Revised Green Guides, available at <http://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-green-guides/greenguidesstatement.pdf> at 121 n.409 (“Statement of Basis and Purpose”). With respect to the Synovate survey in particular, the Commission found that the “results suggest that respondents’ answers may have been not only biased but also influenced by a tendency to avoid extreme answers. As a result, reliable real-world conclusions cannot be drawn from the Synovate survey.” F. 495. The Commission declined to rely on the Synovate survey, finding it less reliable than the APCO survey. Statement of Basis and Purpose, *supra*, at 121.

(c) Summary and conclusions as to APCO and Synovate surveys

For all the foregoing reasons, the APCO and Synovate surveys are entitled to, and are given, little weight. First, none of the survey questions inquired whether or not a claim of “biodegradable” communicates any message to the consumer about a rate for complete biodegradation. Instead, the questions effectively assumed that a representation of “biodegradable” implied a rate for complete degradation, and only assessed consumers’ estimates or beliefs as to such biodegradation rate. In this regard, the surveys shed little or no light on the material issue in this case of whether Respondent’s claim that ECM Plastics are biodegradable conveys any message about the time period for complete biodegradation in the first instance, much less a time period of less than one year.

Moreover, to the extent consumer beliefs or estimates about how long it takes for a biodegradable item to decompose are indirectly relevant to the material issue in this case, the evidence demonstrates that the APCO survey and the Synovate survey are both so seriously flawed that, for the purpose of drawing conclusions about such consumer beliefs, the surveys are either invalid or, at best, entitled to little weight. Dr. Frederick’s opinions that, notwithstanding their many, significant flaws, the APCO and Synovate surveys are “reasonably reliable and valid,” are unsupported and unpersuasive, and are rejected. However, even if these opinions were accepted, “reasonable reliability and validity” is not a ringing endorsement of any survey. As noted in Section III.D.4.b.iv.(a), above, reasonable reliability and validity is the *minimum* standard that must be met for a consumer survey even to be considered by the trier of fact, given that consumer surveys are “obviously hearsay.” *In re Bristol-Myers Co.*, 85 F.T.C.

688, 1975 FTC LEXIS 218 at *127-128 (Apr. 22, 1975). Meeting this bare minimum does not entitle the surveys to any particular weight, and the extensive flaws in these studies detract from any weight to be given the results. *See POM*, 2013 FTC LEXIS 6, at *49 (stating that perfect survey methodology is not required, but flaws in the methodology affect the weight that is given to the results). Indeed, in the more credible opinion of Dr. Stewart, the APCO and Synovate surveys have little probative value beyond suggesting that there is variability in what consumers understand about biodegradability. F. 497.

Accordingly, regardless of whether the APCO and Synovate surveys support a conclusion that consumers believe that biodegradable items will biodegrade in a landfill, the APCO and Synovate surveys carry little weight on the question of whether the evidence proves that a significant minority of reasonable consumers would view Respondent's claims that ECM Plastics are (1) "biodegradable" or (2) "biodegradable in some period greater than a year," as conveying an implied claim that ECM Plastics will completely biodegrade into elements found in nature, in a landfill, within one year.

vi. Convergent validity

Based on the opinions of its expert, Dr. Frederick, Complaint Counsel argues that there is "convergent validity" among the Google survey, the APCO survey, and the Synovate survey, such that, taken together, the evidence demonstrates that 35% of consumers believe that plastic products labeled "biodegradable" will biodegrade within one year. CCB at 32.³⁴ Dr. Frederick testified that he could not determine whether or not the APCO study yielded accurate, *i.e.*, "valid," results regarding people's perception of how long things take to biodegrade, because:

[Dr. Frederick] I don't know what that answer is. There's no gold standard. I can't go out and knock on doors and actually find out whether there's a cat there or not, for example, from the earlier case to determine whether those numbers that I've gotten are matching the truth

³⁴ Complaint Counsel also contends that the survey by Respondent's expert, Dr. Stewart, provides "convergent validity" for the results of the APCO, Synovate, and Google surveys; however, as shown below, Dr. Frederick's convergent validity theory was expressly based on the purported "convergence" of results of the APCO, Synovate, and Google surveys, and does not refer to the results of Dr. Stewart's survey. Thus, Complaint Counsel provides no support for relying on Dr. Stewart's survey to support the "convergent validity" of Complaint Counsel's proffered surveys.

about the world, so I don't know whether that survey is valid or not. I would need to do additional analyses.

Q: You referenced additional analysis. . . . [W]hat, if anything, can be done to ascertain the validity of APCO?

A: So often in cases like this where the construct of interest is not something readily determinable by some other method, you need to compare the results of one survey to the results of other surveys and see whether in fact. . . those results are giving you the same result, the same fact. That's sort of known as convergent validity. Different surveys are yielding the same result. And as you do different surveys -- if different surveys using different designs conducted by different people at different times, independent surveys, are yielding the same results, then you can gain confidence that those results are valid, that they're measuring what they intend to measure.

(Frederick, Tr. 1042-1043). Thus, in an effort to validate the APCO results, Dr. Frederick undertook his Google survey. *See* F. 353.

Dr. Frederick went on to testify as to what he believed were similar results achieved among results from the Google survey, the APCO survey, and the Synovate survey. Dr. Frederick concluded that these three surveys were conducted independently of one another, at different times, and used different designs ("phone, Internet survey, Google Consumer Surveys"), yet yielded "results which are qualitatively comparable to one another and therefore I think providing evidence of convergent validity of the results obtained." Frederick, Tr. 1143-1145, 1155, 1173. *See also* CCX 865 (Frederick Rebuttal Expert Report at 13) ("Though the APCO and Synovate questions differ . . . the important fact remains that both of these studies -- and my own [Google survey] -- all yield fairly similar results, *despite* those differences. This correspondence -- what is known as 'convergent validity' -- is powerful evidence of the validity of the collective results.") (emphasis in original).

With respect to Complaint Counsel's assertion that, based on convergent validity of the APCO, Synovate, and Google surveys, 35% of consumers believe that plastic products labeled "biodegradable" will biodegrade within one year, Dr. Frederick testified as follows:

Q: [W]hat was the range of percentages of respondents giving year or less responses [to questions 3A-3K of the Google survey]?

A -- that ranged from 20 percent to 52 percent.

Q. Now, Professor, what, if anything, does that range tell you about the validity of APCO and Synovate?

A. Well, if you take the center of that range, you know, 35 percent, this is giving -- this is looking a lot like the results that APCO and Synovate obtained using different methodologies. . . . This can be an illustration of that when you have different studies using different methodologies conducted by different investigators at different times using slightly different question wording, different images, and so forth, and yet in all these cases you're getting estimates that are, you know, on the order of a third.

Frederick, Tr. 1155.

Respondent argues that the Google, APCO, and Synovate surveys do not have "similar" results, but even if they do, the convergent validity theory should not apply because each of the three surveys is fatally flawed. RRB at 24-25. Respondent further argues that accepting the convergence validity theory, based on flawed sources of data, creates an unacceptable risk of "imposing legally binding obligations based on unreliable (and thus likely incorrect) survey data" and that the precedent would result in future cases being focused, not on whether the surveys at issue are valid, but on whether such invalid results are sufficiently "similar" to become valid. "The exercise invites departure from reason and logic to become institutionalized as the norm." RRB at 26.

For purposes of the weight to be given to the Google, APCO, and Synovate surveys on the issue of whether Respondent made the alleged Implied One Year Claim, the whole is no greater than the sum of its parts. As explained above, *see* Section III.D.4.b.v.(b), APCO question 4 and Synovate question 19, the pertinent questions upon which Complaint Counsel relies for convergent validity, are each seriously flawed, and Complaint Counsel's expert, Dr. Frederick, agrees with Respondent's expert, Dr. Stewart, that these questions are flawed. The Commission, in issuing the revised Green Guides, acknowledged the flaws in the APCO and Synovate surveys, and further stated that "[r]eliable real world conclusions cannot be drawn from the Synovate study." F. 495-496. As analyzed earlier, the evidence demonstrates that the APCO survey and the Synovate survey are both so seriously flawed that, for the purpose of

drawing conclusions about consumers' beliefs and/or opinions regarding the time a biodegradable product will take to decompose, the surveys are either invalid or, at best, are entitled to little weight. Dr. Frederick's convergent validity theory is based on the assumption that the Google survey results are valid and can thereby somehow cure the APCO and Synovate surveys. However, the Google survey is itself so seriously flawed that no valid conclusions can be drawn from it. *See* Section III.D.4.b.iv. It defies logic to contend that three flawed surveys can somehow rehabilitate one another and create probative weight that otherwise does not exist, on the ground that the results are "fairly similar." Indeed, what is similar in all three surveys is a lack of validity. Accordingly, based on the foregoing, Dr. Frederick's opinions regarding the application of the theory of convergent validity to the survey evidence in this case are unsupported and unpersuasive, and are, therefore, rejected.

In addition, the evidence does not show that results of the three surveys are similar with respect to whether consumers believe biodegradable items will biodegrade in less than one year, such that the convergent validity theory would even be applicable. As noted above, 60% of the responses to APCO question 4 indicated they "believe" that less than one year "is a reasonable amount of time" for a plastic product to biodegrade in a landfill, while only 25% of the responses to Synovate question 19 indicated less than one year. F. 463, 486. The Google responses to similar questions about estimated biodegradation times for plastic products, as calculated by Dr. Frederick, yielded a range from 20% to 52%. F. 435-447. Accordingly, the results are not similar for purposes of the convergent validity theory.

Moreover, there is also no legal precedent for permitting the results of seriously flawed surveys to validate one another for purposes of evidentiary proof in an adjudication. Complaint Counsel relies on *In re Bristol-Myers Co.*, 85 F.T.C. 688, 1975 FTC LEXIS 218 (1975), and *In re American Home Products*, 98 F.T.C. 136, 1981 FTC LEXIS 21 (1981) (Initial Decision) for the proposition that the Commission and ALJs have recognized that convergence of results from different consumer perception studies "confirms that they are 'reasonably reliable and probative.'" CCB at 31. In *Bristol-Myers*, the Commission held that the results of test marketing reports conducted by the respondents were properly admitted for their truth, over any hearsay objection, because they were "reasonably reliable and probative." 1975 FTC LEXIS 218, at *127. The Commission relied on ten supporting factors cited by the ALJ, including that

all three research organizations were experienced in taking such surveys; the respondents had used the research organizations to perform similar work for years; the surveys appeared to have been performed in the usual manner for surveys of that type; those conducting the interviews were experienced and trained; the surveys employed controls and validation procedures; the samples were drawn to be reasonably representative; there was no incentive to be biased; and, finally, “the surveys are from independent sources and [the results] tend to confirm one another.” 1975 FTC LEXIS 218, at *128 n.14.

In the instant case, in contrast to *Bristol-Myers*, the evidence fails to show that the APCO, Synovate, and Google surveys are valid for the evidentiary purposes urged by Complaint Counsel. Moreover, the characteristics of these surveys have little in common with the characteristics cited by the Commission as supporting the reliability and validity of the test reports in *Bristol-Myers*. Among other things, Google is not an experienced survey organization, and Google surveys are a relatively new and untested product, F. 363; closed-ended questions as used in the APCO and Synovate surveys are not an appropriate way of conducting consumer perception surveys on the meaning of biodegradability, F. 327-335; it is not appropriate to use a single question to assess consumer perception of biodegradability, as used in Dr. Frederick’s Google survey, F. 372, or to eliminate survey responses that do not meet predetermined acceptable responses, F. 396-399, 403-404; there were no interviewers for the Google survey, much less “experienced and trained interviewers,” F. 368; and the Google survey sample was not demonstrated to be representative of the relevant population. F. 409-430. Accordingly, even if it could be argued that the results of the three surveys in this case are similar – which is not apparent – this is not a sufficient basis for assigning the surveys greater probative weight than they would otherwise have.

In *American Home Products*, cited by Complaint Counsel, the ALJ held that the respondent made numerous express and implied claims as to the efficacy of its over-the-counter pain reliever, Anacin, without adequate substantiation. 1981 FTC LEXIS 21, at *316-408. As a remedy for this violation, Complaint Counsel sought an order for corrective advertising, which required a showing that members of the purchasing public held images of Anacin’s superior efficacy and as a tension-reliever, that such images were attributable to the

respondent's false advertisements, and that the images would endure without corrective advertising. 1981 FTC LEXIS 21, at *241. Complaint Counsel relied on certain "consumer image" studies to support the requested remedy. The ALJ found that "[t]he various methodological flaws in each of" the relevant consumer image studies were "not fatal," and accepted expert opinion testimony that, even though "each of the commercial image studies could not, standing alone, serve as the basis for any conclusion regarding Anacin's image . . . the four studies could, standing together, provide a basis from which to make conclusions regarding Anacin's image." *Id.* at *251-52.

The ALJ concluded, however, that the fact that respondents had disseminated the challenged advertising for a long period of time supported the conclusion that consumers held an image of Anacin as being a superior pain reliever and a tension reliever, and that the inference was only "confirm[ed] by some empirical data in this case although such empirical evidence is less than overwhelming." *Id.* at *410. Thus, to the extent that the ALJ in *American Home Products* gave any weight to the flawed consumer image studies, it was not for the purpose of finding that the respondent made the challenged claims, as urged in the instant case, but for determining the appropriate remedy. Moreover, the ALJ cited the flawed studies only as "confirming" what other evidence already established, while in the instant case, Complaint Counsel urges reliance on seriously flawed studies as the sole evidence establishing an implied claim that is not at all inferable from the most significant evidence in the case – the challenged advertisements themselves. Accordingly, *American Home Products* does not support applying the theory of convergent validity to the flawed APCO, Synovate, and Google survey results.

vii. Dr. Stewart's survey

(a) Introduction

In the spring of 2014, in connection with his work for Respondent in this case, Dr. Stewart performed a 400-participant landline telephone survey, which included questions designed to ascertain how representative consumers who purchase products made from or packaged in plastic perceive the meaning of the term "biodegradable." F. 498-502.

Complaint Counsel contends that Dr. Stewart's data proves Complaint Counsel's factual assertion that substantial numbers of consumers "understand 'biodegradable' to imply within one year," CCB at 48-50, and at the same time argues that Dr. Stewart's survey "is grossly flawed," for the purposes of supporting Respondent's contrary factual position. CCB at 51-54. Specifically, Complaint Counsel argues that: (1) 33% of survey respondents who reported an estimated rate for biodegradation in response to question 4 of Dr. Stewart's survey, believe that a biodegradable product will take one year or less to decompose or decay (Complaint Counsel's "33% calculation"); and (2) question 5b of Dr. Stewart's survey, which presented respondents with the text of ECM's claim of biodegradation in "some period greater than a year," shows that 50% of survey respondents that perceived any biodegradation rate message in the claim, estimated one year or less (Complaint Counsel's "50% calculation"). CCB at 32, citing CCF 201-207. Respondent rejects Complaint Counsel's calculations as a grossly inappropriate manipulation of Dr. Stewart's raw data. RRB at 61-63.

Based on the results of Dr. Stewart's survey and Dr. Stewart's opinions associated therewith, Respondent asserts that no significant percentage of consumers thinks that products labeled "biodegradable" will degrade within one year, or any specific time frame; consumers have no shared understanding of the meaning of the term "biodegradable"; most consumers recognize differences in the rate of decomposition, and that the rate is dependent on the type of material, context, or disposal environment; and consumers understand that biodegradation is not necessarily a rapid process. RB at 43-44, 47-48. Respondent argues that Dr. Stewart's survey was well-designed, relied on clear, open-ended questions, and closely adhered to established principles of survey research. RB at 44-47. Complaint Counsel responds that Dr. Stewart's questions were confusing and that the survey sample was "psychographically and demographically unrepresentative" because it consisted only of landline telephone users. CCB at 51-54.

(b) Complaint Counsel's statistical analysis of Dr. Stewart's data

Complaint Counsel cites question 4 of Dr. Stewart's survey, which asked: "If something is biodegradable, how long do you think it would take for it to decompose or

decay?” CCB at 48. However, Complaint Counsel asserts that of the 400 survey respondents, “a majority (206) gave codeable estimates,” and of those respondents, 33% “gave estimates of one year or less.” *Id.* Complaint Counsel does not explain what it means by “codeable estimates.” In Dr. Stewart’s survey, unlike in Dr. Frederick’s Google survey, every response was coded, and his codes classified the actual responses of the survey participants. F. 392-395, 507. Complaint Counsel’s 33% calculation excludes the many responses of “I don’t know” and “it depends,” as well as all other responses that did not give a “quantifiable time estimate.” CCB at 48 n.49. In this regard, it is clear that Complaint Counsel is applying Dr. Frederick’s flawed “bright-line” numerical coding rule to Dr. Stewart’s data. *See* F. 392-393. As noted above, it is inappropriate to ignore survey responses that do not fit into the desired result, or to “force-fit” responses into a pre-existing structure. F. 396-397. Ignoring significant portions of data in computing statistics misrepresents the data. F. 397, 403. Complaint Counsel’s 33% calculation eliminates nearly half of the responses to question 4, including facially legitimate answers, such as “I don’t know,” or “it depends,” and misleadingly inflates the percentage of survey responses allegedly supporting Complaint Counsel’s position. *See* F. 398-400. Therefore, in this regard, Complaint Counsel’s manipulation of Dr. Stewart’s survey is improper and is rejected.

To support its 50% calculation, Complaint Counsel relies on responses to question 5b of Dr. Stewart’s survey. Question 5b read the following to survey participants: “Plastic products manufactured with our additives will biodegrade in any biologically-active environment (including most landfills) in some period greater than a year.” The interviewer then asked: “In your own words, what does this claim mean to you?” *See* RX 602 (Stewart Expert Report Appendix B). Complaint Counsel asserts that out of the 400 survey respondents, 150 included a time component in their answer, and that 50% of these mentioned “one year.” However, this 50% calculation that Complaint Counsel derived from the responses to question 5b fails for the same reasons as the 33% calculation that Complaint Counsel derived from the responses to question 4. Complaint Counsel eliminates from the sample over half of the responses, and ignores survey responses that do not fit into its desired structure. F. 396-397. This selective data analysis misleadingly inflates the percentage of survey responses allegedly supporting

Complaint Counsel's position, and misrepresents the data. F. 396-398.³⁵ Accordingly, Complaint Counsel's data analysis of question 5b of the Stewart survey is rejected.

(c) Dr. Stewart's findings and conclusions

The evidence shows that Dr. Stewart's survey was designed and conducted in accordance with generally accepted principles of survey research, F. 542, 552, including, among other things, the drawing of a representative sample of a relevant population, F. 515-528, 543-544; the use of open-ended, non-leading questions, F. 537-539; the use of trained interviewers, F. 512, 532-534; and the use of trained and experienced coders who were "blind" to the sponsor and purpose of the research and who coded all responses received. F. 508-509, 529-531, 535-536.

Of all the survey evidence introduced in this proceeding, only Dr. Stewart's survey asked survey respondents to describe what "biodegradable" means to them. Specifically, question 1 of Dr. Stewart's survey asked, "When you hear the term 'biodegradable' what does that mean to you?" Eighty-two percent of the survey respondents replied with something about disintegration, decomposition, or breakdown. The remaining 26% of survey respondents mentioned something about safety, but the majority of these respondents also mentioned something about breaking down or decomposition. F. 546. These findings weigh heavily against a conclusion that a significant number of reasonable consumers would interpret a biodegradable claim to be communicating that the biodegradable item will biodegrade completely within one year.

In addition, the responses to question 4 of Dr. Stewart's survey, which asked, "[i]f something is biodegradable, how long do you think it would take for it to decompose or decay," weigh against Complaint Counsel's assertion that a significant number of reasonable consumers believe a biodegradable item will biodegrade completely within one year. Question 4 elicited a very wide range of responses. F. 548. The most common answer by far, offered by 39% of the survey respondents, was that biodegradation time depends on the material or type of

³⁵ The distribution of the total responses to question 5b are set forth in Appendix D to Dr. Stewart's Expert Report, RX 605 at 26-27. Complaint Counsel does not argue that any percentages derived from the total responses to question 5b constitute a "significant minority" of consumers who would interpret Respondent's claim that ECM Plastics are biodegradable in "some period greater than a year" to mean "less than one year."

product. No other single response was offered by more than 6% of the respondents. F. 549. Other responses referred to differences in materials or context: 6% stated that paper degrades faster; 6% stated that plastic does not degrade or takes a long time to degrade; 5% indicated that it depends on the climate or other conditions, or on the method of disposal; 3% indicated that vegetation decomposes more quickly; and 3% stated that it depends on size. F. 549. In total, 68% of the survey respondents gave answers to question 4 that indicate recognition of differences in the rate of decomposition related to type of material and/or the context. F. 549. This evidence is contrary to the notion that consumers believe “biodegradable” items will decompose completely within one year, and fails to support a conclusion that a significant minority of reasonable consumers would interpret a claim that an item is “biodegradable” to be communicating the message that the biodegradable item will biodegrade completely within one year.

Based on the foregoing, Dr. Stewart’s survey amply supports Dr. Stewart’s conclusions that consumers interpret the term “biodegradable” to mean the process by which a product breaks down or decays; and consumers understand that the time for this process varies depending on the materials involved and that the process of biodegradability is not always, or even often, a rapid process. F. 554. In fact, based on Dr. Stewart’s survey, no significant minority of Americans define “biodegradation” to mean that a product will completely biodegrade into elements in nature within one year after customary disposal. F. 555. In addition, based on Dr. Stewart’s survey, there is little evidence that consumers’ understanding of biodegradability is restricted to decomposition processes that occur within one year or less. F. 556. Indeed, not one respondent to Dr. Stewart’s survey understood biodegradation to mean the complete breakdown of the substance into elements in nature within one year after customary disposal. F. 553. The foregoing credible and persuasive evidence weighs heavily against Complaint Counsel’s contention that a significant number of reasonable consumers interpret a “biodegradable” claim to mean the item will completely decompose into elements found in nature, in a landfill, within one year.

(d) Complaint Counsel's objections to Dr. Stewart's survey

Complaint Counsel asserts that Dr. Stewart's survey does not provide probative evidence that is contrary to Complaint Counsel's Implied One Year argument. Complaint Counsel argues that Dr. Stewart failed to ask "the most important question," which to Complaint Counsel is, "how much time will it take for plastic labeled 'biodegradable' to degrade?" CCB at 52. As noted above, however, the preliminary, fundamental question for purposes of the Implied One Year Claim is whether a claim of "biodegradable" implies any rate for complete biodegradation at all. The question, "how much time will it take for plastic labeled 'biodegradable' to degrade," improperly presumes that a claim of "biodegradable" implies a rate for complete biodegradation and assesses only what the survey respondent thinks, believes, or estimates is a correct rate. Moreover, question 4 of Dr. Stewart's survey did, in fact, ask respondents to state "how long" they think it will take for a biodegradable item to decompose or decay. Complaint Counsel offers no support, including any expert opinion, for finding that question 4 of Dr. Stewart's survey is not probative, merely because it did not specifically ask "how much time will it take for plastic labeled 'biodegradable' to degrade?"

Complaint Counsel further contends that Dr. Stewart's survey used a sample that was not psychographically or demographically representative. CCB at 53-54. With respect to demographic representativeness, Complaint Counsel asserts that 40% of households do not have landline telephones (*see* CCX 865 (Frederick Rebuttal Expert Report at 4); Frederick, Tr. 1086); that 4,000 potential survey respondents hung up and declined to participate in Dr. Stewart's survey (Stewart, Tr. 2702); that 58% of respondents to Dr. Stewart's survey were over age 50, while only 48%-50% of Americans are over age 50 (Stewart, Tr. 2728); that older Americans are primarily white, which resulted in a survey sample that undersampled Hispanics and other minorities (*see* Stewart, Tr. 2728-2729); and that Dr. Stewart limited participants to those over the age of 18. F. 522. Even if it is accepted as fact that Dr. Stewart's survey sample was slightly older than the population-at-large, Complaint Counsel fails to demonstrate how this flaw is so significant that it detracts significantly from the weight to be given to the survey results. It is also noteworthy that, even if Dr. Stewart's sample was slightly older than the

population-at-large, the sampling was at least based on actual demographic information, which is better than the inferred demographics methodology employed by Dr. Frederick's Google survey. *Compare* F. 522, 526-528, 542-543 *with* F. 409-425. Thus, even if flawed, Dr. Stewart's survey sampling methodology is clearly superior to the methodology of the Google survey.

Complaint Counsel contends that Dr. Stewart's telephone landline sample is psychographically unrepresentative because "relatively few consumers are willing to take a survey lasting as long as twenty minutes without compensation." CCB at 53. However, the evidence cited by Complaint Counsel to support this proposition is inapposite. *See* CCFF 390. Dr. Frederick defined "psychographic representativeness" to mean that the "sample reflects the psychological characteristics – those might be beliefs or attitudes or opinions – of the population about which you're trying to draw an inference." (Frederick, Tr. 1395). Regarding the psychographic representativeness of Dr. Stewart's survey sample, Dr. Frederick opined that the sample was "probably not psychographically representative. One of the psychographic characteristics that would likely differ is their attitudes towards technology, for instance. I would expect that they would have less familiarity with . . . technology, cellular devices, Web browsing, so forth." (Frederick, Tr. 1391). Dr. Stewart's survey, however, did not seek to assess attitudes toward any of the foregoing topics. Thus, Dr. Frederick's opinion is immaterial and does not support rejecting Dr. Stewart's survey results as "psychographically unrepresentative."

(e) Summary and conclusions as to Dr. Stewart's survey

Dr. Stewart's survey does not support a finding that a significant number of reasonable consumers would interpret Respondent's claims that ECM Plastics are (1) "biodegradable," or (2) "biodegradable" in "some period greater than a year," to convey the message that ECM Plastics will completely biodegrade in a landfill within one year, as argued by Complaint Counsel. Rather, Dr. Stewart's survey constitutes substantial contrary evidence that consumers interpret the term "biodegradable" to mean the process by which a product breaks down or

decays, which is not restricted to decomposition processes that occur within one year.³⁶

c. Totality of the evidence on Implied One Year Claim

Complaint Counsel contends that Respondent’s claim that ECM Plastics are (1) “biodegradable,” and (2) “biodegradable” in “some period greater than a year,” impliedly claimed that ECM Plastics will completely biodegrade into elements found in nature, in a landfill, within one year. Whether an advertisement conveys an implied claim “is a question of fact,” derived from a review of the advertisements themselves, and an evaluation of any extrinsic evidence introduced by the parties. *POM*, 2013 FTC LEXIS 6, at *44; *Thompson Medical*, 104 F.T.C. at 794. The primary evidence of the representations that an advertisement conveys to reasonable consumers is the advertisement itself. *POM*, 2013 FTC LEXIS 6, at *21.

In the instant case, the plain language used in Respondent’s Marketing Materials and logo does not state that ECM Plastics will completely breakdown into elements found in nature, in a landfill, within one year. Moreover, there are no additional elements of the materials at issue, such as the juxtaposition of phrasing or associated images, that support a finding that the language, (1) “biodegradable” or (2) “biodegradable” in “some period greater than a year,” is reasonably interpreted to be conveying the Implied One Year Claim. Based on a facial analysis alone, Respondent’s “biodegradable” and “biodegradable” in “some period greater than a year” claims do not, in fact, imply that ECM Plastics completely biodegrade into elements found in nature, including in a landfill, within one year.³⁷ F. 243, 258. As the primary evidence of the meaning of Respondent’s representations, the fact that the advertisements themselves do not support the Implied One Year Claim is given substantial weight.

³⁶ Complaint Counsel also alludes to the results of a 10 respondent survey of certain ECM Customers (the “Manufacturers Pilot Study”), asserting that 3 out of the 10 manufacturer respondents indicated “that they understood biodegradation as something that happens in less than a year or referenced tests (ASTM D5511 and D6400) that are run for less than a year.” CCB at 54, citing CCF 412. The Manufacturers Pilot Survey upon which Complaint Counsel relies is too small from which to draw any valid conclusions. F. 557-565.

³⁷ Indeed, it is arguably absurd to suggest that reasonable consumers would infer that a claim that a product is “biodegradable in some period greater than one year,” means that a product will completely biodegrade into elements found in nature, in a landfill, in less than one year.

In addition, the foregoing facial analysis is supported and confirmed by the ordinary meanings of the term “biodegradable,” based on the dictionary definitions, as “capable of being slowly destroyed and broken down into very small parts by natural processes, bacteria, etc.” or “capable of being broken down especially into innocuous products by the action of living things (as microorganisms).” *Merriam-Webster.com, supra. See Thompson Medical, 1984 FTC LEXIS 6, at *359.* Nothing in the foregoing definitions supports a conclusion that a significant minority of reasonable consumers would interpret “biodegradable,” to mean completely breakdown into elements found in nature, in a landfill, within one year. This evidence also weighs heavily against finding an Implied One Year Claim.

Accordingly, given the strength of the evidence summarized above, it was incumbent on Complaint Counsel to demonstrate with probative, persuasive evidence that Respondent’s claim that ECM Plastics are “biodegradable,” and “biodegradable” in “some period greater than a year,” notwithstanding the plain language, conveyed to a significant number of reasonable consumers the message that ECM Plastics will completely biodegrade into elements found in nature, in a landfill, within one year. Complaint Counsel’s survey evidence fails to accomplish this task. First, Complaint Counsel did not provide any “copy test” evidence indicating that consumers viewing Respondent’s “biodegradable” claims take away the message that ECM Plastics completely breakdown into elements found in nature within one year. *Compare Telebrands, 140 F.T.C. at 316-17* (noting that survey participants were shown an advertisement twice and asked a series of open-ended questions which “asked consumers to state in their own words what they perceived in the ads”); *Stouffer, 1994 FTC LEXIS 196, at *23 n.21, *30* (describing questions about “what point” the advertisement was making and “what reason” the advertisement gives for buying Lean Cuisine). *See also Kraft, 1991 FTC LEXIS 38, at *24, n.13* (relying in part on consumer survey that showed the advertisement to respondents and asked: “Does this ad say or suggest anything about the amount of calcium in a slice of Kraft Singles compared to the amount of calcium in five ounces of milk?”). Such copy test evidence is direct evidence of what consumers actually think upon reading an advertising claim in issue, and, therefore, is “[t]he extrinsic evidence we prefer to use and to which we give great weight” *Thompson Medical, 1984 FTC LEXIS 6, at *315.* Regardless of whether such copy test

evidence is legally required, the absence of this preferred, direct evidence of consumer claim interpretation amplifies the weakness of Complaint Counsel's position.

Second, Complaint Counsel's survey evidence – which purports to show that consumers “understand” or “expect” or “believe” that items labeled “biodegradable” will completely breakdown into elements found in nature, in a landfill, within one year – is weak. This consumer “perception” evidence did not, in fact, assess whether consumers “perceived” ECM's claims to imply any particular biodegradation rate. Rather, the evidence proceeds from the assumption that a biodegradation rate is necessarily implied by use of the term “biodegradable,” and does not address the question of whether Respondent made any implied rate claim in the first place.

Furthermore, to the extent that consumer beliefs about biodegradation rates are indirectly material to the implied meaning of Respondent's claims, the APCO, Synovate, and Google surveys are of insufficient methodological quality to draw any reliable conclusions in this regard. *See Kraft*, 1991 FTC LEXIS 38, at *30-34 (holding that evidence failed to show that advertising impliedly claimed Kraft Singles' superiority over imitation cheese where conclusion was not apparent on the face of the advertisement, or supported by reliable survey evidence or persuasive expert testimony); *Thompson Medical*, 1984 FTC LEXIS 6, at *365-67 (holding that complaint counsel failed to meet burden of proving that certain advertisements implied that Aspercreme is superior to aspirin, where ads did not refer to attributes of aspirin and expert testimony did not support implied claim); *In re Coca Cola Co.*, No. 8839, 1973 FTC LEXIS 245, at *114-24 (Oct. 5, 1973) (holding that evidence failed to prove that claims in “Hi-C” fruit drink advertisements that Hi-C was “high” in Vitamin C and a “sensible” drink implied that Hi-C was comparable to citrus juices, including orange juice, where advertisements did not mention other juices and consumer survey failed to support the implied claim, notwithstanding survey evidence showing that consumers identified orange juice as the one beverage believed best fit the phrase, “highest in Vitamin C”).

In addition, the responses to Dr. Stewart's survey show that consumers interpret the term “biodegradable” to mean the process by which a product breaks down or decays, and do not infer from the term any particular time period, much less a rapid time period. This survey

evidence, which is of high methodological quality, is consistent with the common meaning of the term “biodegradable,” noted above, and inconsistent with the Implied One Year Claim. For this reason as well, the extrinsic evidence in the case fails to prove the Implied One Year Claim.

Accordingly, based on the totality of the evidence, Complaint Counsel has failed to prove the Implied One Year Claim. Rather, to find such an implied claim would be to “inject novel meanings into ads,” which is improper. *Bristol-Myers*, 1983 FTC LEXIS 64, at *249.

E. SUBSTANTIATION

1. Overview

As analyzed above, the evidence shows that Respondent made the Challenged Claims that ECM Plastics are “biodegradable,” including in a “landfill,” and, that ECM Plastics would fully biodegrade in a landfill within “9 months to 5 years.” The evidence also shows that Respondent claimed that independent testing proves ECM Plastics are “biodegradable” and would fully biodegrade, including in a landfill, within “9 months to 5 years.”

Having determined that Respondent disseminated advertisements conveying claims alleged in the Complaint and challenged in this case, the second step in the analysis of whether Respondent violated the FTC Act is to analyze whether the Challenged Claims are false or misleading. *POM*, 2013 FTC LEXIS 6, at *18-19 (citations omitted). In order to analyze whether the Challenged Claims are false or misleading, a review of the evidence presented on landfill conditions and a determination of the meaning of the term “biodegradable” is necessary. Following that evaluation, the legal standards for analyzing whether a claim is false or misleading are addressed. Then, the Initial Decision analyzes what constitutes competent and reliable scientific evidence to substantiate the Challenged Claims and whether Respondent possessed competent and reliable scientific evidence substantiating its claims.

2. Landfill Conditions

Landfilling is the largest management option for municipal solid waste (“MSW”) in the United States, with about 54 percent of solid waste managed in that capacity. F. 566. Both

parties' experts agree that landfills are dynamic and heterogeneous environments. F. 569-573. It is very difficult to describe a "typical" landfill. F. 571. The range of moisture content, temperatures, and oxygen levels in landfills can be considerable. F. 572. Thus, with respect to microbial composition, it would be unreasonable to expect or identify a "one-size-fits-all" description of an MSW landfill; the diversity of potential environments presented in landfills is vast, with many variables, which, in turn, leads to proliferation of many different types of microorganisms. F. 573.

Landfills often have major temperature variations, even within the same landfill. F. 575. A landfill in a hot climate, such as Florida, would have a higher temperature than a similar landfill in a cold climate, such as Alaska. F. 574. Landfills often also have major variations in moisture content. F. 586. A landfill in Florida, where it rains a lot, will have a higher moisture content than a landfill in Arizona, where there is hardly any rain. F. 587. In addition, within each landfill, there can be pockets of dry areas as well as pockets of very moist areas. F. 588.

Researchers have identified many specific microorganisms that populate MSW landfills. F. 601. Biodegradation processes are highly variable in the heterogeneous landfill environment, where there are different microenvironments throughout the landfill. F. 599. Because landfill environments are highly variable with respect to moisture content and temperature, even within a single landfill, landfill conditions can support many different rates of biodegradation, including accelerated rates of biodegradation in areas of high moisture or temperature. F. 630.

3. Definition of Biodegradable

Complaint Counsel has taken the position that, in order to claim that an item is "biodegradable," one must show that the item completely degrades into elements found in nature, in a landfill, within one year. That position permeates this case and is patterned after the position presented by the FTC in the 2012 revised Green Guides. Under the FTC's revised Green Guides, "[i]t is deceptive to make an unqualified degradable claim for items entering the solid waste stream if the items do not completely decompose within one year after customary disposal." 16 C.F.R. § 260.8(c); F. 238; *see also* F. 671. Mirroring that position, the definition

of “biodegradable” that Complaint Counsel provided in this case to its degradable polymer expert, Dr. Stephen McCarthy, is as follows: “[T]he unqualified marketing claim ‘biodegradable’ means that the entire treated plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (*i.e.*, incinerator, landfill, or recycling).” F. 633.

The Complaint charges that Respondent made express or implied claims that ECM Plastics are “biodegradable,” which the Complaint, in effect, defines as: “will completely break down and decompose into elements found in nature within *a reasonably short period of time* after customary disposal.” Complaint ¶ 9A (emphasis added). Through its arguments on the consumer survey evidence in this case (Section III.D.4., *supra*) and the opinion offered by its expert, Dr. McCarthy (discussed below), Complaint Counsel has defined the phrase, “a reasonably short period of time,” to mean “within one year.” *See* Transcript of Closing Arguments, Oct. 22, 2014 at 26-27, 36 (Complaint Counsel stating that Respondent’s “biodegradable” claim is false because “[n]othing biodegrades in a landfill in . . . one year”). In its Proposed Order, Complaint Counsel specifically explained that “[f]or unqualified biodegradability claims, any scientific technical protocol (or combination of protocols) substantiating such claims must assure complete decomposition within one year and replicate, *i.e.*, simulate, the physical conditions found in landfills, where most trash is disposed.” Proposed Order, Definitions, ¶ 4A.

As determined in Section III.D.4., *supra*, the evidence fails to prove that, as a matter of claim interpretation, a significant minority of reasonable consumers would interpret Respondent’s “biodegradable” claim to mean the complete break down into elements found in nature, in a landfill, within one year. In this section, the Initial Decision analyzes whether the scientific evidence demonstrates that “biodegradable” means complete degradation in a landfill within one year.

It is noteworthy that, although Complaint Counsel’s position throughout this case has been that, in order to claim that an item is “biodegradable,” one must be able to substantiate that the item degrades completely in one year, in its proposed findings of fact, Complaint Counsel does not seek a factual determination that “biodegradable” is defined in such a

manner. Rather, Complaint Counsel urges only a finding that “[b]iodegradation is described as the chemical process by which microorganisms such as bacteria and fungi use the carbon found in organic materials as a food source.” CCF 6.

As explained below, the evidence fails to prove that, as a scientific matter, the term “biodegradable” means that an item will completely break down and decompose into elements found in nature within one year after customary disposal. Rather, the scientific evidence in this case demonstrates that the term “biodegradable” refers to the biological process by which microorganisms such as bacteria and fungi use the carbon found in organic materials as a food source, and does not necessarily include a time requirement for completion.

a. The testimony of Complaint Counsel’s expert fails to prove the contention that “biodegradable” means complete decomposition within one year

To support its allegation that “biodegradable” means the complete break down and decomposition into elements found in nature within one year after customary disposal, Complaint Counsel relies upon its expert, Dr. Stephen McCarthy. Dr. McCarthy is a professor of plastics engineering at the University of Massachusetts Lowell and is the director of the University’s Biodegradable Polymer Research Center, where he coordinates and supervises research on biodegradable polymers. F. 108-109. His research has led to seven patents related to polymers or plastics engineering. F. 109. Dr. McCarthy is also the editor of the Journal of Polymers and the Environment, the official journal for the BioEnvironmental Polymer Society, which promotes research to develop degradable polymers. F. 110. He has authored or co-authored more than a hundred publications related to polymer or plastics engineering, including peer-reviewed articles specifically on biodegradable blends. F. 110.

In his expert report, Dr. McCarthy defined “biodegradable” as follows:

Complaint Counsel asked me to assume that the unqualified marketing claim “biodegradable” means that the entire treated plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (*i.e.*, incinerator, landfill, or recycling). I use this definition and the scientific definition of biodegradable interchangeably in this Expert Report, because there is no substantive difference between the two that affects my analysis or my opinions.

F. 633; CCX 891 (McCarthy Expert Report at 5 n.1). However, Dr. McCarthy's expert report does not contain any citations to any scientific literature to support the definition proposed in footnote one of his report. F. 639.

Dr. McCarthy testified that he prepared his expert report as a "collaborative effort between [himself] and complaint counsel."³⁸ F. 634. Dr. McCarthy further testified that Complaint Counsel wrote the first sentence of the definition of biodegradable set forth in footnote one of his expert report. F. 635; McCarthy, Tr. 482-483.

Dr. McCarthy has been inconsistent with respect to the definition of biodegradable. Dr. McCarthy initially testified that the definition in footnote one of his expert report was equivalent or interchangeable with the scientific definition of biodegradable; however, he later testified that his definition in footnote one and the scientific definition of biodegradable were "similar," but were not the same. F. 633, 638. Later in his expert report, Dr. McCarthy defines biodegradation as "a chemical process by which microorganisms such as bacteria and fungi use the carbon found in organic materials as an energy source (*i.e.*, as a food source)." F. 636. This definition of biodegradation does not incorporate any temporal element, and clearly does not include a requirement of complete biodegradation within one year. F. 637. Furthermore, in his rebuttal expert report, Dr. McCarthy agreed "that 'biodegradable' is not always used to describe complete mineralization in a specific timeframe," but that he had "evaluated the evidence in terms of whether it satisfies that definition of biodegradation provided to [him], which does include those concepts." CCX 892 (McCarthy Rebuttal Expert Report at 3).

It is worth noting that Dr. McCarthy criticizes Respondent's proffered substantiation for its biodegradable claims in part, because, in Dr. McCarthy's opinion, ECM could have performed confirmatory testing to show biodegradation "by conducting a gas evolution test showing at least 60% conversion to methane and carbon dioxide within 18 months." F. 644. Eighteen months is obviously more than twelve months and thus inconsistent with Dr. McCarthy's contention that Respondent's testing must show complete biodegradation "within one year."

³⁸ See footnote 32, *supra*.

Furthermore, although Dr. McCarthy has previously defined the term “biodegradable” in articles he has authored, he has never, in any of his published scientific literature, defined “biodegradable” to mean that the entire plastic will completely break down and return to nature within one year after customary disposal. F. 646. Indeed, Dr. McCarthy authored and/or co-authored numerous articles wherein he concluded that certain test samples were proven to be biodegradable without demonstrating that the samples would completely break down into elements found in nature within one year of customary disposal. F. 647.

In addition, Dr. McCarthy has invented some polymer blends that are the subject of a United States patent, patent number 5,883,199 (“‘199 patent”). F. 659. In the ‘199 patent, Dr. McCarthy does not define biodegradation as something that should be complete in one year and also does not say that the blend will completely biodegrade within one year. F. 664-665.

Dr. McCarthy has also admitted that he was unaware of any instance in which a peer-reviewed article concerning plastics biodegradation ever defined the term biodegradable as entailing a complete break down and return to nature within one year after customary disposal. F. 645. Dr. McCarthy has acknowledged that “[t]he definition of biodegradable polymer varies greatly among scientists, manufacturers, and consumers” and, because of this disagreement, ASTM International, formerly known as the American Society for Testing and Materials (“ASTM”), needed to come up with an agreed-upon definition. F. 649-650.³⁹ In an article published in 2003, Dr. McCarthy relied upon the ASTM definition of biodegradable polymers as a “‘plastic designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties’ . . . ‘in which the degradation results from the action of naturally-occurring micro-organisms such as bacteria, fungi, and algae.’” F. 651-652. As Dr. McCarthy acknowledges, that ASTM definition does not define “biodegradable” to mean that there must be a complete breakdown and return to nature of the plastic within one year after customary disposal. F. 653.

³⁹ The ASTM definition is discussed below.

The definition provided to Dr. McCarthy by Complaint Counsel is inconsistent with commonly accepted definitions, which do not require complete degradation within one year.⁴⁰ The requirement that, to be called “biodegradable,” an item must completely break down and return to nature within one year after customary disposal is also inconsistent with practical experience. Commonly recognized “biodegradable” substances, such as banana peels, orange peels, tree trunks, and paper, do not reliably break down completely into elements in nature within one year after customary disposal. F. 673. Indeed, Complaint Counsel’s own expert in landfills, Dr. Thalbet Tolaymat, explained that even “rapidly degrading wastes,” such as food waste and sewage sludge, might take between 9 and 14 years to biodegrade fully. F. 674, 699. Dr. Tolaymat also explained that, in one part of a landfill that he went to, a newspaper was “really gooey, black waste,” but that on the other side of the same landfill, he was able to read a newspaper that was ten years old. F. 588. The notion that items that are commonly thought of as biodegradable, such as food wastes or paper, cannot be considered biodegradable if they do not fully degrade within one year belies common sense.

Furthermore, drawing a “bright line” at one year leads to arbitrary results. When asked whether a product could be considered “biodegradable” if it degraded to only 95 percent in 364 days, but then degraded to 100 percent on day 366, Dr. McCarthy testified that that scenario “would not satisfy the definition” provided to him by Complaint Counsel and used in his expert report. F. 672.

For the above stated reasons, Complaint Counsel did not prove the allegation in the Complaint ¶ 9A, as refined through Complaint Counsel’s Post-Trial Briefing and Proposed Order ¶ 4, that, for purposes of evaluating whether Respondent’s claims are false or unsubstantiated, the term “biodegradable” means that an item must completely break down and decompose into elements found in nature within one year after customary disposal.

⁴⁰ As discussed in III.D.4.b.i., *supra*, the Merriam-Webster dictionary defines “biodegradable” as something “capable of being slowly destroyed and broken down into very small parts by natural processes, bacteria, etc.” or “capable of being broken down especially into innocuous products by the action of living things (as microorganisms).” *Merriam-Webster.com*. Merriam-Webster, n.d. Web. 22 July 2014, available at <http://www.merriam-webster.com/dictionary/biodegradable>).

b. The greater weight of the scientific evidence shows that biodegradable means the process by which microorganisms decompose materials

The greater weight of the scientific evidence presented in this case establishes that there are many scientifically accurate definitions for term “biodegradable” and that these definitions describe a biological process of breakdown which does not include either a time limit for completion of the process or a specified degree of disintegration or elimination of the degrading product. *See* F. 676-696. A summary of the scientific evidence presented in this case regarding the definition of biodegradation follows.

ASTM develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services. F. 677. Standards are developed within committees, and membership in the ASTM is open to anyone with an interest in its activities. F. 677. The ASTM defines biodegradation, as related to plastic products, as the process by which natural biota decompose a plastic product into different chemical materials. F. 678. Based on the record evidence, the ASTM D883-12 definition of biodegradability as it pertains to plastics is:

A degradable plastic is defined as a plastic that is designed to undergo a significant change in its chemical structure under specific environmental conditions resulting in a loss of some properties that may vary as measured by standard test methods appropriate to the plastic and the application in a period of time that determines its classification. A Biodegradable Plastic is defined as a degradable plastic in which the degradation results from the action of naturally occurring microorganisms such as bacteria, fungi and algae.

F. 679. The ASTM definition does not include any specific time period or require complete degradation. *See* F. 679, 683.

Respondent called Dr. Ranaji Sahu to testify concerning the mechanisms of action involved in plastics biodegradation and the totality of the scientific evidence concerning biodegradation of plastics in general and biodegradation of ECM Additive-infused plastics in particular. RB at 17-19. Dr. Sahu has more than 20 years of experience in environmental, mechanical, and chemical engineering, and has performed numerous projects over the past 16 years involving aspects of polymer behavior in the environment. F. 124-126. Dr. Sahu

supported his opinion in this case with his knowledge of chemistry and material science and peer-reviewed literature, much of which is quoted in his expert report. F. 893. He reviewed hundreds of scientific publications concerning the degradability of plastic polymers and the biological mechanisms that support those mechanisms. F. 894.

Dr. Sahu opined that “[t]here is no one generally accepted definition of biodegradation. There are different variants of this definition, but they all speak to the same idea . . . of degrading the object . . . of interest using biological means.” F. 680. He further opined that “biodegradation means different things to different researchers . . . or in different contexts.” F. 680. “[I]n all contexts [biodegradation] simply means the breakdown of whatever is the object of interest using biological means, using essentially biota such as bacteria or fungi or other type of naturally occurring or evolving biota in the environment.” F. 681. There is not a scientific definition that constrains this any further, especially with regard to completeness or an arbitrarily selected time frame. F. 683-684.

Respondent also called Dr. Morton Barlaz, a civil and chemical engineer, to testify on biodegradation of plastics in landfills and biodegradation testing. RB at 19-20. Dr. Barlaz is the head of the Department of Civil, Construction, and Environmental Engineering at North Carolina State University; has published at least 115 articles in peer-reviewed journals, most of which concern landfill science, biodegradation, landfill gas, or similar issues related to waste disposal and material degradation; and has been involved in researching solid waste issues. F. 133-135. Dr. Barlaz has been hired by the United States Environmental Protection Agency (“EPA”) as an expert in the fields of waste management and biodegradation. F. 136. As a leading authority in the field of waste management, Dr. Barlaz has advised Complaint Counsel’s own expert witness, Dr. Tolaymat, on issues of biodegradation. F. 139.

Dr. Barlaz opined that, to his knowledge, no scientist who has published in the publicly available peer-reviewed literature has ever defined the term “biodegradable” to be limited to a complete breakdown of plastic into elements found in nature. F. 640. A product that is “biodegradable” will biodegrade at various rates and to various extents based on the external environmental conditions, but will remain “biodegradable” regardless. F. 686-687.

In addition, Respondent called Dr. Ryan e to offer an opinion concerning the various laboratory test environments used to assess biodegradation of materials. RB at 20-22. Dr. Burnette regularly consults on issues of microbiology, including anaerobic microbiology, and has worked as an environmental consultant for multi-national companies. F. 141-142. He has performed substantial work in industrial, commercial, and landfill environments characterizing soil and groundwater. F. 142-143.

Dr. Burnette testified that there are several definitions of biodegradation used to describe a biological process. F. 691. Based on his review of the peer-reviewed literature, Dr. Burnette thinks that most biologists would agree that biodegradation means the biological activity resulting in the breakdown of a substrate of a product. F. 690, 692. In general, biodegradation refers to the chemical alteration, or “break down,” of any material as a consequence of biological action. F. 691. From a microbiological standpoint, biodegradation really is the conversion of one substance to another substance as the result of biological activity. F. 692. Based on his review of publicly available peer-reviewed literature, Dr. Burnette knows of no scientist who has defined the term “biodegradation” as the complete breakdown of a plastic or material into elements found in nature within one year after customary disposal. F. 641 (further explaining, “in microbiology and in biochemistry, it’s rare that we think of things in terms of completion. We certainly don’t put rates on things that we don’t have a clear definition for.”).

In addition to Dr. McCarthy, Complaint Counsel called Dr. Tolaymat, as a landfill expert. CCB at 56. Dr. Tolaymat has been employed by the EPA from 2004 to the present as an environmental engineer and researcher in the fields of solid waste management, bioreactor landfills, waste containment performance, construction and demolition waste landfills, and the fate and transport of environmental pollutants. F. 102. A significant part of Dr. Tolaymat’s education, training, and experience has involved conducting and evaluating tests that purport to show biodegradation and/or replicate landfill conditions. F. 106. Dr. Tolaymat testified that “[b]iodegradation is the conversion of organic matter through the action of bacteria and fungi into more elementary components or elements.” F. 693. Dr. Tolaymat’s definition of biodegradation includes no time limit or time constraint. *See* Tolaymat, Tr. 130; CCX 893 (Tolaymat Expert Report at 8).

Complaint Counsel also offered Dr. Frederick Michel, a microbiologist and expert in enzymatic and microbial polymer conversion, as a rebuttal expert to the testimony offered by Dr. Sahu and Dr. Burnette. CCB at 64, 68. Dr. Michel has conducted research on a wide range of environmental topics, including the biodegradation of plastics, bioplastics, biofoams and natural fibers in anaerobic digesters, composting systems and soils. F. 119. Dr. Michel has authored over 40 peer-reviewed publications and many other reports and papers in these areas. F. 119. Dr. Michel testified that “[b]iodegradation is the mineralization of materials as a result of the action of naturally-occurring microorganisms such as bacteria and fungi.” F. 694. In his expert report, Dr. Michel opined that “[b]iodegradation in the context of disposable consumer products . . . means that a material will biodegrade to natural products over a time frame used for municipal waste management via composting, anaerobic digestion and/or land filling. It also implies that materials will biodegrade rapidly if they end up in natural environments and will not accumulate.” CCX 895 (Michel Rebuttal Expert Report at 11). While Dr. Michel offered that opinion in this case, he acknowledged that he has not defined biodegradation as requiring a complete breakdown of material into elements found in nature within one year after customary disposal, or within any specific time period, in any of his peer-reviewed articles. F. 642. Indeed, Dr. Michel recognized in his testimony concerning cellulose that a biodegradable material is still “fully” biodegradable even if it biodegrades only to 44% in a test environment, and reported in a published article that cellulose, a material known to be biodegradable, degraded roughly 74% in approximately 400 days. F. 675. These positions are clearly inconsistent with the notion that, to be “biodegradable,” an item must completely decompose within one year.

c. Summary

As analyzed above, Complaint Counsel did not prove its contention that the term “biodegradable” means that the entire treated plastic will completely break down and return to nature (*i.e.*, decompose into elements found in nature) within one year after customary disposal (*i.e.*, incinerator, landfill, or recycling). Complaint Counsel’s attempt to graft a temporal element, especially a “within one year” requirement, onto the scientific meanings of “biodegradable” fails. Instead, the greater weight of the evidence supports the conclusions that

biodegradation is the mechanism of degradation via biotic or biological agents such as bacteria, fungi, or other living organisms, and that the scientific literature defining biodegradation does not require completion or impose a time restraint.

Consistent with the greater weight of the credible scientific evidence and with Complaint Counsel’s Proposed Finding of Fact number 6, biodegradation is defined as the biological process by which microorganisms such as bacteria and fungi use the carbon found in organic materials as a food source. Thus, for the purpose of analyzing whether Respondent’s claims, that ECM Plastics are “biodegradable,” including in a landfill, or that tests prove the same, are false or unsubstantiated, this definition is employed.

4. Applicable Legal Standards

Respondent’s claims that ECM Plastics are “biodegradable,” including in a “landfill,” and that ECM Plastics will fully biodegrade in a landfill within “9 months to 5 years,” are “efficacy claims” or “non-establishment claims,” which are claims about a product’s attributes, performance, or efficacy, without indicating any particular level of support for such claim. *Thompson Medical*, 1984 FTC LEXIS 6, at *368; *Removatron*, 884 F.2d at 1492 n.3 (“Non-establishment’ claims are statements to the effect that a product works.”). Respondent’s claims that “tests prove” that ECM Plastics are “biodegradable,” including in a “landfill,” and that ECM Plastics will fully biodegrade in a landfill within “9 months to 5 years,” are “establishment claims” – statements to the effect that scientific tests establish that a product works as represented. *Removatron*, 884 F.2d at 1492 n.3.

Two approaches have been used to prove that an advertisement is deceptive: (1) the “falsity” theory, or (2) the “reasonable basis” or “substantiation” theory. *POM*, 2013 FTC LEXIS 6, at *52-53; *Pantron*, 33 F.3d at 1096; *Thompson Medical*, 1984 FTC LEXIS 6, at *380-81.

The first approach, the falsity theory, requires Complaint Counsel to demonstrate that the express or implied message conveyed by the advertisements is false. *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 135 n.11 (D. Conn. 2008); *POM*, 2013 FTC LEXIS 6, at

*53; *Thompson Medical*, 1984 FTC LEXIS 6, at *382. The burden is on Complaint Counsel to prove that the Challenged Claims are false. *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008).

A claim of product effectiveness is “false” where evidence developed under accepted standards of scientific research demonstrates that the product does not work as represented. *Pantron*, 33 F.3d at 1097. A claim that “studies prove” that a product works as represented is “false” where a respondent represents expressly or implicitly that there is scientific proof for its claims, but the respondent lacked such proof at the time the representations were made. *POM*, 2013 FTC LEXIS 6, at *53. “Because Complaint Counsel bears the burden of showing that these claims are false, . . . Complaint Counsel must demonstrate that Respondent[] did not have the amount and type of substantiation [it] claimed to have had. . . . To meet this burden, Complaint Counsel must establish the standards that [scientific tests] must meet to pass muster in the view of the relevant scientific . . . communities as support for the claims Respondent [was] making, and then show that the studies Respondent[] possessed did not meet those standards.” *POM*, 2013 FTC LEXIS 6, at *67. If the respondent does not possess the level of studies demanded by the relevant scientific communities, then the respondent’s claims of scientific proof establishing its biodegradability claims are false. *POM*, 2013 FTC LEXIS 6, at *67.

The second approach, the “reasonable basis” or “substantiation” theory,⁴¹ requires Complaint Counsel to demonstrate that a respondent did not possess and rely upon a “reasonable basis” for asserting that the Challenged Claims are true. *Pantron*, 33 F.3d at 1096; *Bronson Partners*, 564 F. Supp. 2d at 135 n.11; *QT, Inc.*, 448 F. Supp. 2d at 959; *POM*, 2013 FTC LEXIS 6, at *53; *Thompson Medical*, 1984 FTC LEXIS 6, at *380. “This theory rests on the principle that an objective claim about a product’s performance or efficacy carries with it an express or implied representation that the advertiser had a reasonable basis of support for the claim.” *POM*, 2013 FTC LEXIS 6, at *54 (citing *Thompson Medical*, 104 F.T.C. at 813 n.37). Thus, failure to have such reasonable basis renders that claim deceptive. *Removatron*, 884 F.2d at 1498; *POM*, 2013 FTC LEXIS 6, at *119.

⁴¹ A claim that lacks a reasonable basis is also sometimes referred to as “unsubstantiated.” *E.g.*, *QT, Inc.*, 448 F. Supp. 2d at 959.

The first step in the evaluation of Respondent’s substantiation is to “determine what level of substantiation [Respondent was] required to possess [T]his determination is a question of fact.” *QT, Inc.*, 448 F. Supp. 2d at 961. “Then, the Court must determine whether [Respondent] possessed that level of substantiation.” *Id.* Respondent bears the burden of establishing what substantiation it relied on for its product claims. *Id.* Next, “[t]he FTC has the burden of proving that [Respondent’s] purported substantiation is inadequate, and the FTC need not conduct or present clinical studies showing that the product does not work as claimed.” *Id.* (citing *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1008-09 (N.D. Ill. 1998)).

To determine what constitutes a “reasonable basis” substantiating a claim of product effectiveness, the *Pfizer* factors are evaluated. *POM*, 2013 FTC LEXIS 6, at *54 (citing *In re Pfizer*, 81 F.T.C. 23 (1972); *Substantiation Statement*, 104 F.T.C. at 840 (the “determination of what constitutes a reasonable basis depends . . . on a number of relevant factors relevant to the benefits and costs of substantiating a particular claim . . . [including,] the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable”)).

To determine what constitutes a “reasonable basis” substantiating a “tests prove” claim, “complaint counsel [is] required: (1) to establish the particular evidence that would pass muster in the . . . scientific community for the types of claims made; and (2) demonstrate that the proffered substantiation failed to meet these standards.” *In re Removatron Int’l Corp.*, 111 F.T.C. 206, 1985 FTC LEXIS 21, at *195-96 (Sept. 30, 1985) (citing *Thompson*, 104 F.T.C. at 820), *aff’d*, 884 F.2d 1489 (1st Cir. 1989); *Pantron*, 33 F.3d at 1096; *QT, Inc.*, 448 F. Supp. 2d at 959. Unlike efficacy claims, an evaluation of the various factors set out in *Pfizer* is not required to establish the appropriate level of substantiation for Respondent’s establishment claims. *POM*, 2013 FTC LEXIS 6, at *65 n.18. Instead, Respondent is held to the level of substantiation that the advertisements claim. *Id.*

“[W]here advertising expressly or impliedly represents that [a claim] is based on scientific evidence, the advertiser must have that level of substantiation, and, in particular, must satisfy the relevant scientific community that the claim is true.” *Removatron*, 1985 FTC

LEXIS 21, at *195; *In re Sterling Drug*, 102 F.T.C. 395, 1983 FTC LEXIS 66, *436 (July 5, 1983) (“when an advertiser represents in its ads that there is a particular level of support for a claim, the absence of that support makes the claim false”). *Accord QT, Inc.*, 512 F.3d at 862 (holding that a representation that a product’s efficacy had been “test-proven” is misleading unless a reliable test has been used and statistically significant results achieved). In this case, Respondent’s claim that ECM Plastics “have been shown” to be biodegradable, including in a landfill, within 9 months to 5 years under “various scientific tests including, but not limited to ASTM D5511,” F. 265, 272, “is inherently a substantiation claim[. Thus,] the falsity and reasonable basis theories collapse into the same inquiry: did [Respondent] possess adequate substantiation to make such a claim?” *QT, Inc.*, 448 F. Supp. 2d at 966.

The net impression of ECM’s Marketing Materials and its Certificate of Biodegradability is that ECM Plastics are biodegradable and that testing by independent laboratories proves that ECM Plastics are biodegradable. F. 265, 272. In this case, the efficacy claims made in ECM’s Marketing Materials and Certificate of Biodegradability need the same level of substantiation as is needed for Respondent’s establishment claims. In *Removatron*, where the net impression of the advertisements and promotional materials was that respondents’ claims were based on competent scientific proof, the Commission stated it did not need to apply the *Pfizer* analysis in determining the appropriate level of substantiation for respondents’ claims. *Removatron*, 1985 FTC LEXIS 21, at *193-94. In *POM*, for advertisements where respondents made efficacy claims without also representing that there was clinical proof of the challenged products’ efficacy, the Commission applied the *Pfizer* factors and concluded that “appropriate scientific testing” was required for efficacy claims and noted that under that analysis, it expected the same level of scientific testing as it required for respondent’s establishment claims. *POM*, 2013 FTC LEXIS 6, at *107, 118.

In the instant case, the parties agree that, applying the *Pfizer* factors, the appropriate level of substantiation for Respondent’s claims is “competent and reliable scientific evidence.” CCB at 61-62 (arguing that under the *Pfizer* factors, “the appropriate level of substantiation is competent and reliable scientific evidence . . . [which] requires well-controlled, well-conducted studies”); RB at 87 (arguing that “[i]n assaying what is ‘reasonable’ to prove efficacy claims, the proper point of reference is what the scientific community considers reliable proof”). At

issue in this case is what constitutes “competent and reliable scientific evidence” and, then, whether Respondent’s substantiation evidence constitutes “competent and reliable scientific evidence.” The evidence presented on those issues is analyzed below.

5. Tests Showing Complete Biodegradation in a Landfill Within One Year Not Required

Both parties agree that Respondent must possess and rely on “competent and reliable scientific evidence” in support of its claims. CCB at 62; RB at 89-90; F. 704 (McCarthy and Sahu). “Competent and reliable scientific evidence” means “tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” *POM*, 2013 FTC LEXIS 6, at *109; *Removatron*, 884 F.2d at *1493 n.5; *Automotive Breakthrough Sciences*, 1998 FTC LEXIS 112, at *55; F. 705.

Complaint Counsel’s theory that Respondent’s claims that ECM Plastics are biodegradable and biodegradable in a landfill are false or unsubstantiated is based on Complaint Counsel’s assertion that competent and reliable scientific evidence fails to show that ECM Plastics will completely biodegrade after customary disposal within one year. *See* CCX 891 (McCarthy Expert Report at 5 n.1). Complaint Counsel’s position on substantiation is, in turn, driven by its theory that Respondent’s “biodegradable” claims are “unqualified” biodegradability claims that necessarily imply to consumers that complete biodegradation will occur, in a landfill, within one year. Thus, Complaint Counsel contends, Respondent must substantiate such implied claim with competent and reliable scientific evidence demonstrating that ECM Plastics will completely biodegrade after customary disposal within one year. (*See* CCB 29-34, 95-96; Transcript of Closing Arguments, Oct. 22, 2014 at 36-37).⁴²

Respondent’s position is that, in order to show that materials are “biodegradable,” the scientific community does not require proof that materials fully biodegrade within a year.

⁴² Complaint Counsel’s theory that Respondent’s “biodegradable” claims are deceptive because they imply complete biodegradation in a landfill within one year is further conveyed in its Proposed Order, which would require that Respondent substantiate future “unqualified” biodegradable claims by competent and reliable scientific evidence that “must assure complete decomposition within one year and replicate, *i.e.*, simulate, the physical conditions found in landfills, where most trash is disposed.” CCB at 95.

Instead, the primary scientific concern related to biodegradability is whether the item is intrinsically biodegradable. RB at 88. Respondent further argues that Complaint Counsel offered no proof of what scientific evidence would be sufficient to support biodegradable “rate” claims in landfills. RB at 91.

As analyzed above, the evidence fails to prove that Respondent’s biodegradability claims implied complete biodegradation, including in a landfill, within one year. Surely, Respondent cannot be required to substantiate a claim that has not been proven by Complaint Counsel. For this reason alone, Respondent need not produce competent and reliable scientific evidence showing complete biodegradation, in a landfill, within one year. Moreover, the evidence in this case fails to show that the scientific community requires competent and reliable scientific evidence demonstrating complete decomposition within one year in a landfill in order to substantiate a claim that ECM Plastics are “biodegradable.” Section III.E.3., *supra*. The evidence at trial, instead, shows that biodegradability of a product describes a property of the material, much like its color or weight or density. F. 686. A product is either biodegradable, or it is not. F. 686. A product that is biodegradable will biodegrade at various rates and to various extents based on the external environmental conditions, but will remain biodegradable regardless. F. 687. Changes in temperature and moisture do not influence intrinsic biodegradability of a material. F. 688. For example, a piece of paper in a dry environment, at 70 degrees Fahrenheit, will biodegrade because that is an intrinsic property of paper. F. 688. The moisture and temperature affect the rate of biodegradability, but not whether it will biodegrade. F. 688. This evidence weighs against a conclusion that the scientific community would require Respondent’s biodegradable claims to be substantiated by proof that ECM Plastics fully biodegrade in a landfill within one year.

In addition, the evidence at trial shows that no one test can support a rate of biodegradation of plastics in landfills and the rate of biodegradation is a matter of scientific judgment. F. 712. When Complaint Counsel’s expert, Dr. Tolaymat, was questioned concerning which tests, if any, could be used by a company to prove the rate of biodegradation in an MSW landfill, Dr. Tolaymat did not have one test to recommend. F. 712.

Respondent's expert, Dr. Sahu, testified that in the publicly available peer-reviewed literature and in his experience, he has not seen a study that has taken a rate derived from a laboratory test and then extrapolated from that rate to attempt to state a time period for complete biodegradation. F.714. Rates change due to many factors, and there are good reasons not to extrapolate that far. F. 715.

The difficulty in projecting rates is even more difficult when applied to a landfill environment. Any test fundamentally is trying to capture in a lab environment a very complex ecosystem. F. 706, 711. A landfill, by its nature, is different from a controlled laboratory reactor; a landfill cannot be standardized or homogenized. F. 706. It would be scientifically impractical to design a perfect closed-system test that would be representative of all the potential microenvironments in an MSW landfill. F. 709. Further, it is not practical to try to simulate the landfill ecosystem at that time scale in a laboratory. F. 708. Because landfills are heterogeneous, one has to be cautious in projecting rates that one gets from a lab environment, which tends to be homogeneous. F. 711. While laboratory experiments are useful to assess whether a material is biodegradable and to assess the relative rate of biodegradability for multiple materials, there is not a uniformly utilized method to extrapolate rate data as measured at laboratory-scale to field-scale landfills. F. 713.

Having weighed the scientific evidence, Complaint Counsel has not proven its contention that, in order to claim that a product is biodegradable, the scientific community demands competent and reliable scientific evidence that assures complete decomposition within one year in a landfill environment.

6. Competent and Reliable Scientific Testing Methods to Prove Biodegradability

a. Gas evolution reactor tests

The expert testimony in this case establishes that "gas evolution" test data is the most practical and widely used measure of biodegradation in the scientific field. F. 743. The scientific community does not consider weight loss tests alone sufficient for determining biodegradation. F. 741. In addition, aerobic tests (with oxygen) do not provide scientific

support for claims of biodegradation in landfills. F. 1045 (“To begin, for purposes of biodegradability under landfill conditions, only anaerobic biodegradability is of relevance.”).⁴³

Tests that rely on gas evolution to detect biodegradation measure the carbon dioxide (CO₂) and methane (CH₄) that evolve as a result of biodegradation. F. 744. In a gas evolution test, the laboratory exposes test articles to conditions that theoretically favor biodegradation, and then monitors the gas emissions. F. 745, 763. By comparing the levels of gas emitted from the test vessel, the laboratory can measure the amount of gas produced from the test articles themselves. F. 744-745, 764, 767.

In gas evolution tests, within a closed, watertight vessel, test articles are exposed to “inoculum”⁴⁴ that is comprised, in part, of leachate from local municipal waste stations and thus contains microbes that would also be present in the landfill environment. F. 763-764, 766. Gas collection tubes are connected to the test vessel, and gas produced by the vessel is gathered and later measured. F. 767. The laboratory records the total amount of gas produced and the ratios of methane gas to carbon dioxide. F. 764, 765, 768.

In gas evolution tests, items are tested against negative controls, positive controls, and inoculum blanks. F. 764. The laboratory can determine the proper gas level attributable to the test vessel by comparing the overall gas levels of the inoculum blank to those of the test article and negative control. F. 1069. The laboratory can calculate the percentage of biodegradation by comparing the level of gas attributable to the test sample with the theoretical maximum yield of gas from that same sample. F. 764-765, 1069.

One gas evolution test for biodegradability of plastics is the ASTM D5511 test, titled, a “Standard Test Method for Determining the Anaerobic Biodegradation of Plastic Materials Under High-Solids Anaerobic-Digestion Conditions.” F. 759-760. The ASTM sets forth protocols established by the scientific community to evaluate materials. F. 758. The ASTM

⁴³ For this reason, only the anaerobic tests offered into evidence by Respondent are evaluated. Section III.E.10.a., *supra*.

⁴⁴ Inoculum is source material used to introduce microorganisms to an environment. As used in anaerobic test methods, inoculum is an anaerobically digested organic waste that includes all groups of microorganisms required to convert a substrate to methane and carbon dioxide. F. 763.

D5511 test is a gas evolution test and laboratory-scale reactor test performed in a “high-solids environment.” F. 759. The ASTM D5511 test is designed to record data under accelerated conditions. F. 731. Thus, materials are tested under conditions designed to enhance the rate of decomposition, including the incubation temperature and the use of leachate neutralization and recirculation. F. 722.

Although the ASTM D5511 test is not representative of all possible MSW landfill conditions, it is an appropriate microcosm characteristic of an MSW landfill subset. F. 778. The ASTM D5511 test prescribes a methodology that creates an environment that is found in MSW landfills. F. 778. From a microbiological perspective, ASTM D5511 or similar laboratory reactor testing is a competent and reliable scientific method to assess biodegradability of materials in landfills. F. 775.

The more credible and persuasive expert testimony in this case establishes that the ASTM D5511 test is generally recognized in the field as a competent and reliable scientific method to show biodegradability, including in a landfill:

- Complaint Counsel’s expert, Dr. Michel, acknowledged that the ASTM D5511 test is generally recognized in the field as a competent and reliable scientific method to show biodegradation and that he has utilized the ASTM D5511 test because it resembles the environment in a biologically active landfill. F. 769, 780.
- Complaint Counsel’s expert, Dr. McCarthy, used a gas evolution test similar to the ASTM D5511 test to support claims of biodegradability for his bioplastic polymers. F. 731.
- Respondent’s expert, Dr. Sahu, opined that, with proper controls (such as the positive, negative, and inoculum controls), as required and included in the ASTM D5511 method, an ASTM D5511 test should be able to indicate, via gas evolution, if biodegradation of the test article has occurred; and that the ASTM D5511 test is the closest, most practical, and standardized test currently available for mimicking landfill conditions. F. 771, 779.
- Respondent’s expert, Dr. Barlaz, opined that the ASTM D5511 test method is capable of assessing intrinsic biodegradability and that data from gas evolution testing is broadly accepted by the scientific community of evidence of anaerobic biodegradation. F. 749, 773.

- Respondent’s expert, Dr. Burnette, testified that ASTM D5511 or similar laboratory reactor testing is a competent and reliable method evidence to assess biodegradability of materials in landfills. F. 775-776.

b. BMP testing

A biochemical methane potential (“BMP”) test is a gas evolution test that evaluates the decomposition of various materials by measuring the amount of carbon that is decomposed in an anaerobic environment. F. 750. The BMP test is performed in a liquid environment, with very high moisture content. F. 751. BMP testing varies significantly from one laboratory to another. F. 752. In BMP tests, laboratories can choose to follow different protocols when adding types of vitamins and minerals and can make adaptations to the temperature or duration of the test, and modifications to the preparation of the test sample. F. 754. In many instances, BMP testing calls for grinding the test product and screening it through a 1 millimeter screen. F. 754. When a laboratory grinds material to be small enough to pass through a 1 millimeter screen, it becomes the consistency of whole wheat flour. F. 754.

Although Dr. Tolaymat testified that the BMP test is competent and reliable scientific evidence to show that a product degrades in a landfill, he also testified that the BMP test environment differs dramatically from the typical landfill in the United States, that the protocol for BMP tests are highly variable from one laboratory to another, and that the BMP test has a much higher moisture content than the typical landfill. F. 750-754. Dr. Barlaz opined that the “BMP is an appropriate screening tool for biodegradability in landfills,” but explained that BMP tests are not appropriate for testing slower degrading materials, and that the amount of biodegradation observed through the BMP testing is likely to be only a fraction of the total biodegradation possible. F. 755-756.

c. Testing showing 60% conversion and C14 testing are not required

Complaint Counsel argues, through its expert witness, Dr. McCarthy, that to have competent and reliable scientific evidence, “at least one confirmatory test must be conducted to establish that the plastic component of the ECM Plastics will biodegrade” and that “ECM could have performed confirmatory testing by radiolabeling or by conducting a gas evolution test showing at least 60% conversion to methane and carbon dioxide within 18 months.” CCX 891

(McCarthy Expert Report) at 27. The greater weight of the scientific evidence does not support this position.

Carbon 14 (“C14”) testing is radiolabeling testing involving tagging radioisotopes of carbon of a high-molecular weight plastic, such as polyethylene (“PE”), before conducting a gas evolution test. F. 828. Although Dr. McCarthy opines that to scientifically prove a claim that the plastic – not merely the additive and inoculum—is biodegrading, the claimant must support its claim with at least one test with positive results from C14 labeling of the conventional plastic, Dr. McCarthy does not explain how C14 testing could be done as a practical matter. F. 829. He does not explain how one can formulate materials with the ECM Additive in small batch quantities, just for C14 testing purposes. Further, Dr. McCarthy does not address the practical impediments associated with such a task, including handling the radiological materials and their proper disposal; contamination and decontamination issues in the manufacturing plant and the laboratory when such tests would be done; or the time and cost involved. F. 829. In the pre-complaint phase of this case, Dr. Sahu searched for a commercial laboratory that could perform radiolabeled testing for ECM and could not find any company able to radiolabel the polymer or create the radiolabeled polymer that would then be subject to further laboratory testing. F. 834.

Carbon 14 testing is not the industry standard or reasonably required by any expert in the field as necessary evidence to show biodegradation of materials. F. 832-833 (Dr. Barlaz would be “surprised” if any expert had performed C14 testing on plastics because it is very difficult to find a company that could properly make the test article, and the impracticalities outweigh any benefit.). At his deposition, Dr. Tolaymat explained that radiolabeled testing “could be as expensive as . . . doing the study in a landfill environment” and that “it’s not used frequently.”

F. 840.

Despite opining that Respondent ECM should have performed C14 testing, Dr. McCarthy has not used C14 radiological testing in any biodegradation experiments that he has performed at UMass Lowell. F. 842. In addition, the C14 radiolabeled test method was not used to test biodegradation of the polymer blends claimed to be biodegradable in Dr.

McCarthy's '199 patent. F. 841. In several of Dr. McCarthy's articles pertaining to biodegradability of polymer blends, Dr. McCarthy did not use C14 radiological testing to measure degradation. F. 843-845. Complaint Counsel's rebuttal expert, Dr. Michel, similarly has never performed a radiolabeled test to measure biodegradation of plastic polymers or products. F. 846-847.

Alternatively, Dr. McCarthy opined, in order to scientifically establish that the plastic component of the ECM Plastics will biodegrade, ECM could have conducted a gas evolution test showing at least 60% conversion to methane and carbon dioxide within 18 months. F. 848. However, Dr. McCarthy provided no literature or documentary evidence showing that scientists in the field require 60% or greater biodegradation within 18 months before a product can be deemed biodegradable. F. 849. Moreover, Dr. McCarthy did not perform tests showing at least 60% biodegradation to support biodegradable claims in his '199 patent and, in fact, labeled a substrate biodegradable even though the rate of biodegradation was lower than 60%, reaching only 14% in 45 days. F. 850, 852. There is no consensus in the peer-reviewed literature that a gas evolution test should produce 60% biodegradation within 18 months before a test article can be deemed biodegradable. F. 860.

d. Summary

Having weighed and considered the scientific evidence, the preponderance of the more persuasive and credible expert testimony presented at trial establishes that ASTM D5511 tests can provide competent and reliable scientific evidence of biodegradability of plastics in a landfill.

7. Whether Respondent's "9 Months to 5 Years Claim" and Tests Prove "9 Months to 5 Years Claim" Are False or Unsubstantiated

Before evaluating whether Respondent had adequate substantiation for its claims that the ECM Additive rendered plastics "biodegradable," including in a "landfill," and that independent testing proved that ECM Plastics are "biodegradable," the evidence regarding Respondent's 9 Months to 5 Years Claim and the claim that tests proved Respondent's 9 Months to 5 Years claim is discussed.

All of the experts in this case agreed that ECM Plastics do not fully biodegrade in 9 months to 5 years in a landfill. F. 697. Notably, Respondent’s plastics expert, Dr. Sahu, confirmed that ECM Plastics would take 30 years, and possibly up to 100 years, to completely biodegrade. F. 701. Complaint Counsel’s plastics experts, Dr. McCarthy and Dr. Michel, concurred, opining that ECM Plastics will not completely biodegrade in periods of time as short as five years. F. 698, 700.

In addition, both parties’ landfill experts agree that landfill conditions do not support the biodegradation times of less than five years. F. 699, 702. Complaint Counsel’s landfill expert, Dr. Tolaymat, opined that even the most biodegradable material would not completely biodegrade in a landfill within 5 years, even under optimum conditions for biodegradability. F. 699. Dr. Barlaz confirmed that plastics generally biodegrade slower than food waste and that even most of the most readily degradable municipal solid waste will not completely biodegrade in five years or less. F. 702.

Because the expert testimony convincingly establishes that ECM Plastics are not fully biodegradable in a period of 9 months to 5 years in a landfill, Complaint Counsel has demonstrated that this claim, and the claim that tests prove as much, are both false and unsubstantiated.

8. Whether Respondent’s Efficacy Claims Are False

Complaint Counsel argues that ECM Plastics are not biodegradable at all, without regard to rate, and for this reason as well, Respondent’s “unqualified” biodegradability claims are false or unsubstantiated. CCB at 54-76. In support of its position that Respondent’s biodegradable claims are false, Complaint Counsel asserts: (1) physical blends do not affect plastic recalcitrance; and (2) tests show no biodegradation of ECM Plastics. CCB at 56-61. The arguments and evidence on these two points are set forth below.

a. Evidence on how the ECM Additive works

Complaint Counsel asserts that “[a] physical blend of 1% ECM Additive and 99% conventional plastic cannot change the underlying recalcitrance of the remaining 99% plastic – and ECM offers no reliable expert opinion the contrary.” CCB at 55. Complaint Counsel

further asserts that there is no real disagreement that conventional plastics – high molecular weight, synthetic polymers derived from petrochemicals – are not biodegradable. CCB at 56. Finally, Complaint Counsel asserts: “The ECM Additive is mostly a synthetic biodegradable polymer like polycaprolactone (PCL). ECM recommends that a small concentration, about 1%, of its Additive be melt-batch blended with a non-biodegradable conventional plastic, such as polyethylene. This type of physical blend does not alter the chemical structure of the plastics. Therefore, the Additive does not alter the chemical characteristics that make conventional plastics resistant to biodegradation and the non-biodegradable plastic component is no more susceptible to biodegradation after blending than it was before.” CCB at 58.

Respondent argues that its experts have presented many scientific papers discussing the biodegradability of conventional plastics and scientific support for the position that, although conventional plastics biodegrade very slowly, they still biodegrade. RRB at 76 (citing Sahu, Tr. 1848-1859; RX 855 (Sahu Expert Report at 24-40); Burnette, Tr. 2426-2429; RX 854 (Burnette Expert Report at 16-22)). Respondent further argues that Complaint Counsel offered no support for its claim that microbes have not evolved to biodegrade plastics, aside from speculation from its experts that is lacking peer-reviewed journal support. RRB at 76. In addition, Respondent argues that Complaint Counsel’s theory that the ECM Additive does not chemically alter conventional plastic conflicts with the scientific record, including Complaint Counsel’s own expert’s work. RRB at 77. Finally, Respondent argues that the ECM Additive, when melted uniformly throughout the plastic, creates weak points in the conventional plastic that can be broken down by enzymatic digestion; that the ECM Additive serves as an attractant that helps bacteria develop, mature, reproduce, and thus metabolize the ECM Additive, along with the conventional plastic in which the ECM Additive is integrated; and that because the ECM Additive appears throughout the plastic, the plastic is completely biodegradable and biodegradation of the plastic substrate would continue until completion. RRB at 81-82.

As an initial matter, Complaint Counsel’s experts have conceded that conventional plastics can and will, in fact, biodegrade – albeit over a significant period of time. *See* Complaint Counsel’s Proposed Finding of Fact No. 7 (“Given enough time, all things are ‘biodegradable’”) (citing Michel, Tr. 2869 (“[d]oes polyethylene biodegrade over thousands of year. Well, yes, it does . . .”). Complaint Counsel’s expert Dr. Tolaymat also conceded that,

over time, plastic biodegrades. (CCX 893 (Tolaymat Expert Report at ¶ 73) (“given enough time ... *anything* will biodegrade”) (emphasis in original). While Dr. McCarthy opines in his expert report that there is “overwhelming scientific consensus that conventional plastics are not biodegradable after customary disposal,” he cites no support for that statement and has acknowledged that there are peer-reviewed scientific publications that conclude that conventional plastics are, in fact, biodegradable. F. 900.

Contrary to Dr. McCarthy’s opinion, Respondent’s experts presented many scientific papers discussing the biodegradability of conventional plastics. *E.g.*, F. 901, 914-915. Dr. Sahu opined that although conventional plastics biodegrade very slowly, they still do biodegrade, and cited to peer-reviewed scientific literature revealing specific proof that conventional plastics do biodegrade. *Id.*; *see also* RX 855 (Sahu Expert Report at 24-40) (citing peer-reviewed literature). Similarly, Dr. Burnette’s research revealed peer-reviewed publications demonstrating that there are organisms that make an enzyme that can degrade plastics. F. 895.

In support of its statement that the ECM Additive is mostly a synthetic biodegradable polymer like polycaprolactone (“PCL”), Complaint Counsel cites to the report of its expert, Dr. McCarthy, CCX 891 ¶ 61. Dr. McCarthy has not tested the ECM Additive, or obtained the proprietary trade secret formula from ECM in discovery. F. 160, 931. Moreover, Dr. McCarthy’s opinion, that the physical blend of a synthetic biodegradable polymer like PCL does not alter the chemical structure of the plastics and does not alter the chemical characteristics that make conventional plastics resistant to biodegradation, is not adequately supported by the record or his underlying work in this case. As an initial matter, Dr. McCarthy does not provide support for his opinion that the physical blend of a biodegradable polymer with a conventional plastic does not alter the chemical structure of the conventional plastic. *See* CCX 891 ¶ 64. Studies, including those relied on by Dr. McCarthy himself outside of this litigation, do address this point on blending. F. 927-928. For example, in the article, “A Review on Recent Trends and Emerging Perspectives,” published in the Journal of Polymers and the Environment, which Dr. McCarthy edits, the authors specifically discussed the methods to create “biodegradable polymer blends,” and one of the methods they cited was “blending a thermoplastic resin with a biodegradable one.” F. 928. In addition, Dr. McCarthy wrote in his

own article that “binary blends of bacterial polyesters with polyethylene (PE) and polystyrene (PS)” can result in a biodegradable “blend.” F. 930. Furthermore, in an article he co-authored, Dr. McCarthy specifically addressed the “reactive compatibilization of biodegradable blends of poly(lactic) acid and poly(e-caprolactone).” RX 944. Thus, contrary to the opinion offered by Dr. McCarthy in this case, the manufacture of immiscible biodegradable blends is supported by peer-reviewed literature. *See* F. 915, 927-928.

Dr. McCarthy testified that “co-polymers” and blends (like the technology used in his ‘199 patent (F. 659)) were distinct chemical blends of the material, while ECM’s Additive is simply two independent materials never combining. (McCarthy, Tr. 387; CCX 891 (McCarthy Expert Report at ¶ 64); CCX 895 at 13). Dr. McCarthy further testified that the ECM Additive would not alter the chemical characteristics of the conventional plastic, unlike the co-polymer technology identified in his ‘199 patent, which he claimed was biodegradable. *Id.*; F. 661-662. But Dr. McCarthy also explained in his ‘199 patent how he created these “blends,” which method uses the same manufacturing processes that manufacturers use when introducing the ECM Additive into plastics. (*See* RX 756 at column 6). According to Dr. McCarthy in sworn statements made to the United States Patent and Trademark Office (F. 660):

Standard melt processing equipment and processing conditions can be used to prepare the new blends. Examples of polymer melt processing equipment that can be used to make the new blends include melt mixers (Banbury mixer), blenders, extruders for sheet, film, profile and blown-film extrusion, vulcanizers, calenders, and spinnerets for fiber spinning, molding, and foaming.

RX 756 at column 6. In that section of his patent, Dr. McCarthy described the method by which one makes a “biodegradable blend,” whereby the blending process alters the chemical characteristics of the plastic, which process is the same manufacturing process used by ECM. *Compare* RX 756 and F. 665, *with* F. 870-874, 891-892. *See also* F. 663.

ECM Plastics are made when the ECM Additive, a biodegradable component, is melt-compounded into a conventional plastic, in a manner similar to that used by Dr. McCarthy in his ‘199 patent. *Compare* F. 183-191, 870-880 *with* RX 756 at column 6. Dr. McCarthy does not explain why melt-compounding of a co-polymer alters the chemical composition of plastics when using the manufacturing process used by Dr. McCarthy in his ‘199 patent, but does not

alter the chemical composition of ECM Plastics when used with the ECM Additive. By contrast, Respondent's experts, Dr. Sahu and Dr. Burnette, credibly and persuasively explained the mechanism of action of the ECM Additive in detail, as set forth in F. 870-1005 and summarized below. Dr. Sahu explained that the ECM Additive is uniformly melted throughout the plastic, and it becomes part of the entire plastic matrix. F. 871. As Dr. Sahu explained:

The ECM Additive goes into the blend uniformly no matter whether it has a high or low weight distribution. It will be present along with varying chain lengths of original polymers that were there in the plastic and as they have cooled down and formed crystalline and amorphous regions.

F. 871.

Dr. Sahu further explained that the process of "blending" the ECM Additive with the plastic resin involves heat blending, so that the two components become one. F. 872. Dr. Sahu compared the ECM Additive to colorants, which are usually introduced into plastics at a 0.5% to 2% load rating (where the ECM Additive is introduced at a 1% load rate). F. 874, 885. The ECM Additive is dispersed within the plastic and the additive becomes one with the plastic, uniform throughout. F. 871. By comparison, when viewing a common colored plastic product, such as a red water bottle or a blue plastic coffee mug, each one of those products does not look like two separate components (*i.e.*, a plastic and a distinct color additive), but instead, each looks like one uniform material. Even when those plastics are cut into pieces, the plastic remains one uniform color inside.

When the ECM Additive is melted into the plastic, it necessarily alters the structure of the plastic. F. 891-892. As Dr. Burnette explained, the ECM Additive likely promotes biodegradation in two ways: by serving as an attractant for microbial growth on and within plastics; and/or by weakening or perturbing the carbon-carbon bonds through weaknesses in the chain or the addition of more weak points in the form of the additive. F. 918.

Dr. Sahu and Dr. Burnette explained that the presence of biofilms on the plastic serves as an attractant that helps bacteria develop, mature, reproduce, and thus metabolize the additive along with the conventional plastic into which the additive is integrated. *See* RX 855 (Sahu Expert Report at 27-28); RX 854 (Burnette Expert Report at 21-23); F. 892, 910-951. Dr. Sahu

further explained that the biological digestion of the substrate (plastic and additive) continues indefinitely as the biota slowly peel back layers of plastic and continue to find the ECM Additive that is melted throughout the plastic material. *Id.*

Dr. Sahu and Dr. Burnette also explained that the ECM Additive, when melted uniformly throughout the plastic, creates weak points in the conventional plastic that can be broken down by enzymatic digestion, identifying the precise kinds of microbial life, microbial colony formation on plastic (so-called biofilms) and enzymes responsible for that degradation. *See* RX 855 (Sahu Expert Report at 27-28); RX 854 (Burnette Expert Report at 21-23); F. 892, 910-951. As Dr. Burnette explained, when the ECM Additive is added to the plastics mixture, it perturbs the plastics mixture. Enzymes look for points of weakness. If there is a way to take a bond that is already favorable for an enzyme and make it even more favorable, it would be to further reduce that bond strength. *See* RX 854 (Burnette Expert Report) at 21-23; F. 918-919, 956-981.

While Dr. McCarthy did not support his opinion with peer-reviewed literature (F. 900), the opinions offered by ECM's experts were supported by peer-reviewed literature. F. 604, 607, 735, 894-895, 901, 914-916, 926-927, 943-947, 951. For instance, the authors of the article titled, "*A Review on Recent Trends and Emerging Perspectives*," published in the *Journal of Polymers and the Environment*, edited by Dr. McCarthy, state: the insertion of weak links into polymers can cause biodegradation; compounding polymers with photosensitizers can cause biodegradation; and "the most frequently adopted approach to degradability design of [Low Density Polyethylene] LDPE has been to introduce pro-degradant additives such as starch and cellulose into synthetic polymers." F. 928.

In summary, a claim of product effectiveness is "false" where evidence developed under accepted standards of scientific research demonstrates that the product does not work as represented. *Pantron*, 33 F.3d at 1097. Having fully considered and weighed the expert testimony presented in this case, and the underlying support for the proffered expert opinions, Complaint Counsel has not proven its factual assertions that "[a] physical blend of 1% ECM Additive and 99% conventional plastic cannot change the underlying recalcitrance of the remaining 99% plastic" and "does not alter the chemical characteristics that make conventional

plastics resistant to biodegradation.” Complaint Counsel’s argument that Respondent’s claims are false, however, rests not only on these factual propositions, which Complaint Counsel failed to prove, but also on certain tests upon which Complaint Counsel relies. The Initial Decision next turns to the evidence on those tests.

b. Evidence on the tests upon which Complaint Counsel relies

In further support of its position that Respondent’s claims are false, Complaint Counsel argues that “tests show no biodegradation of ECM Plastic.” CCB at 59-61. This section of the Initial Decision analyzes only the tests that Complaint Counsel points to in its post-trial briefing as support for its argument that Respondent’s “biodegradable” claims are false because “tests show no biodegradation of ECM Plastic.” An analysis of the tests that Respondent relies upon to support its claims, and whether those tests are adequate to substantiate Respondent’s biodegradability claims, judged by the requirements of the relevant scientific communities, is addressed in Section III.E.10., *infra*.

Complaint Counsel points out tests performed by Dr. Barlaz, Dr. Michel, Stevens Ecology, Advance Material Center, and Organic Waste Systems. The arguments and evidence on each of these tests follows. Thereafter, Complaint Counsel’s testing evidence is considered as a whole, based on the totality of the evidence presented at trial.

• **Dr. Barlaz’s BMP tests**

Complaint Counsel asserts that Dr. Barlaz conducted at least four biodegradation tests of ECM Plastics under the Biochemical Methane Potential (“BMP”) test. Complaint Counsel further asserts that Dr. Barlaz’s BMP results showed no or negligible amounts of methane production and, in no case, an amount of methane exceeding the amount of gas attributable to the additive alone. CCB at 59-60.

Respondent points to the shortcomings of BMP testing (discussed in Section III.E.6.b., *supra*⁴⁵); argues that the presence of inconclusive tests does not nullify favorable tests; and

⁴⁵ In BMP tests, laboratories can choose to follow different protocols when adding types of vitamins and minerals; make adaptations to the temperature or duration of the test; or make modifications to the preparation of the test sample, such as screening the material by passing it through a 1 millimeter screen. F. 754.

states that in one of Dr. Barlaz's BMP tests, Dr. Barlaz obtained data showing that the plastic article had biodegraded substantially more than the amount reasonably attributed to the ECM Additive. RB at 99.

Dr. Barlaz, ECM's expert witness, has performed several tests on ECM Plastics. *See* F. 1433-1436. Respondent states that Dr. Barlaz performed those tests prior to, and independent of, his role as an expert witness in this case. RB at 99. Dr. Barlaz opined that the "BMP [test] is an appropriate screening tool for biodegradability in landfills." F. 755. However, he also explained that BMP tests are not appropriate for testing slower degrading materials, and that the amount of biodegradation observed through the BMP testing is likely to be only a fraction of the total biodegradation possible. F. 756. *See also* F. 1447.

Of the four BMP tests that were run by Dr. Barlaz on ECM Plastics, one showed no methane production; two showed negligible amounts of methane production; and one showed significant methane production. F. 1434-1436. In the test that showed that the plastic article had biodegraded substantially more than the amount reasonably attributed to the ECM Additive (CCX 952), Dr. Barlaz observed that the gas production was consistent throughout the 60-day test window, indicating that when he stopped the test at 60 days, the product had likely not finished biodegrading. F. 1442-1446. With respect to tests that showed no or negligible amounts of methane production, Dr. Sahu, Dr. Burnette, and Dr. Barlaz each testified that the presence of inconclusive tests does not nullify favorable tests. F. 800-807.

Dr. Barlaz acknowledged, as did Dr. Sahu, that many variables can affect the test results in a biodegradation study, including the manufacture of the plastic artifact tested. F. 800-801, 805. The few inconclusive BMP tests produced by Dr. Barlaz did not affect Dr. Barlaz's ultimate opinion in this case, discussed in Section III.E.10.a., *infra*, which, based on the totality of competent and reliable scientific evidence, was that plastics infused with the ECM Additive are anaerobically biodegradable. F. 1041.

Dr. Barlaz's BMP tests were only a few datasets among a much larger body of scientific evidence. F. 1044. The proper analysis must consider the evidence as a whole. For the reasons discussed above, Dr. Barlaz's BMP tests are not given significant weight on the issue

of whether Complaint Counsel has met its burden of proving its charge that Respondent's claims are false.

- **Dr. Michel's study**

Complaint Counsel asserts that the only published, peer-reviewed study to address whether ECM Plastic is biodegradable concluded that "plastics containing additives that supposedly confer biodegradability to polymers such as polyethylene and polypropylene did not improve the biodegradability of these recalcitrant polymers." CCB at 60-61 (citing CCX 164 (E. Gomez & F. Michel, *Biodegradability of conventional and bio-based plastics and natural fiber composites during composting, anaerobic digestion and long term soil incubation*, 98 *Journal of Polymer Degradation & Stability* 2583-91 (2013))). This study ("Dr. Michel's study"), published by E. Gomez and F. Michel, Complaint Counsel's rebuttal expert witness, reports that the authors ran a soil test lasting over two years and an ASTM D5511 test on polyethylene and polypropylene treated with the ECM Additive. *Id.*

Dr. Michel's study was funded in part by Myers Industries ("Myers"), a company that produces products marketed as compostable. F. 1467, 1480. The ECM Additive competes in the marketplace with compostable technologies. F. 1481. Myers prepared the two sample materials said to contain the ECM Additive. F. 1471. Dr. Michel does not have a certificate of ingredients regarding those samples and his study does not identify the conditions for the injection molding or the particular processing conditions that were used in the injection molding of the blends containing the ECM Additive. F. 1472-1474. Dr. Michel did not conduct an investigation of the inoculum used in his study to determine if the inoculum remained viable halfway through the test. F. 1476.

When he submitted his study to Elsevier for publication, Dr. Michel did not disclose that Myers funded his study, or that Mr. Eddie Gomez, a co-author of Dr. Michel's article on the study, was financially supported mostly by Myers' contributions to Ohio State University. F. 1467, 1485-1486. Furthermore, Dr. Michel did not disclose to Elsevier or in the article itself, that, under an agreement between Dr. Michel, Mr. Gomez, and Myers, Dr. Michel could disseminate the data from the study only after revision by Myers; that Mr. Gomez asked an

employee of Myers for suggestions regarding the article; or that Myers approved the article before Dr. Michel submitted it to Elsevier. F. 1487-1494.

When Dr. Michel submitted his article on the study to Elsevier for peer-review publication, he submitted only the article itself, and no other documentation, such as the underlying data upon which the study was based. F. 1483. Dr. Michel's article does not report the methane levels, the percentages of total gas composition, or the triplicate data. F. 1483. That absence of data would have precluded the peer reviewers from assessing the accuracy of his test. F. 1484.

Respondent contends that Complaint Counsel is incorrect in asserting that Dr. Michel's study produced "no biodegradation," because the study revealed 3.1% biodegradation as an average of the test vessels. RRB at 98-99 (citing CCX 164). Respondent further asserts that the data projected in Dr. Michel's test report demonstrates a progressive, steady increase in biodegradation of the ECM test plastic over time, until the entire laboratory system failed around the 30-day mark. RRB at 98-99 (citing CCX 164 at 2590 (showing system-wide plateau)). Respondent argues that because every test vessel, including the cellulose (which has been shown in other tests to biodegrade beyond 90%), plateaued right around the exact same time in the test, the system-wide plateau relates to the environmental conditions in the test. RRB at 99. Respondent's experts explained that a plateau in a test environment means that the test is simply no longer capable of sustaining biodegradation testing. F. 798-799. Respondent further asserts that Dr. Michel performed no statistical analysis to determine if the percent of biodegradation was more than what would be sourced from the ECM Additive during the period when the test was actually viable and that Dr. Michel did not investigate to identify the actual cause for test failure. RRB at 100 (citing Michel, Tr. 2961-2962).

Having evaluated the evidence and the arguments of the parties, and as discussed above, the Michel study and evidence presented at trial thereon is not given significant weight on the issue of whether Complaint Counsel has met its burden of proving its charge that Respondent's claims are false.

- **Stevens Ecology**

Complaint Counsel next asserts that Stevens Ecology, an independent lab in Oregon, ran several anaerobic tests, each finding no biodegradation under anaerobic conditions. CCB at 61 (citing CCX 174-CCX 176). In support of that assertion, Complaint Counsel cites only to the tests themselves. *Id.* See also CCPFF 144, 174, 453 (proposing, without explanation, that studies that show very little or no biodegradation of ECM Plastics were conducted by independent or reputable laboratories, were well-documented, and included other necessary information necessary to interpret the results). The only trial testimony offered on the Stevens Ecology tests was provided by Complaint Counsel's expert, Dr. McCarthy, who opined that the tests performed by Stevens Ecology are reliable because they used the proper standards, the test samples were exposed to the proper period of time, and the testers performed the proper standard deviation and included information on the loading rate, the inoculum, the length of time, the temperature, the moisture, and volatile solids. (McCarthy, Tr. 467-468).

With respect to CCX 174, Stevens Ecology, 2008 Test of FP International's Loose Fill Product, Respondent asserts that the laboratory claimed to follow the ASTM D5511 test protocol, which says that "[f]or the test to be considered valid, the positive control must achieve 70% biodegradation within 30 days," RRB at 88 (citing CCX 84 at 3 ¶ 11.2.1.1), but that none of the test procedures in CCX 174 produced the 70% value within the 30-day period and, thus, the tests are invalid. RRB at 88. Respondent further asserts that the purpose of that requirement is to ensure that the test environment is viable enough to actually measure biodegradation. RRB at 88.

Respondent next asserts that it is clear by looking at the test environment, as pictured by the laboratory on page 9 of CCX 174, why those tests reported little biodegradation – the test materials are not even contacting the inoculum that contains the microbes responsible for biodegrading material. RRB at 89-90 (citing CCX 174 at 9). Respondent contends that the laboratory recognized that problem, and decided to remedy that design error by shaking the vessels every now and then. RRB at 89 (citing CCX 174 at 9 (“[T]his arrangement introduced a potential difficulty, since most of the test material in treatments T was not in contact with the compost inoculum. To alleviate this, and to ensure even aeration, the vessels were physically

agitated each day.”)). Respondent further argues that neither Complaint Counsel nor its experts attempted to explain how this type of test could be valid when the inoculum is not in continuous contact with the test material, and when whatever contact that does occur is constantly broken by agitating the test material. RRB at 90.

With respect to CCX 175, Stevens Ecology 2008 Biodegradation Testing of Plastic Film Product, Respondent raises the same point it did in relation to CCX 174, that the anaerobic testing failed to reach 70% biodegradation of the positive control within 30 days and, thus, the test is considered invalid under the ASTM D5511 test protocol. RRB at 91 (citing CCX 84 at 3 ¶ 11.2.1.1).

Respondent next asserts that the collection system used by Stevens Ecology, apparently manufactured out of PVC tubing, is not permitted by the ASTM D5511 standard. RRB at 91-92 (citing CCX 175 at 17; CCX 84; RX 356). Respondent contends that there is no evidence or discussion in the record supporting the competence or accuracy of this testing method, how this system works, or how the laboratory could calibrate its testing system. RRB at 91-92. Respondent points out that Complaint Counsel’s expert, Dr. Tolaymat, criticized ECM’s tests because the laboratories had used a graduated cylinder to record gas totals, even though the ASTM D5511 standard itself calls for the use of a graduated cylinder for that purpose. RRB at 92 (citing Tolaymat, Tr. 206; CCX 84 at 2 ¶ 6.1 (requiring the use of an “inverted graduated cylinder or plastic column”)) and that Complaint Counsel also criticized NE Labs’ use of metal canisters, instead of glass vessels, during biodegradation testing. RRB at 92 (citing CCX 891 at 34). Respondent contends that Complaint Counsel is inconsistent in its criticism of the collection systems used in tests relied upon by ECM (analyzed in Section III.E.10.b., *infra*), while accepting what Respondent calls “makeshift gas totalizers” used in the Stevens Ecology test, as appropriate vessels.

With respect to CCX 176, Stevens Ecology 2008 Biodegradation Testing of Plastic Film Product, Revision A, Respondent points out that this test report is a revised version of the test report marked CCX 175, and asserts the same issues and concerns with CCX 176 as it does with CCX 175.

Having evaluated the evidence and the arguments of the parties, and as discussed above, the Stevens Ecology studies and evidence presented at trial thereon are not given significant weight on the issue of whether Complaint Counsel has met its burden of proving its charge that Respondent's claims are false.

- **Advance Material Center**

Complaint Counsel next asserts that two tests conducted by Advance Material Center, Inc., showed no biodegradation under both aerobic and anaerobic conditions. CCB at 61 (citing CCX 173). In support of that assertion, Complaint Counsel cites only to the tests themselves. *Id.* See also CCPFF 453 (proposing without explanation that studies that show no biodegradation of ECM Plastics were conducted by independent or reputable laboratories, were well-documented, and included other necessary information necessary to interpret the results). No trial testimony was offered on the Advance Material Center tests. Respondent objects to the use of these tests as they were never discussed by Complaint Counsel's experts at the hearing, was subject to no testimony to explain the tests, and had no sponsoring witness to explain any flaws or information gaps. RRCCFF 453.

The Advance Material Center studies, with no supporting fact or expert testimony, and as discussed above, are not given significant weight on the issue of whether Complaint Counsel has met its burden of proving its charge that Respondent's claims are false.

- **Organic Waste Systems, Inc. ("OWS")**

Finally, Complaint Counsel asserts that Organic Waste Systems, Inc. ("OWS") conducted several composting studies and several anaerobic tests that report no biodegradation. CCB at 61 (citing CCX 156; CCX 157; CCX 163; CCX 169-CCX 171). In support of that assertion, Complaint Counsel cites only to the exhibits themselves. *Id.* See also CCPFF 144, 453 (proposing without explanation that the studies that show very little or no biodegradation of ECM Plastics were conducted by independent or reputable laboratories, were well-documented, and included other necessary information necessary to interpret the results). Respondent charges, with respect to each of these OWS exhibits, that Complaint Counsel failed

to support the documents with any fact witness or expert testimony of any kind (at deposition or at the hearing). RRCCFF 143, 453.

With respect to CCX 156, Respondent asserts that this exhibit is a collection of emails between non-parties and that the piecemeal reports submitted through email do not disclose the methane content of the test vessels or the triplicate data. RRB at 92 (citing CCX 156). Respondent further states that because the laboratory reported a negative amount of biodegradation in the test vessel over the short duration test and because Complaint Counsel has stipulated that the ECM Additive is biodegradable (JX 3 at 3), if the laboratory records negative amounts of biodegradation showing that the test article inhibited biological activity, that data strongly suggests that (a) the ECM Additive was not present in the test plastic; (b) the test plastic contained other components that are antimicrobial or inhibitory of biodegradation; (c) the ECM Additive was not properly manufactured in the test article, either due to burning or scorching; or (d) the lab environments for the various test plastics were not biologically conducive to biodegradation testing. RRB at 92-94 (internal citations omitted). Respondent argues that without exploring those possibilities, a result of the kind seen in CCX 156 is inconclusive and highly suspect. *Id.*

With respect to CCX 157, OWS 2010 Biodegradation Test for Covidien, Respondent asserts that CCX 157 is not a valid test under the ASTM D5511 standard because the test environment plateaued prematurely, demonstrating that the environment was not competent to permit assessment of biodegradability, and that the test never reached the minimum 70% biodegradation for the positive control, as required by the test standard. RRB at 94 (citing CCX 157 at ECM114737; CCX 84 at 3 ¶ 11.2.1.1). *See also* F. 1458-1462.⁴⁶ Furthermore, Respondent asserts, the test environment ostensibly plateaued, even for the cellulose control, around the sixth day of testing, which strongly suggests that the test was not conducive to protracted biodegradability testing. RRB at 94 (citing Burnette, Tr. 2401-2402, 2412-2413, 2442-2443; Barlaz, Tr. 2272-2273). *See* F. 1461-1464. Respondent also asserts that the test reported as CCX 157/RX 268 included none of the data necessary to evaluate the tests themselves – no data concerning the methane production in the anaerobic test, no gas readings

⁴⁶ The OWS 2010 Biodegradation Test for Covidien was entered into evidence as both CCX 157 and RX 268.

or triplicate data, and no information as to the nature of the plastic or the load rating of the ECM Additive. RRB at 94-95 (citing CCX 157). The OWS test marked CCX 157 and RX 268 revealed 3.9% biodegradation of the test sample in 15 days of anaerobic degradation. F. 1463.

With respect to CCX 163, OWS 2009 Biodegradation Test for Masternet, Respondent notes that this test demonstrated a biodegradation of -3.7% in the test article and reiterates the same concerns with CCX 163 as with CCX 157. RRB at 95. Respondent also states that because OWS did not include a negative control in its tests, it is impossible to determine whether that inhibitory effect was also observed in an untreated plastic. RRB at 95-96. Respondent argues that because of these flaws, this test is not sufficiently reliable. *Id.*

Regarding CCX 169, OWS Review of Several Documents, Reports and Statements on Biodegradation of ECM Masterbatch Pellets, Respondent asserts that this document is not a “test,” as described by Complaint Counsel, but a review of other materials, and that the document does not include any original test data considered by OWS, or any of the statements and marketing materials relied on by OWS in its review letter. RRB at 96-97 (citing CCX 169). Respondent thus asserts that CCX 169 is unreliable hearsay and should be given no weight. *Id.*

As to CCX 170, 2007 Aerobic Biodegradation Test of Plastic Bag Under Composting Conditions, Respondent asserts that the study authors provided no data from the study that would be necessary to verify the testing method used or to determine the amount of biodegradation recorded in the study. RRB at 97 (citing CCX 170). For example, Respondent states, this OWS test did not report total gas volume data, provide percentages of carbon dioxide, provide information concerning the calculation of the theoretical gas yields from the sample, and did not report information concerning the test plastic itself, including the load rating of the ECM Additive, or if the ECM Additive was even involved. RRB at 97 (citing CCX 170). Thus, Respondent argues, CCX 170 is an inconclusive test with serious methodological flaws. *Id.*

With respect to CCX 171, OWS 2012 Anaerobic Biodegradation Study for Shields, Respondent reiterates its previous concerns noted above with the OWS laboratory testing,

including the lack of supporting data, particularly the absence of any methane data. RRB at 98 (citing CCX 171). Respondent further states that CCX 171 failed to use a negative control, which is significant because the reported biodegradation in the sample vessel was -4.4%, meaning that the test plastic actually inhibited rather than promoted biodegradation, and that the test therefore reveals a high likelihood that the plastic contained a component that was inhibitory of biodegradation, or that the test plastic containing the ECM Additive was not properly manufactured. RRB at 98. Respondent argues that CCX 171 is unreliable hearsay and inconclusive, as it fails to include any identification or scientific evaluation of the actual cause for test failure. RRB at 98.

The OWS studies, with no supporting fact or expert testimony, and as discussed above, are not given significant weight on the issue of whether Complaint Counsel has met its burden of proving its charge that Respondent's claims are false.

- **Summary of tests cited by Complaint Counsel**

Without expert testimony or a sponsoring witness, it is not possible to evaluate the reliability or validity of many of the tests relied upon by Complaint Counsel. Respondent has pointed out numerous flaws in those tests. In addition, Respondent's experts testified that many variables could influence the outcome of a gas evolution test, and that an inconclusive test is expected in light of those variables and must be examined and assessed to determine what, if anything, those tests reveal. F. 800-806. Moreover, Complaint Counsel disregards every single positive ECM test in the record which Respondent's expert, Dr. Barlaz, explains. Section III.E.10.a., *infra*. It should also be noted that, while Complaint Counsel criticizes tests relied upon by Respondent as flawed because they "look to the ASTM D5511 method to support ECM's biodegradation claims," (CCB at 68) several of these tests cited by Complaint Counsel also look to the ASTM D5511 method to assess biodegradability.

Complaint Counsel, as the proponent of its charge that "tests show no biodegradation of ECM Plastic," CCB at 59, has the burden of proving that assertion. Weighing the evidence presented and for the reasons set forth above, Complaint Counsel has failed to meet that burden.

In alleging that the Challenged Claims are false, Complaint Counsel “must carry the burden of proving the claims to be false” and the fact finder is “required to determine whether the evidence put on by [Complaint Counsel] shows the claims to be false.” *Thompson Medical*, 1984 FTC LEXIS 6, at *381-82. As set forth above, and based on the totality of the evidence presented at trial, Complaint Counsel has not met its burden of showing that the ECM Plastics are not biodegradable, including in a landfill. Therefore, Complaint Counsel has not proved that Respondent’s efficacy claims are false.

9. Whether Respondent’s Establishment Claims Are False

Complaint Counsel, in its Post-Trial Brief, argues that Respondent’s “claims” (generically and without further specification) are both false and misleading. The allegation in the Complaint that “ECM Plastics have been shown to be biodegradable, biodegradable in a landfill, or biodegradable in a stated qualified timeframe under various scientific tests, including, but not limited to, ASTM D5511,” (Complaint ¶ 9D), is an establishment claim.

As noted above, Complaint Counsel can prove an establishment claim is “false” where Respondent represents expressly or implicitly that there is scientific support for its claims, but Respondent lacked such proof at the time the representations were made. *POM*, 2013 FTC LEXIS 6, at *53. If Respondent’s substantiation does not meet the level of studies demanded by the relevant scientific communities, then Respondent’s claims of scientific proof establishing its biodegradability claims are false. *See POM*, 2013 FTC LEXIS 6, at *67. When a respondent makes a claim that “tests prove” that its product works, because such a claim “is inherently a substantiation claim, the falsity and reasonable basis theories collapse into the same inquiry: did Defendants possess adequate substantiation to make such a claim?” *QT, Inc.*, 448 F. Supp. 2d at 966. Thus, to evaluate whether the challenged establishment claim is false, the analysis turns to Respondent’s proffered substantiation and whether it constitutes competent and reliable scientific evidence.

10. Whether Respondent Possessed Adequate Substantiation For Its Claims

Complaint Counsel can prove a claim that “studies prove” that a product works as represented is “unsubstantiated” by demonstrating that the proffered substantiation fails to meet

the standards required in the scientific community for that type of claim. *Removatron*, 1985 FTC LEXIS 21, at *195-96; *QT, Inc.*, 448 F. Supp. 2d at 959. Respondent is held to the level of substantiation that the advertisements claim. *POM*, 2013 FTC LEXIS 6, at *65 n.18.

This section of the Initial Decision analyzes, first, the evidence presented by Respondent as its proffered substantiation. This section analyzes, second, the evidence presented by Complaint Counsel in support of its position that Respondent's proffered substantiation fails to meet the standards required in the relevant scientific community, and is therefore inadequate to substantiate Respondent's claims.

a. Tests relied upon by Respondent

To support its position that competent and reliable scientific evidence supports its efficacy claims that ECM Plastics are biodegradable, including in a landfill, and that it has the level of substantiation that ECM claimed in its Certificate of Biodegradability and Marketing Materials ("various scientific tests, including, but not limited to, ASTM D5511") (Complaint ¶ 9D; F. 265, 272), Respondent relies upon the reports and testimony of its experts who reviewed the tests offered by Respondent including ASTM D5511 tests on ECM Plastics. Extensive findings on these tests and the experts' evaluations of these tests are set forth in F. 1006-1424 and summarized below.

The ASTM D5511 test method is a competent and reliable scientific method for assessing intrinsic biodegradability. Section III.E.6., *supra*. As detailed in F. 1043-1424, Respondent introduced numerous ASTM D5511 anaerobic gas tests upon which ECM relied to substantiate its claims. Dr. Barlaz reviewed many of the gas evolution studies involving the ECM Plastics. F. 1008, 1043. He examined the raw data produced by Northeast Laboratories ("NE Labs") and Eden Research Laboratories ("ERL"), particularly the data concerning methane generation from the test substrate and methane generation from the inoculum that would be the background methane. F. 1008, 1011, 1043. For those tests where Dr. Barlaz had raw data or triplicate data, Dr. Barlaz performed statistical analyses, including t-tests,⁴⁷ to

⁴⁷ The t-test is a statistical procedure that allows one to determine the significant difference between two sets of data. A t-statistic is the most common statistical test after a calculation of the average. F. 1013.

determine whether there were statistically significant differences between the methane generation in the reactor with test substrate and the methane attributable to the inoculum alone. F. 1012; *see also* F. 1014.

For other studies where triplicate data was not available, Dr. Barlaz examined the ratios of methane generation in the test material plus inoculum to methane generation from the inoculum only. F. 1016. Dr. Barlaz concluded for those studies, that ratios varied, but the ratios were generally significant, even at the lower end. F. 1015. From those ratios, Dr. Barlaz determined that the methane generation in the test vessels could be attributable to the test substrate, which suggests that the substrate was undergoing anaerobic biodegradation and conversion to methane. F. 1017. Dr. Barlaz prepared a spreadsheet of his statistical calculations and updated his spreadsheet to include additional calculations based on the data. F. 1018-1019.

To address the question of whether only the ECM Additive had biodegraded, Dr. Barlaz estimated the amount of methane that could theoretically be produced by the ECM Additive alone. F. 1020. Dr. Barlaz made certain conservative assumptions about the ECM Additive when calculating the amount of potential methane. F. 1021. Dr. Barlaz's conservative calculation was that one gram of ECM Additive would produce 933 mL of methane gas. F. 1022. Based on that calculation of 933 mL, Dr. Barlaz looked at the methane yields in the test vessels during biodegradation testing, and determined that the amount of biodegradation exceeded the amount that could potentially be sourced from the ECM Additive. F. 1023. Dr. Barlaz's calculation of the potential methane yield of the ECM Additive is likely conservative because of the assumptions he made. For example, Dr. Barlaz assumed the ECM Additive was 50% carbon because most items are about 50% carbon. F. 1024. Polyethylene, by contrast, is almost 90% carbon. F. 1025.

In addition, Dr. Barlaz calculated the methane yield of the ECM Additive based on the formula for the ECM Additive that Dr. McCarthy used in his expert report at page 24, footnote 17, which was stated to be the result of reverse engineering of the ECM product. F. 1026-1027. Based on Dr. McCarthy's assumptions about the ECM Additive's contents, Dr. Barlaz calculated a methane yield for the ECM Additive of 838 mL per gram. F. 1027. Using Dr.

McCarthy's assumptions, the data produced in the gas evolution tests suggests that even more of the substrate plastic (not the additive) biodegraded because the ECM Additive would have had a lower potential methane yield. F. 1028.

Using the test performed by NE Labs on behalf of Minigrips, conducted on a plastic amended with 1.5% ECM Additive as an example ("NE Labs Minigrips test") (F. 1286-1312),⁴⁸ Dr. Barlaz explained the arithmetic summarized in his spreadsheet. F. 1029. Dr. Barlaz calculated the weight of the ECM Additive (in grams) by multiplying the percentage of the ECM Additive load rating (in the Minigrips test, 1.5%) by the starting weight of the entire test plastic. F. 1030. Once Dr. Barlaz had calculated the amount of total methane potential from one gram of ECM Additive, he was then able to determine the total amount of methane possible in the ECM Additive in each specific test by multiplying the actual weight of the ECM Additive by the conservative 933 mL calculation (or 838 mL if using Dr. McCarthy's assumptions). F. 1031. Dr. Barlaz's calculation of the ECM Additive's methane potential shown in the NE Labs Minigrips Testing (RX 838) is set forth in F. 1298-1303.

Dr. Barlaz also calculated the net methane for each test vessel, which he did by subtracting the mean triplicate methane data from the inoculum blanks from the test vessels. F. 1032. For those studies where Dr. Barlaz had raw data or triplicate data, he calculated t-tests and standard deviations. F. 1012, 1014. Dr. Barlaz looked for a 95% certainty in the statistics that he ran, which would mean that the researchers are 95% "certain that you got the right answer." F. 1033. Dr. Barlaz's t-statistics were generally well below the .05 that indicates statistical significance at the 95% level. F. 1034. Dr. Barlaz's mathematical process is explained in his testimony. F. 1035.

Dr. Barlaz explained convincingly that where the methane produced from the test vessel is not attributable to the inoculum, and not attributable to the ECM Additive, then the biodegradation must come from the plastic substrate itself. F. 1036. Dr. Barlaz also analyzed the ratios of methane to carbon dioxide in the lab tests. F. 1037. A ratio of methane to carbon

⁴⁸ In the NE Labs Minigrips test, marked RX 838, from May 2011 through August 2012, NE Labs reported biodegradation test data from an anaerobic ASTM D5511 biodegradation test in laboratory reactors. F. 1286. The NE Labs Minigrips test included the use of an inoculum blank, a negative control (untreated plastic), a positive control (cellulose), and a test sample, all of which were run in triplicate. F. 1289. The test sample was plastic amended with 1.5% ECM Additive. F. 1290.

dioxide that is greater than 1:1, respectively, is a good indication that the anaerobic environment was behaving properly. F. 1038. Dr. Barlaz explained that gas evolution testing also does not account for carbon that may have been cleaved from the substrate but converted to cell mass instead of gas. F. 1039. Therefore, Dr. Barlaz persuasively testified, the biodegradation numbers calculated by the laboratories based on gas data alone are a lower limit of the carbon conversion than was actually realized. F. 1040.

In the NE Labs Minigrips test, the test results were confirmed through other standards, including the ASTM D6579, which is a standard for calculating molecular weight averages and molecular weight distribution in the test sample vs. the negative control. F. 1305-1309. The NE Labs Minigrips test had reported approximately 17% biodegradation of the test sample after 365 days of testing. F. 1310. The test sample consisted of LLDPE (linear low density polyethylene) plastic bags with a 1.5% ECM Additive. F. 1291. In its August 1, 2012 Analytical Report (RX 838), NE Labs demonstrated that the plastic “zip bags” treated with the 1.5% ECM Additive had a molecular weight that was approximately 16% less than the untreated test sample. F. 1307. Both the number average and the weight average molecular weights of the 1.5% ECM treated plastic had declined by about 16%. F. 1037. Thus, the results of the ASTM 6579 test confirmed the results of the ASTM D5511 test in the NE Labs’ Minigrips study. NE Labs reported in its analysis that the “change in molecular weight is a measure of bulk deterioration. As an analytical method it indicates that polymer chains are breaking down or cleaving during biodegradation.” F. 1309.⁴⁹

Results from ASTM D5511 tests in evidence showed net methane yields greater than the amount of biodegradation that could have possibly been sourced from the ECM Additive alone. *E.g.*, F. 1128, 1149, 1162, 1181-1182, 1196, 1215-1216, 1283, 1302, 1328, 1353, 1379, 1402-1403. Dr. Barlaz credibly and persuasively testified that “[b]ased on checking of the lab reports, there were numerous examples where specific plastics were shown to anaerobically biodegrade to methane.” F. 1043. Thus, Respondent has met its burden of producing the scientific evidence upon which it relies.

⁴⁹ The biodegradation of plastic polymers involves hydrolytic cleavage of polymer bonds. F. 920.

While Respondent has the burden to produce the evidence upon which it relies to substantiate its representations, Complaint Counsel bears the burden of proving that the substantiation is inadequate. *In re Daniel Chapter One*, No. 9329, 2009 FTC LEXIS 259, at *63 (Dec. 24, 2009). After Respondent meets its burden of establishing what substantiation it relied on for its claims, under the reasonable basis theory, “[t]he FTC has the burden of proving that [Respondent’s] purported substantiation is inadequate,” *QT, Inc.*, 448 F. Supp. 2d at 961; and, under the falsity theory, Complaint Counsel must show that the studies Respondent possessed did not pass muster in the view of the relevant scientific communities. *POM*, 2013 FTC LEXIS 6, at *67. The next section, thus, analyzes whether Complaint Counsel has met its burden of proving that Respondent’s substantiation is inadequate or that Respondent’s tests do not meet the standards demanded by the scientific community.

b. Complaint Counsel’s challenges to Respondent’s substantiation

In support of its position that Respondent’s substantiation is inadequate or does not meet the standards demanded by the scientific community, Complaint Counsel contends: (1) the tests that Respondent relies upon are fatally flawed; and (2) the tests that Respondent relies upon cannot support claims of complete biodegradation in landfills. The arguments and evidence on these points are discussed below.

i. Challenged flaws in Respondent’s tests

Complaint Counsel contends that many of Respondent’s tests are so methodologically flawed that they are not reliable evidence. As discussed above, the ASTM D5511 test is a competent and reliable method to show whether a material is biodegradable in a landfill. The critiques of the anaerobic gas evolution tests conducted by Eden Research Labs (“ERL”) and Northeast Labs (“NE Labs”) and a determination on whether these tests were well-conducted and well-controlled are discussed below.

• Eden Research Labs’ Testing

Complaint Counsel criticizes the anaerobic gas evolution ASTM D5511 tests conducted by ERL, stating, first, that Mr. Thomas Poth, the owner of ERL, testified that: ERL does not report statistical information, so it does not know if the test results are statistically significant.

CCB at 69 (citing Poth, Tr. 1512-1513, 1538). Respondent responds to this criticism, stating: although ERL did not report standard deviations, it did report triplicate data in its final reports, and it reported detailed findings concerning the amount of biogas produced in the studies. RRB at 119 (citing RX 248; RX 839; RX 403; RX 402; CCX 548; CCX 546; CCX 534; CCX 547). As analyzed in III.E.10.a., *supra*, for those gas evolution studies on ECM Plastics where Dr. Barlaz had raw data or triplicate data, he performed statistical analysis, including t-tests, to determine whether there were statistically significant differences between the methane generation in the reactor with the test substrate and the methane attributable to the inoculum alone. F. 1012.

Second, Complaint Counsel asserts that ERL provides primarily “quick-and-dirty” updates that are not given the same level of rigorous review as the reports. CCB at 69 (citing Poth, Tr. 1499-1500). Respondent asserts that ERL’s “update” reports, which note the progress of studies (instead of full reports that would issue at the end of a study, or upon request by a customer), do not include all of the information relevant to the studies, but that is not an indication that the data is unreliable. RRB at 119 (citing Poth, Tr. 1475; RX 403; CCX 548; CCX 546; CCX 534; CCX 547). ERL produces update reports to keep customers abreast of the status of testing. Update reports do not include all of the information relevant to the test, or all of the information included in a final report. F. 1118.

Third, Complaint Counsel asserts that ERL adjusts the biodegradability percentage of positive control to 100% even though ASTM D5511 does not provide for the adjustment and Mr. Poth is aware that cellulose will never reach 100% biodegradation. CCB at 69 (citing Poth, Tr. 1505-1507). Respondent asserts that while ERL provided adjusted calculations, ERL also provided the unadjusted percentage without any additional calculations, *e.g.*, the pure percentage of biodegradation based on the loss of methane from the test vessel. RRB at 120 (citing, *e.g.*, RX 403 at 1 (listing “Percent Biodegraded (%)” immediately above “Adjusted Percent Biodegraded (%)”). Respondent states that ECM relies on that pure “percent biodegraded” number in this case, rendering the criticism of the adjusted number immaterial (citing the spreadsheet prepared by Dr. Barlaz, RX 968) and, thus, argues there is no basis to suggest that ERL’s adjusted number calculation affected the test results, affected ECM’s experts’ opinion of the tests, or affected the underlying data. RRB at 120.

In addition to those criticisms of the ERL tests noted above, Complaint Counsel asserts that in his expert report, Dr. McCarthy, based on the deposition transcript of ERL, finds at least four things that call into question the validity of ERL's test results. CCB at 70. While Dr. McCarthy posits these four criticisms of ERL's testing in his report, he did not convincingly explain those points in his testimony at trial. *See generally* McCarthy, Tr. 359-680.

First, Dr. McCarthy contends that ERL "is run by a person lacking the proper credentials" to run biodegradation tests. CCX 891 ¶ 89(i). However, Dr. McCarthy had never visited ERL, or spoken with its owner, Mr. Poth. *See* CCX 891 ¶ 89 (McCarthy Expert Report) (basing his opinion on the deposition transcript provided to him). The evidence at trial shows that ERL's tests are performed by Mr. Poth and Dr. Brian Esau. F. 1048. Dr. Esau has a master's degree and a Ph.D. in biochemistry from the University of Illinois at Champaign-Urbana. F. 1049.

Second, Dr. McCarthy discounted the ERL testing because, according to Dr. McCarthy, ERL replaced the inoculum during long-term testing. CCX 891 ¶ 89(ii). However, when asked about replacing inoculum, Mr. Poth testified unequivocally at the hearing that "[w]e don't do that." F. 1074.

Third, Dr. McCarthy opined that ERL "conducted tests for periods well-beyond the validation period of the test." CCX 891 ¶ 89. However, contrary to Dr. McCarthy's opinion, the ASTM D5511 method does not specify a cutoff time or duration for the test and, in fact, the method specifically contemplates tests of varying durations: "The incubation time shall be run *until* no net gas production is noted for at least five days from both the positive control and the test substance reactors." F. 785 (RX 356 at 3 § 11.2.1.2) (emphasis added). Moreover, Dr. Sahu persuasively testified that extending the duration of an ASTM D5511 test does not render the data unreliable. F. 787. Dr. Sahu testified that, consistent with the ASTM D5511 standard itself, as long as the conditions of the test are maintained, there is no reason to simply reject a test based on an increase in study duration. F. 787. Although Dr. Tolaymat rejected ECM's ASTM D5511 tests that were run longer than 60 days because those tests did not "follow the standard test method," he acknowledged that an ASTM D5511 test could be conducted for

several years while remaining viable. F. 789. Moreover, Dr. Tolaymat acknowledged that the BMP test, which he himself used and recommended to test biodegradability of plastics, does not even have a standard test method. F. 753. In addition, Complaint Counsel's rebuttal expert, Dr. Michel, has performed biodegradation gas evolution studies in his laboratory that exceeded 500 days. F. 790.

Fourth, Dr. McCarthy stated, without explanation, that ERL "improperly modifies the raw data." CCX 891 ¶ 89(iv). Without any explanation, it is unclear as to how, if at all, ERL has "improperly modified" the data, and Dr. McCarthy has not supported that statement in his report with any record evidence that would suggest any "improper modification" of the data. *See id.* By contrast, as found in F. 1008-1042, Dr. Barlaz examined and assessed the raw data produced by ERL. Dr. Barlaz's evaluation of the data is summarized in Section III.E.10.a., *supra*. In addition, almost all of ERL's tests employed negative controls. *E.g.*, F. 1084, 1103, 1119, 1139, 1154, 1166, 1186, 1200. Respondent's experts persuasively explained that the use of negative controls in those tests undercuts Complaint Counsel's asserted criticisms of the methodology. *See* F. 764, 772, 1011-1041.

Dr. Barlaz further testified that he had visited ERL in an unrelated trip before this case began. F. 1077. Dr. Barlaz reviewed ERL's testing model and procedures, and was satisfied that ERL's testing was strictly under anaerobic conditions and that ERL had the appropriate capability to accurately monitor gas volume and composition. F. 1078-1079. By contrast, Dr. McCarthy's opinion was based on his review of the deposition of ERL's representative. CCX 891 ¶ 89.

Weighing the criticism offered by Complaint Counsel's expert, Dr. McCarthy, against the more credible and persuasive evidence offered by Respondent's experts, the greater weight of the evidence fails to show that the anaerobic gas evolution tests performed by ERL are so fatally flawed as to not constitute reliable and competent scientific evidence substantiating that ECM Plastics are biodegradable, or that these tests are inadequate to substantiate ECM's "biodegradable" or "tests prove" claims.

- **NE Labs' Testing**

Complaint Counsel and its expert, Dr. McCarthy, criticize the anaerobic gas evolution ASTM D5511 tests conducted by NE Labs on a number of grounds. Dr. McCarthy based his opinion on the deposition of NE Labs' corporate designee, Ms. Alyssa Ullmann. CCX 891 ¶ 88.⁵⁰

First, Complaint Counsel states that Mr. Alan Johnson, the current owner and laboratory director of NE Labs, testified at trial that NE Labs does not undergo any audits, does not hold any certifications, and has never been evaluated. CCB at 68 (citing Johnson, Tr. 1580-1581). Respondent replies to this criticism stating, although it is true that NE Labs' biodegradable testing group was not audited, the rest of NE Labs was audited by state and federal authorities. RRB at 115 (citing Johnson, Tr. 1559-1560). NE Labs passed its audits, and it holds several certifications relevant to sensitive testing areas. F.1220-1221. NE Labs' chemistry lab, which performs services for the biodegradation laboratory during the biodegradation testing, is audited. F. 1221. Respondent further argues that whether or not NE Labs is audited is not a substitute for proof of invalidity of the specific tests performed, is highly speculative because the absence of an audit is not the same as an audit failure, and has no bearing on the accuracy or reliability of NE Labs' tests. RRB at 115. In addition, Respondent argues that Complaint Counsel has not produced evidence that the auditing of biodegradation labs is common, that Complaint Counsel's own experts' labs have been audited, or that other biodegradation labs are audited. RRB at 115.

Second, Complaint Counsel argues that NE Labs did not maintain anaerobic conditions throughout the duration of the extended anaerobic ASTM D5511 tests. CCB at 68 (citing Johnson, Tr. 1574). Dr. McCarthy, in his expert report, also opines that NE Labs replaced the inoculum, which "would likely lead to overestimation of biodegradation, expose the inoculum

⁵⁰ Ms. Ullmann testified in her deposition that Mr. Alan Johnson and Mr. Garrett Johnson, counsel for NE Labs, determined that Ms. Ullmann was the best person to provide deposition testimony in response to Complaint Counsel's subpoena because she handles all the clients, puts clients' reports together, and has "been doing biodegradation stuff the longest," but that Alan Johnson would be the most knowledgeable person in NE Labs to answer questions concerning scientific issues, tests, and protocols. RX 873 (Ullmann, Dep. at 130).

to oxygen, thus not simulating anaerobic conditions. This deviates from the ASTM method and calls into question the credibility of those conducting the lab.” CCX 891 ¶ 88.

Respondent first asserts that no evidence supports the contention that NE Labs re-inoculated its canisters in the ECM testing, but, even if NE Labs did do that, the use of nitrogen gas to sparge canisters clearly maintained an environment that produced methane gas. RRB at 116; *see also* F. 1255. Respondent next asserts that Complaint Counsel failed to acknowledge that NE Labs sparged its canisters with nitrogen (an inert gas that does not affect biodegradation testing) after re-inoculating. RRB at 116 (citing Johnson, Tr. 1573-1574; Barlaz, Tr. 2276).

For longer-term extension testing over 45 days past the planned termination date, NE Labs would assess whether the activity in the triplicate vessels had leveled off. F. 1251. If the activity in the test vessels had leveled, and the positive control had already been digested, NE Labs would remove the test materials and negative controls from the stale testing environment, and place those materials into a new reactor canister with fresh inoculum. F. 1252. To maintain anaerobic conditions during a long-term extension test, NE Labs would sparge (or flush) the new canisters with nitrogen to remove excess atmospheric gases. F. 1253-1254. Dr. Sahu expressed no concern with the process of replenishing the inoculum. F. 1265.

Relying on Dr. Barlaz, Respondent notes that the percentage of biodegradation recorded in the test environments is based on methane production. RRB at 115; F. 764-765; *see also* F. 744. Methane can only be produced by an anaerobic system. F. 1077. The presence of oxygen either destroys or severely limits an anaerobic system. F. 1262. Thus, Respondent argues, even assuming the NE Labs tests were aerobic at times, the amount of anaerobic biodegradation would be minimized as oxygen kills off the anaerobes. RRB at 115. Respondent further points to the evidence that NE Labs’ tests consistently produced methane during the course of the tests. F. 1282-1285, 1301-1304, 1321-1328, 1337, 1349-1353, 1372-1379, 1394-1402. Because the amount of biodegradation in the ASTM D5511 test is calculated based on methane production, which is exclusive to anaerobic systems, F. 744, 759, 764, 1007, this evidence undermines Complaint Counsel’s theory that aerobic conditions either existed or factored into the data from NE Labs’ tests.

Third, Complaint Counsel states that the ASTM D5511 test method does not allow for extension testing, *i.e.*, testing beyond the 30-day period of the test. CCB at 69 (citing Johnson, Tr. 1583). Dr. McCarthy in his report, too, opines that NE Labs conducted tests for periods well beyond the validation period of the test. CCX 891 ¶ 88. The evidence on the duration of ASTM D5511 testing, summarized above in relation to the criticisms of ERL's tests, shows this criticism is without merit.

Fourth, Complaint Counsel maintains that the protocol for extended ASTM testing was set up by Dr. Bill Ullmann and has never been independently re-evaluated. CCB at 69 (Johnson, Tr. 1560, 1583). Dr. McCarthy's report also opines that NE Labs did not have someone with the proper education or training overseeing the test. CCX 891 ¶ 88. Respondent contends that this criticism is not relevant to the reliability of NE Labs' testing. Respondent further points to evidence that Dr. Ullmann was a well-credentialed and established researcher, was the former director of the state of Connecticut's Public Health Laboratory, and held a Ph.D. in microbiology (RRB at 116-117 (citing Johnson, Tr. 1562)) and notes that he was well qualified to design NE Labs' biodegradation testing. *See* F. 1223-1225.

Fifth, Complaint Counsel asserts that NE Labs' system for gas monitoring involves using an inverted cylinder and metal paint cans and that there would be no way to identify a small leak in the system from gas generation. CCB at 69 (citing Johnson, Tr. 1584). Dr. McCarthy's report, too, opines that NE Labs used an inappropriate apparatus and that the apparatus used deteriorated over time, causing leaks and other potential problems in the system. CCX 891 ¶ 88.

Respondent argues, first, that if there were a small leak, it would not involve the ingress of external gases, but, rather, would permit the pressurized system to expel gas through other channels, meaning that, if anything, the test reading would be lower than actual gas generation due to leakage. RRB at 117. NE Labs did not have indications that its test systems were leaking. F. 1234-1238. NE Labs explained that it uses several materials, including a silicone sealant, and that it pressure treats its containers, to ensure that the vessels remain airtight. F. 1234-1235. Mr. Johnson and Dr. Barlaz both explained that the presence of methane

indicates that no leakage in the test system occurred. F. 1240 (Mr. Johnson explaining that if oxygen was “getting into the can, then you won’t be producing methane”); F. 1261 (Dr. Barlaz explaining, “[y]ou either have a leak in your system or you don’t have a leak in your system . . . [a]nd the fact that they were getting methane generation from their positive controls indicates to me that they have an ability to make a gas-tight system out of a metal can”).

Respondent argues, second, that there is no evidence that any leakage occurred in the vessels (F. 1257), which are run in triplicate so the laboratory can determine if the data recorded is an outlier. RRB at 117; *see, e.g.*, F. 1270, 1289, 1316, 1332, 1341, 1357, 1366, 1386, 1407, 1418. Dr. Barlaz’s statistical t-tests were designed to identify the standard deviations and determine statistical anomalies. F. 1012-1014. Dr. Barlaz determined that the data shows statistical significance, meaning that the fluctuations between triplicate test vessels was not extraordinary. *See* F. 1012-1014, 1280, 1284, 1299, 1303, 1325, 1375, 1380. Lastly, the ASTM D5511 test standard specifically calls for the use of inverted cylinders to measure gas totals. F. 1230.

Sixth, Complaint Counsel asserts that NE Labs waits for a paint can to rust before swapping it out for a new one, only replaces the paint cans that have been rusted, and did not consider whether the rusting test vessel affected results of biodegradation testing. CCB at 69 (citing Johnson, Tr. 1585-1586, 1592-1593). Respondent replies that there is no evidence in the record that NE Labs had that type of problem with any tests of ECM Plastics, F. 1256, and the testimony from NE Labs established that rust corrosion was a very rare anomaly. RRB at 117-118 (citing Johnson, Tr. 1566-1567 (explaining that NE Labs had never had a problem with leakage resulting from rust or otherwise)). Dr. Barlaz convincingly explained that the use of the metal canisters (*i.e.*, the cans ordinarily used for paint, but here, simply the empty cans) would not affect the validity of NE Labs’ test results. F. 1259. As analyzed in Section III.E.10.a., *supra*, Respondent further states that Dr. Barlaz examined the statistical data to determine whether certain vessels had an observable variance that would render data not statistically significant and found none. *See* F. 1011-1035, 1280, 1285, 1299, 1303, 1325, 1375, 1380.

Seventh, Complaint Counsel asserts that the methane readings produced by the infrared machine used by NE Labs have a precision of plus or minus 20%. CCB at 69 (citing Johnson, Tr. 1587). Respondent charges that Complaint Counsel mischaracterizes the factual record by suggesting that NE Labs' infrared machine had an error rate of 20%. The testimony was that the error rate may be as low as 1% or less for the higher amounts of methane, but may be as high as 20% for very low amounts of methane recorded. F. 1244-1245. Respondent states that any precision considerations would apply to all vessels tested, including the positive and negative controls, and the inoculum blank, and that variance in the readings would be factored by Dr. Barlaz's statistical t-test calculations across the triplicate test data. RRB 118-119 (citing Barlaz, Tr. 2247-2249, 2263-2264; RX 968).

Dr. Sahu reviewed NE Labs' testing protocol and credibly testified that he had no concerns with NE Labs' testing methodology. F. 1264. Dr. Barlaz convincingly testified, based on his statistical analysis of the raw data, that the NE Labs' tests were good scientific evidence showing that the test materials underwent anaerobic biodegradation. F. 1041-1042. Dr. McCarthy did not run any statistics for the ASTM D5511 studies on ECM Plastics. F. 1009. Indeed, Dr. Barlaz was surprised that Dr. McCarthy was dismissive of ECM's gas evolution testing without having even examined the data. F. 1010.

Weighing the criticisms offered by Complaint Counsel's expert, Dr. McCarthy, against the more credible and persuasive evidence offered by Respondent's experts, the greater weight of the evidence fails to show that the anaerobic gas evolution tests performed by NE Labs are so fatally flawed as to not constitute reliable and competent scientific evidence substantiating that ECM Plastics are biodegradable, or that these tests are inadequate to support ECM's "biodegradable" or "tests prove" claims.

Therefore, through its criticism of the ASTM D5511 tests performed by ERL and NE Labs, Complaint Counsel has not met its burden of showing that Respondent's tests do not meet the standards demanded by the relevant scientific community.

ii. Complete biodegradation of ECM Plastics in landfills

Complaint Counsel next asserts that in order to support claims of biodegradation for ECM Plastics: (1) tests must be conducted for a sufficient length of time to demonstrate that the entire treated plastic, not just the biodegradable additive, will be consumed; (2) tests must also reflect the disposal conditions claimed, in this case, “landfills”; and (3) tests must show biodegradation of ECM Plastics above the “priming effect.” CCB at 70-71. Complaint Counsel’s assertions, Respondent’s responses, and the evidence pertaining to them, are discussed below.

(a) “Complete biodegradation”

Complaint Counsel argues that the evidence fails to show that ECM Plastics biodegrade “completely.” It is not apparent that the Complaint alleges, or that Complaint Counsel argues, that Respondent claimed that ECM Plastics would “completely biodegrade,” except in relation to the Implied One Year Claim (“completely” decompose into elements found in nature within one year), which allegation was not proven, and also in relation to Respondent’s claim that ECM Plastics would “fully biodegrade” including in a landfill, within 9 months to 5 years. Although it is unclear, Complaint Counsel appears to argue that Respondent’s biodegradable claims are false or unsubstantiated because the testing fails to show biodegradation to completion.

Complaint Counsel asserts that Respondent’s claim of biodegradation rests on an incorrect assumption that, once started, biodegradation will go to completion. CCB at 71. Complaint Counsel notes that Respondent’s expert, Dr. Sahu, testified that he had not seen instances of taking a rate derived from a test, and then extrapolating from that, holding the rate constant, to attempt to state a time period for complete biodegradation. F. 714-715. Furthermore, the ASTM D5511 standard explicitly prohibits extrapolation of test results. RX 356 at 1 (Section 1.4)).

Thus, according to Dr. McCarthy, if a test shows 10% biodegradation in 300 days, the test cannot be used to support a claim of 100% biodegradation in 3000 days. CCB at 72. Dr. McCarthy reasons that extrapolation is prohibited because there is no evidence that

biodegradation is a linear process and, according to Dr. McCarthy, the rate of biodegradation is likely to slow because of recalcitrance. CCB at 72 (citing CCX 891 (McCarthy Expert Report ¶ 69)).

Respondent asserts that there is no scientific support for requiring testing that actually shows a plastic completely biodegraded in a laboratory environment before one can claim that plastics are completely biodegradable. RRB at 121-122. Indeed, Complaint Counsel's experts have themselves claimed plastics to be biodegradable without showing complete biodegradation. Dr. McCarthy labeled a substrate biodegradable after observing just 14% biodegradation in a gas evolution test. F. 716. Also, in his '199 patent, Dr. McCarthy concluded that a substance that biodegraded by 25% in 45 days was biodegradable. F. 853. In addition, Dr. Michel testified that an article which biodegrades to 44% would be considered "fully" biodegradable in a gas evolution test. F. 685. Dr. Michel also noted that cellulose (a material that is indisputably "fully biodegradable"), could be fully biodegraded at just 74% in a test conducted for 400 days. F. 675. Thus, Complaint Counsel seeks to hold Respondent to a standard that Complaint Counsel's own experts, outside of this litigation, have not applied to or met themselves.

As analyzed in Section III.E.3., *supra*, the greater weight of the scientific evidence shows that the term biodegradation does not require complete biodegradation. Complaint Counsel's insistence that Respondent's substantiation fails because ECM's tests do not show that the plastic "completely" biodegraded ignores the scientific evidence that biodegradation is a process and not a clearly identified endpoint. F. 680-696. *E.g.*, F. 687-688 ("biodegradability" is an inherent or intrinsic characteristic of a material); F. 696 (biodegradation is not subject to a time span limitation because it is an ongoing process); F. 683 (scientific literature defining biodegradation does not require complete degradation). Accordingly, Complaint Counsel's criticism that Respondent's tests do not show complete biodegradation does not satisfy Complaint Counsel's burden of showing that Respondent's substantiation is inadequate.

Complaint Counsel next argues that extrapolation of biodegradation test data is inappropriate. CCB at 71-72. Respondent agrees that one cannot extrapolate the rate of

biodegradation easily from a lab test environment into the landfill. RB at 124 (citing Barlaz, Tr. 2282). That is because too many variables exist that might increase or decrease that rate of biodegradation over time. F. 713-714. The rate could thus vary, and it would be nearly impossible to predict with precision. F. 716.

By contrast, scientists agree that it is perfectly acceptable to extrapolate whether a material is biodegradable, including in a landfill, from accelerated lab test data. F. 717-731. Dr. Sahu convincingly explained that in accelerated testing, scientists try to mimic a slow natural process in the lab in a manner faster than would have occurred in nature so that they can get results in a reasonable period of time; accelerated testing is commonly done in fields of science where the natural phenomena of interest happens to be of a long time scale; and accelerated testing is appropriate for biodegradation studies. F. 718-720. Dr. Barlaz also explained that testing over long periods of time to show complete biodegradation would be impractical and unnecessary. F. 724. He explained that the central question was whether the material is “intrinsically biodegradable” because, if the product biodegrades, then it will do so as long as environmental conditions support biodegradation. F. 687-688. *See also* F. 729 (there is no reason that the microbes would not continue to attack those base polymers until it was completely biodegraded).

Finally, Complaint Counsel charges that Respondent’s explanation of how ECM Plastics will biodegrade to completion is a “fantastical” mechanism of action and asserts that Dr. Michel and Dr. Burnette testified that the presence of a biofilm does not indicate that the microorganisms are using the plastic as a food source. CCB at 73 (citing Michel, Tr. 2865; RX 840 (e, Dep. at 41-43)). Respondent asserts that Complaint Counsel has misinterpreted the concept of causation expressed by ECM’s experts concerning biofilm formation. RRB at 125. Respondent acknowledges that its experts concede that the presence of a biofilm does not necessarily indicate that the microorganisms are using the plastic as a food source, but instead opine that the formation of biofilms is a considerable step towards the ultimate biodegradability of plastics. RRB at 125-126 (citing RX 855 at 27; Burnette, Tr. 2406-2409). As summarized in Section III.E.8.a., *supra*, Respondent’s experts, Dr. Sahu and Dr. Burnette, explained the mechanism of action for the ECM Additive.

Weighing the criticisms offered by Complaint Counsel's experts against the more credible and persuasive evidence offered by Respondent's experts, the greater weight of the evidence fails to show that the scientific community demands proof of complete biodegradation in order to claim that a product is biodegradable. Thus, in this regard, Complaint Counsel has not demonstrated that Respondent's substantiation was inadequate.

(b) Biodegradation in landfills

Complaint Counsel argues that to support claims of biodegradation in landfills, tests should be run at appropriate landfill temperatures, with appropriate anaerobic bacteria, and that of the few tests purporting to show biodegradation, none mimics these conditions. CCB at 73-74. Complaint Counsel acknowledges that the primary test used to evaluate biodegradability of plastics is the ASTM D5511 test and states that this test, like other gas evolution tests, uses methane gas generation as a proxy for biodegradation. CCB at 74. Complaint Counsel contends, however, that the ASTM D5511 test is typically conducted at 52°C and that running tests at 52°C results in two potentially serious flaws: (1) the hot temperatures could cause non-biological degradation that would not occur at more typical landfill temperatures of 37°C; and (2) the types of anaerobic bacteria that survive at the hotter temperatures are not the same types of anaerobic bacteria that operate at cooler landfill temperatures. CCB at 74. Accordingly, Complaint Counsel asserts, one cannot conclude that because "some" biodegradation is observed under one set of conditions, it will be observed under all conditions. *Id.*

As an initial matter, the evidence shows that temperatures in MSW landfills in the United States do average around 37°C, and thus, in general terms, the range of temperatures wherein landfills usually operate are in the mesophilic range. F. 577-578. However, temperatures in landfills vary greatly, sometimes even within the same landfill, and can often meet or substantially exceed the 52°C that is used in the ASTM D5511 test. F. 547-576.⁵¹

Furthermore, accelerated testing, which allows laboratories to record data in an expedited manner without having to wait out the results of a field-scale timeline, is very

⁵¹ The ASTM D5511 test method states: "Incubate the Erlenmeyer flasks in the dark or in diffused light at 52°C (±2°C) for thermophilic conditions, or 37°C (±2°C) for mesophilic conditions for a period of normally 15-30 days." F. 781.

common and widely used to measure biodegradation. F. 718-720. One way to accelerate a biodegradation test is to increase the temperature. F. 732. Dr. Tolaymat, Complaint Counsel's expert, agreed that accelerated testing to demonstrate biodegradation was proper. F. 723.

Respondent argues that Complaint Counsel has no factual basis to conclude that anaerobic bacteria that survive at the hotter temperatures are not similar to bacteria that operate at lower temperatures. RRB at 126-127. Respondent's expert, Dr. Sahu, explained that, at a fundamental level, there is no difference in the way thermophilic bacteria metabolize waste versus the way mesophilic bacteria metabolize waste. F. 739.⁵² Dr. Barlaz explained that the difference between mesophilic and thermophilic conditions affects only the rate of biodegradation. F. 738. And, Dr. Burnette explained that mesophilic and thermophilic bacteria function at different temperatures and pace, but use common and universal mechanisms of action to gain access to food sources. F. 737. Dr. Burnette also testified that there are also mesophilic bacteria in landfills that would degrade plastics, and those bacteria would not be represented in the thermophilic systems, meaning that the ASTM D5511 tests may not actually capture all of the biodegradation that occurs in landfills. F. 740. The scientific evidence presented shows that tests run at 52°C are relevant for assessing biodegradability of a plastic in a landfill and that the elevated temperature in the ASTM D5511 test affects only the "rate" of biodegradation, but does not affect a determination of whether the test plastic is, in fact, biodegradable in a landfill. F. 737-739, 771, 773, 775, 776.

Lastly, citing to its Proposed Finding of Fact 157, Complaint Counsel asserts that tests conducted under the appropriate temperature range showed no biodegradation at all. CCB at 74. The tests Complaint Counsel refers to, CCX 946, CCX 951, and CCX 954, were BMP tests conducted by Dr. Barlaz in his laboratory at North Carolina State University. F. 1433-1435.⁵³ Dr. Barlaz testified that his BMP tests were performed in a completely liquid environment and explained that his tests were not well suited to measure the biodegradability of slowly biodegrading substances. F. 1428-1431. Furthermore, Complaint Counsel omitted from its

⁵² "Mesophilic" refers to a class of microorganisms that have optimal temperature around 98.6 degrees Fahrenheit. At temperatures above 43 to 44 degrees Celsius, mesophiles are killed off or severely inhibited. "Thermophiles" have an optimal temperature closer to 60 degrees Celsius or about 130 to 140 degrees Fahrenheit. F. 733-736.

⁵³ A more extensive discussion of Dr. Barlaz's BMP tests is in Section III.E.8.b., *supra*.

citations, CCX 952, another BMP test performed by Dr. Barlaz under the same temperature conditions, which revealed positive evidence of biodegradation of ECM Plastics. F. 1436.

Weighing the criticism offered by Complaint Counsel's experts against the more persuasive and credible evidence offered by Respondent's experts, the greater weight of the evidence fails to show that tests run at 52°C are not competent and reliable scientific evidence for determining whether a plastic is biodegradable in a landfill. In this regard, Complaint Counsel has not met its burden of showing that the Respondent's substantiation was inadequate.

(c) Priming effect

Complaint Counsel acknowledges that some tests do purport to show minimal levels of methane gas generation beyond that from the ECM Additive. CCB at 74-75. Complaint Counsel points to the opinions of its expert witnesses, Dr. McCarthy and Dr. Michel, that the biodegradation observed in these tests is likely the result of the "priming effect." CCX 891 (McCarthy Expert Report ¶¶ 19, 44); CCX 895 (Michel Rebuttal Expert Report at 10) ("Many of the reports where ECM amended plastics have been observed to biodegrade greater than the negative control can be attributed to the biodegradation of the ECM additive, or to the priming effect (Shen and Bartha, 1996), and not the plastic to which it has been added."). As explained by Dr. Michel: "It is true that ECM amended plastics will biodegrade to a greater extent than unamended plastics, but only because the ECM additive itself apparently biodegrades at a much faster rate than the plastics to which it has been added." CCX 895 (Michel Rebuttal Expert Report at 13).

Dr. McCarthy defines the "priming effect" as the biodegradation of the ECM Additive (which contains organic compounds highly susceptible to biodegradation) and the organic materials of the test medium (the bacteria used for testing), rather than of the plastic. CCX 891 (McCarthy Expert Report ¶¶ 19, 44). Dr. McCarthy also testified that the priming effect occurs when you are getting degradation from the inoculum, but then recording it as biodegradation of the nonbiodegradable polymer. McCarthy, Tr. 412-413.

Complaint Counsel argues that Dr. Barlaz's calculations from tests conducted by ERL and NE Labs prove nothing because the existence of the ECM Additive both increases the total amount of material available for biodegradation (compared to the test of the inoculum by itself), and stimulates increased biodegradation of the inoculum (the priming effect). CCB at 75. Complaint Counsel further asserts that Dr. Barlaz acknowledges that the priming effect exists in anaerobic conditions, but does not explain how his calculations account for it. CCB at 75 (citing Barlaz, Tr. 2279). Complaint Counsel also contends that Dr. Barlaz tries to explain away the impact of the priming effect on these tests by asserting that the ECM Additive is not a readily degradable substance like glucose, in contradiction to Dr. Barlaz's recent testing of the ECM Additive that showed that it is almost as biodegradable as paper and other testing in the record that shows that ECM Additive alone is readily biodegradable. CCB at 75-76 (citing CCX 946 (reporting copy paper has a methane yield of 200 mL CH₄/dry gram), CCX 951 (reporting 151 mL CH₄/ dry gram for ECM Additive); RX 269; RX 265; RX 264; *see also* F. 159.

Respondent contends that the priming effect is a theoretical proposition never shown in the peer-reviewed literature to exist in an anaerobic environment and disproven by the record evidence. RRB at 128-132. Respondent argues that the major flaw in the priming effect theory is that it depends on the idea that the biodegradation recorded is solely attributed to the ECM Additive, or catalyzed by the ECM Additive, but the test data upon which ECM relies shows amounts of degradation far in excess of the amount of ECM Additive present in the test plastic. RB at 140. Thus, Respondent argues, if the priming effect theory is that the inoculum is triggered by the ECM Additive, then Complaint Counsel has failed to explain why the amounts of degradation continue beyond the amount fairly attributed to the additive (*e.g.*, 1% degradation). RB at 140. Respondent further argues that, even assuming a priming effect exists in these systems, there is no evidence that the effect is quantifiable, consistent, or sufficient to account for the amount of methane generated. RB at 140.

In addition, Respondent argues that if the priming effect was actually a significant element in determining biodegradability, other scientists (including Dr. McCarthy) would account for it in the test models proposed to test for biodegradation, but that none of the ASTM biodegradation test standards (*e.g.*, ASTM D5511, D5526, D6400, etc.) require that the test

laboratories consider or account for a priming effect. RRF 143 (citing CCX 84 (ASTM D5511); CCX 87 (ASTM D5526); CCX 91 (ASTM D6400)).

Although Complaint Counsel has the burden of proof on its position that any test results showing biodegradation are likely the result of the priming effect, in its proposed findings of fact, Complaint Counsel does not offer a single proposed finding on the priming effect.⁵⁴ The greater weight of the scientific evidence shows that there is no consensus in the peer-reviewed literature as to what the priming effect is, or the degree to which it could be in action during biodegradation testing of plastics. F. 862. Moreover, peer-reviewed literature concerning the priming effect of a substrate in the test environment has generally been in reference to aerobic systems and with readily degradable substrates. F. 863-864. Comparing a potential priming effect from a readily degradable substrate in an aerobic environment to a slowly degradable substrate in an anaerobic environment is not an appropriate scientific comparison. F. 865. Dr. Barlaz explained that, in the absence of supporting data and any peer-reviewed literature, the priming effect theory is “quite speculative as a way to shoot down a test.” F. 866.

In addition, Dr. Barlaz explained that Dr. McCarthy assumed that the ECM Additive was 60% polycaprolactone (“PCL”), and that, in Dr. Barlaz’s own research, the amount of degradation solely from PCL was not that significant to stimulate background methane. F. 867. Dr. Barlaz also persuasively explained that the amount of biodegradation observed in the ECM tests is much higher than any reasonable interpretation of a priming effect theory. F. 868. It is worth noting that when Dr. McCarthy relied on gas evolution testing to demonstrate that his polymer blends in the ‘199 patent were biodegradable, Dr. McCarthy did not account for, or even mention, any biodegradation that might result from the priming effect. F. 869.

Weighing the criticism offered by Complaint Counsel’s experts against the more credible and persuasive evidence offered by Respondent’s experts, the greater weight of the evidence fails to show that the priming effect theory is more than mere speculation about ECM’s tests or that the priming effect accounts for the amounts of biodegradation shown in

⁵⁴ Furthermore, in its responses to Respondent’s proposed findings, Complaint Counsel does not offer a single response to Respondent’s proposed findings on evidence against Complaint Counsel’s priming effect theory.

ECM's anaerobic gas evolution tests. In this regard, Complaint Counsel has not met its burden of showing the Respondent's substantiation was inadequate.

c. Summary

Based on his statistical analyses and the test data he reviewed concerning ECM Plastics and based on his review of the procedures used by the labs conducting the ASTM D5511 tests, Dr. Barlaz credibly and persuasively testified that Respondent's testing constitutes competent and reliable scientific evidence demonstrating that plastics manufactured with the ECM Additive are anaerobically biodegradable. *E.g.*, F. 1041, 1043-1044.

Having weighed the evidence, considering the totality of the expert witness testimony, and placing substantial weight on the better supported and more credible testimony of Respondent's experts, Complaint Counsel has not met its burden of proving, pursuant to the reasonable basis theory, that Respondent's substantiation is inadequate, or that the studies upon which Respondent relies do not pass muster in the view of the relevant scientific communities. In addition, Complaint Counsel has not met its burden of proving, pursuant to the falsity theory, that tests do not prove the biodegradability of ECM Plastics, or that the studies Respondent possessed do not pass muster in the view of the relevant scientific communities.

11. Conclusion

The evidence establishes that the ASTM D5511 test is a competent and reliable scientific method to prove biodegradability, including in a landfill. Respondent presented evidence of numerous ASTM D5511 tests on ECM Plastics conducted by independent laboratories. Respondent's experts provided convincing expert testimony that the ASTM D5511 tests on ECM Plastics were well-conducted and well-controlled. Dr. Barlaz persuasively and credibly testified that competent and reliable scientific evidence shows that plastics manufactured with the ECM Additive are anaerobically biodegradable.

Based on the greater weight of the more credible and persuasive evidence, Complaint Counsel did not meet its burden of demonstrating that Respondent's claims of biodegradability, including in a landfill, or that tests show the same, were false or not adequately substantiated.

Complaint Counsel did, however, meet its burden of demonstrating that Respondent's 9 Months to 5 Years Claim, and tests prove its 9 Months to 5 Years Claim, are false and unsubstantiated. Accordingly, the analysis next addresses whether those claims are material.

F. MATERIALITY

1. Introduction

It has been determined that Respondent claimed, falsely and/or without substantiation, that ECM Plastics would fully biodegrade in a landfill within "9 months to 5 years" (the "9 Months to 5 Years Claim") and that testing proved the 9 Months to 5 Years Claim. Accordingly, the next step is to determine whether those claims are material to prospective consumers. *Kraft*, 970 F.2d at 314. It must be noted preliminarily that Complaint Counsel's argument in support of finding materiality relies, in substantial part, on evidence that the "biodegradability" of ECM Plastics is a central characteristic of ECM's marketing, and that "biodegradability" is important to ECM Customers, downstream customers, and "consumers," *i.e.*, members of the general public who would be exposed to ECM claims in the marketplace. *See* Section III.C., n.16 *supra*; CCB at 77. Indeed, there is no dispute between the parties that ECM Customers buy the ECM Additive because they want to provide "biodegradable" plastics to meet their customers' demand for such products, or that biodegradable products are "important," at least in a general sense, to consumers. Furthermore, the evidence supports these facts. F. 1503-1507.

However, Complaint Counsel has failed to prove that Respondent's generalized "biodegradable" claims, properly interpreted as a matter of both consumer perception and science, are false or misleading. The issue at this stage of the analysis is whether any false or misleading claim of ECM was material, and the only false or misleading claims found to have been made in this case are ECM's claims that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years, and that tests prove such claim. Thus, the dispositive issue is whether these demonstrated deceptive claims are material, not whether Respondent's general claims of "biodegradability" are material.

“The basic question” on the issue of materiality is whether a false or misleading claim is “likely to affect the consumer’s conduct or decision with regard to a product or service. If so, the practice is material, and consumer injury is likely, because consumers are likely to have chosen differently but for the deception.” *Deception Statement*, 1984 FTC LEXIS 71, at *171; *see also In re Novartis Corp.*, 127 F.T.C. 580, 691, 1999 FTC LEXIS 63, at *38 (May 27, 1999) (noting that materiality is a test of the likely effect of the claim on the conduct of a consumer). In other words, information is material if it is important to a consumer’s purchasing decision. *POM*, 2013 FTC LEXIS 6, at *17-18; *Deception Statement*, 1984 FTC LEXIS 71, at *188. “Materiality turns upon whether those consumers who have drawn the claim from the advertisement and been misled by it are also likely to have their conduct affected by the misrepresentation.” *Novartis Corp.*, 1999 FTC LEXIS 63, at *38.

Express claims, and claims that pertain to the central characteristics of a product, are presumed to be material. *Telebrands*, 140 F.T.C. at 292; *Thompson Medical*, 1984 FTC LEXIS 6, at *373. The presumption of materiality reflects the “general judgment that substantive claims in advertisements (in other words, claims other than ‘puffery’ or window-dressing) would not have been made except to affect a consumer’s choice of or conduct regarding a product. Thus, the very existence of the claim ordinarily is sufficient evidence for [the Commission] to conclude it is material. However, respondent is always free to counter this evidence either with arguments pertaining to the content of the ad itself or with extrinsic evidence.” *Thompson Medical*, 1984 FTC LEXIS 6, at *374 n.45.

In the instant case, Respondent argues that, notwithstanding any presumption, the preponderance of the evidence shows that Respondent’s claims as to the rate of biodegradation were not, in fact, material. Respondent asserts that ECM’s claims were not intended to be a performance claim, but were only a way to differentiate the ECM Additive technology from more rapidly degrading compostable products; that its Customers and downstream customers were not concerned with the rate of biodegradation, but only with whether the ECM Additive would render plastics more biodegradable than without the ECM Additive; and that ECM Customers were sophisticated purchasers, who did not rely on Respondent’s representations and were not misled by them. RB at 169-170, 177-184. With respect to end-use consumers, Respondent asserts that, with few exceptions, end-use consumers saw only ECM’s

“generalized” biodegradable claims, such as an ECM “biodegradable” logo; and that Dr. Stewart concluded, based on his survey, that Respondent’s claims were not likely to influence consumer purchasing decisions because consumers did not “understand” the claims and were skeptical of them. RB at 171-174.

In *Novartis*, the Commission explained the operation of the presumption of materiality as follows:

Certain categories of information are presumptively material, including, but not limited to, express claims, claims significantly involving health or safety, and claims pertaining to the central characteristic of the product. *Deception Statement*, 103 F.T.C. at 182. Similarly, the Commission will infer materiality where the record shows that respondent intended to make an implied claim.

1999 FTC LEXIS 63, at *26-27. The opinion in *Novartis* continued:

“To establish a ‘presumption’ is to say that a finding of the predicate fact,” here, any of the factors listed above, “produces a required conclusion in the absence of explanation,” here, materiality. *St. Mary’s Honor Ctr. v. Hicks*, 509 U.S. 502, 506 (internal quotation marks omitted). In order to rebut the presumption, respondent must come forward with sufficient evidence to support a finding that the claim at issue is not material. Respondent can present evidence that tends to disprove the predicate fact from which the presumption springs (*e.g.*, that the claim did *not* involve a health issue) or evidence directly contradicting the initial presumption of materiality. This is not a high hurdle. Unless the rebuttal evidence is so strong that the fact-finder could not reasonably find materiality, the fact-finder next proceeds to weigh all of the evidence presented by the parties on the issue. *See id.* at 516 (noting that after the presumption drops out, “the inquiry . . . turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals . . . the parties have introduced”). While the presumption itself is negated by sufficient rebuttal evidence, as previously noted, the predicate facts that gave rise to the presumption are not. These facts remain evidence from which materiality can be inferred. *See Boise Cascade*, 113 F.T.C. at 975 (1990). However, this evidence is simply part of the entire body of evidence considered. *See also* 21 *Charles Alan Wright and Kenneth W. Graham, Jr., Federal Practice and Procedure: Evidence* §§ 5122 *et seq.* (1977 and 1998 Supp.) (discussing the history and application of presumptions).

1999 FTC LEXIS 63, at *27-28.

Applying the principles of *Novartis* to the evidence in this case, even if a presumption arises, and even if Respondent's evidence sufficiently rebuts the presumption, as further discussed below, a "weigh[ing] of all of the evidence presented by the parties on the issue" shows that Respondent's claims that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years, and that tests prove such claim, are material to the purchasing decisions of ECM Customers, and to downstream customers. *See Novartis*, 1999 FTC LEXIS 63, at *28. Because the evidence is sufficient to prove materiality in the instant case, irrespective of any legal presumption, logic dictates that this Initial Decision need not, and it does not, analyze the effect of a presumption of materiality in this case.

2. Analysis

The evidence shows that Respondent's 9 Months to 5 Years Claim was expressly made in a variety of ECM's Marketing Materials, F. 245-247, 1498, and was repeated in its communications with Customers. F. 1501. Moreover, Respondent's claim that tests prove ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years, while not an express statement, was nevertheless sufficiently clear and conspicuous based on the overall net impression of the documents in which the claim appeared. F. 265, 1499. In addition, Respondent's claims that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years, and that tests prove such claim, pertain to the central characteristics of plastics infused with the ECM Additive. F. 1500. It is logical to conclude from the foregoing that Respondent would not promote the ECM Additive with these claims unless it was likely to have an effect on the purchasing decisions of its Customers. Respondent's argument that it "intended" the 9 Months to 5 Years Claim only to differentiate its technology from more rapidly degrading compostable products, which, according to Respondent, are generally expected to fully degrade in aerobic conditions in under 6 months, RB at 169, is not persuasive. The express language of the 9 Months to 5 Years Claim outweighs Respondent's purported intent, and Respondent's self-described intent does not constitute evidence that the claim was not important to ECM's Customers.

In addition, the evidence shows that ECM's Customers asked ECM questions about Respondent's claim of biodegradation within 9 months to 5 years, F. 1502, which is further

proof that this claimed characteristic of ECM Plastics was an important factor to ECM's Customers in determining whether to purchase the ECM Additive. ECM provided its Customers with its Marketing Materials, including materials containing the 9 Months to 5 Years Claim and the claim that tests prove such claim, and encouraged its Customers to use these materials for its Customers' marketing of ECM Plastics to their own customers. F. 245-247, 280. This evidence supports a finding that these claims were likely to affect the purchasing decisions of customers of ECM Customers. As further evidence of the materiality of these claims, some of ECM's plastic manufacturer customers used the 9 Months to 5 Years Claim in advertising to their own customers, frequently in language mirroring that in ECM Marketing Materials. F. 286, 292-293, 1512. For example, Island Plastic Bags ("IPB"), an ECM Customer who manufactures plastic bags, stated in an advertisement for IPB's "Bio Ultra Blend" trash liners, that it was using "ECM BioFilms' technology" which will cause the liners to "completely degrade [including in a landfill] in 9 months to 5 years depending on conditions." F. 292. IPB advised, Down-to-Earth ("DTE"), a grocery store chain that bought bags from an IPB distributor, that ECM Plastics would biodegrade within 9 months to 5 years. F. 293. Ultimately, IPB manufactured ECM Plastic bags reflecting the 9 Months to 5 Years Claim for 50 to 100 different customers. In total, IPB alone manufactured approximately 10 million such bags. F. 300. The foregoing evidence amply supports the conclusion that these claims likely affected the purchasing decisions of IPB's customers. Simply put, the conduct of Respondent and its Customers in promoting ECM Plastics with the 9 Months to 5 Years Claim supports the inference that the claim was important to the purchasing decisions of those in ECM's commercial supply chain.

Respondent's assertions that the claims at issue were not material to its Customers or downstream customers are not supported by the record and are not persuasive. Respondent points to testimony of ECM's president, Mr. Sinclair, that ECM customers are not concerned with the rate of biodegradability. Such testimony is belied by ECM's conduct, summarized above, in emphasizing the rate claims in its Marketing Materials and customer communications. Respondent also points to testimony from ECM Customers that they, and their own customers, were interested in "biodegradable" plastics. However, this is not evidence that ECM Customers and others were not also interested in the claims that ECM Plastics will

fully biodegrade in a landfill within 9 months to 5 years, and that tests prove such claim. To be material, “a claim does not have to be the *only* factor or the *most* important factor likely to affect a consumer’s purchase decision, it simply has to be *an* important factor.” *Novartis*, 1999 FTC LEXIS 63, at *46 (emphasis in original).

Respondent further argues that its claims that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years and that tests prove such claim were not material because ECM’s Customers were “sophisticated purchasers” who received full information from ECM over the course of a long sales cycle, and some of whom tested the ECM Additive themselves. In these circumstances, Respondent argues, it is unlikely that any Customer actually relied on Respondent’s biodegradation rate and testing claims, and, therefore, such purchasers were not “misled” by Respondent’s claims. Respondent’s argument fails as a matter of evidence and law.

First, the evidence fails to support Respondent’s assertions that ECM Customers were “sophisticated” with respect to evaluating ECM’s claims and did not rely on Respondent’s claims. The evidence shows that, contrary to Respondent’s assertions, ECM’s Customers include entities that have no expertise in biodegradability, landfills, or disposal conditions for plastics, F. 1513-1514, 1518-1520, 1522, 1525-1527, and did not consult any experts in these areas to evaluate ECM’s claims. F. 1518, 1520, 1522, 1527. In addition, based on the deposition testimony in the case, ECM’s Customers include entities that do not have laboratory facilities capable of conducting biodegradability testing, and did not seek outside testing. F. 1513, 1515-1516, 1521, 1524-1525, 1528.

Second, there is direct evidence that ECM Customers believed ECM’s representations to be true. For example, ANS Plastics Corporation (“ANS”), an ECM Customer, testified that it received ECM’s literature and certificate, including a flyer, which included the statement “fully biodegrade in 9 months to five years . . . in a landfill,” and believed that ECM Plastics would biodegrade as claimed. F. 1508. Flexible Plastics, Inc. (“Flexible”), another ECM Customer, testified that it believed that ECM Plastics would biodegrade in 9 months to 5 years. F. 1509; *see also* F. 1537 (testimony that D&W Fine Pack, an ECM Customer, believed that Respondent’s 9 Months to 5 Years Claim was true). In addition, the fact that ECM Customers

“passed on” Respondent’s claims directly to their own customers, as noted above, also indicates that such Customers believed Respondent’s claims to be true.

In addition, contrary to Respondent’s argument, liability under Section 5 does not require proof that particular purchasers relied upon or were actually deceived by ECM’s representations. *Cliffdale*, 1984 FTC LEXIS 71, *105 (“[U]nder Section 5 actual deception of particular consumers need not be shown.”); *see also In re Travel King, Inc.*, 1975 FTC LEXIS 73, at *129 (May 17, 1974) (“[I]t need not be shown that even one consumer actually relied” on a claim.). “Advertisements having the capacity to deceive are deceptive within the meaning of the FTCA; actual deception need not be shown.” *Simeon Mgmt. Corp. v. FTC*, 579 F.2d 1137, 1146 n.11 (9th Cir. 1978); *see also American Home Products Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982) (“It is true that on some crucial points in the case at hand the Commission lacked direct evidence that consumers were in fact misled. But the Commission need not buttress its findings that an advertisement has the inherent capacity to deceive with evidence of actual deception.”). In asserting that proof of reliance is necessary, Respondent relies on common-law fraud cases, which are inapposite. Respondent also relies on trademark and similar cases to argue that “sophisticated” customers are less likely to be “confused” by Respondent’s claims. As noted above, it cannot be concluded that ECM’s Customers are sophisticated in matters of biodegradability or biodegradability testing, and the evidence fails to demonstrate that ECM Customers were “confused” about ECM’s claims.

Based on the foregoing, the preponderance of the evidence shows that Respondent’s claims that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years, and that tests prove such claim, were likely to affect the purchasing decisions of ECM’s Customers and downstream customers. Accordingly, Complaint Counsel has demonstrated that these claims, which have been found to have been false and unsubstantiated, violated the FTC Act.⁵⁵

⁵⁵ Because the evidence demonstrates that Respondent’s false or misleading claims were material to ECM’s Customers and downstream customers, it is not also necessary, in order to establish a violation of Section 5, to demonstrate that the claims were similarly material to end-use consumers. Thus, it is not necessary to address Respondent’s arguments against a finding of materiality as to end-use consumers. Respondent’s arguments in this regard are addressed, to the extent relevant, in the context of determining the appropriate remedy in this case in Section III.I., *infra*.

G. MEANS AND INSTRUMENTALITIES LIABILITY

It has been determined that Respondent violated Section 5 of the FTC Act in making the false or misleading material claims in its Marketing Materials that ECM Plastics would fully biodegrade in a landfill within “9 months to 5 years” (the “9 Months to 5 Years Claim”) and that testing proved the 9 Months to 5 Years Claim. Complaint Counsel argues that Respondent is also liable for these claims that were made by ECM Customers, through their own advertising, to downstream customers in the ECM supply chain, pursuant to the “means and instrumentalities” doctrine.

As noted in Section III.C., *supra*, the means and instrumentalities doctrine holds that “those who put into the hands of others the means by which they may mislead the public, are themselves guilty of a violation of Section 5 of the Federal Trade Commission Act.” *Waltham Watch Co.*, 318 F.2d at 32 (quoted in *Five-Star Auto Club*, 97 F. Supp. 2d at 530). *See also Regina*, 322 F.2d at 768 (“One who places into the hands of another a means of consummating a fraud or competing unfairly in violation of the Federal Trade Commission Act is himself guilty of a violation of the Act.”); *Litton Indus.*, 1981 FTC LEXIS 94, at *105 (stating that it is “well established that one who puts into the hands of others the means by which such others may deceive the public is equally as responsible for the resulting deception”). In this way, the “means and instrumentalities” doctrine ensures that “[t]he author of false, misleading and deceptive advertising may not furnish customers with the means of misleading the public and thereby insulate himself against responsibility for its deception.” *Irwin*, 143 F.2d at 325.⁵⁶

The evidence shows that Respondent put into the hands of others the means to communicate Respondent’s deceptive marketing claims. Not only did Respondent provide its Customers with its Marketing Materials, but Respondent also encouraged its Customers to use these materials for its Customers’ marketing of ECM Plastics to their own customers. F. 280. Further, the evidence shows that those ECM Customers did so. At least some of ECM’s Customers used the 9 Months to 5 Years Claim in their advertising to their own customers,

⁵⁶ The record shows that, in some instances, ECM would offer to provide, and/or would provide, guidance on advertising copy of its Customers, including approval of use of the 9 Months to 5 Years Claim. F. 281-282, 297-299. Respondent is, of course, liable for this direct participation in disseminating false or misleading advertising. “Means and instrumentalities” liability seeks to impose vicarious liability for the conduct of others, and does not require a showing of direct participation in disseminating deceptive claims.

frequently in language mirroring that in ECM Marketing Materials. F. 286. Indeed, Eagle Film, an ECM Customer, would forward ECM's Marketing Materials directly to its customers. F. 287. Kappus, another ECM Customer, conveyed to its customers that it was selling a biodegradable product through a letter it submitted, on Kappus' letterhead, in which it reprinted information from ECM's materials, including the time frame of 9 months to 5 years. F. 312. Similarly, IPB, an ECM Customer, stated in an advertisement for IPB's "Bio Ultra Blend" trash liners, that it was using "ECM BioFilms' technology" that will cause the liners to "completely degrade [including in a landfill] in 9 months to 5 years depending on conditions." F. 292. IPB's customer, grocery store chain DTE, was encouraged by IPB to visit ECM's website, which DTE did. F. 293. DTE ultimately placed the claim of complete biodegradation within 9 months to 5 years in a landfill, on its grocery bags. F. 297.

Respondent argues that it is not responsible for representations made by its Customers to "downstream" purchasers because, under the Restatement (Second) of Torts, a supplier has no duty to warn sophisticated purchasers about the "potential dangers" of a product and is entitled to rely on these sophisticated purchasers to "warn" downstream purchasers. RB at 187-188. Respondent cites *Akin v. Ashland Chemical Company*, 156 F.3d 1030 (10th Cir. 1998), which, quoting the Restatement at Section 388, states:

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) *has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition*, and (c) fails to exercise reasonable care to inform them of this dangerous condition or of the facts which make it likely to be dangerous.

Id. at 1037 n.8 (emphasis in original). As analyzed and held above, the evidence fails to demonstrate that ECM Customers are "sophisticated purchasers" in the matter of evaluating Respondent's biodegradation rate claim. Moreover, the concept of "duty to warn" in the context of tort liability for dangerous products has no application to whether Respondent can be liable, under the FTC Act, for providing to its Customers the means and instrumentalities to make false or misleading claims to downstream purchasers.

Based on the foregoing, Complaint Counsel has demonstrated that Respondent is liable for deceptive claims made by ECM's Customers by providing them with the "means and instrumentalities" to convey the deceptive marketing claims to others in the supply chain.

H. DUE PROCESS ARGUMENTS

1. Violation of Separation of Functions Doctrine

Respondent argues that these administrative proceedings violate Respondent's due process rights because the process fails to separate the Commission's adjudication function from its investigation and prosecution functions, as contemplated by Section 554(d) of the APA, 5 U.S.C. § 554(d). Specifically, Respondent argues that "[a]fter a decision is reached by the ALJ, the decision is submitted to the FTC [C]ommissioners for *de novo* review, [and] . . . [i]f the Commission does not agree with the ALJ, the Commission is free to overturn the decision and create a ruling as it so chooses. . . . The Commission brought the allegations against ECM and will be the ultimate adjudicator against ECM. Thus, the Commission necessarily has an interest in the outcome sufficient to violate the doctrine of separation of functions." RB at 212-213. Complaint Counsel responds that it is well established by case law that the Commission's combined investigative and judicial functions do not violate due process. Complaint Counsel states further that Respondent has not presented any evidence to demonstrate that the Commission or its staff has acted in bad faith and that Respondent has had a full opportunity to defend itself. CCRB at 25-26.

Congress specifically authorized the Commission, in the FTC Act, to issue a complaint, determine the facts, and, if a violation is found, to issue a cease and desist order. 15 U.S.C. § 45(b). As the court stated in *FTC v. Cinderella Career & Finishing Schools, Inc.*, 404 F.2d 1308, 1315 (D.C. Cir. 1968), "Congress has, as a general practice, vested administrative agencies with both the specified power to act in an accusatory capacity through the initiation of an action designed to enforce compliance with or prevent further violation of a statutory provision and with the responsibility of ultimately determining the merits of the charges so presented. In fact, this procedure is recognized by the Administrative Procedure Act, 5 U.S.C. § 500 (Supp. II, 1965-6), et seq." Moreover, Section 554(d) of the APA, upon which

Respondent relies, specifically excepts the “agency” or a “member or members of the body comprising the agency” from any requirement to separate the adjudicatory and prosecutorial functions. *Cinderella*, 404 F.2d at 1315.

Section 554(d) of the APA provides in pertinent part:

The employee who presides at the reception of evidence pursuant to section 556 of this title [5 USCS § 556] shall make the recommended decision or initial decision required by section 557 of this title [5 USCS § 557], unless he becomes unavailable to the agency. . . . An employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review pursuant to section 557 of this title [5 USCS § 557], except as witness or counsel in public proceedings. *This subsection does not apply--*

- (A) in determining applications for initial licenses;
- (B) to proceedings involving the validity or application of rates, facilities, or practices of public utilities or carriers; or
- (C) *to the agency or a member or members of the body comprising the agency.*

5 U.S.C. § 554(d) (emphasis added).

Thus, to the extent that “the Federal Trade Commission combines the functions of investigator, prosecutor and judge and that Congress designed it in that manner,” Respondent’s complaint “goes to the nature of the law itself. As to this, the courts have uniformly held that this feature [of combining functions] does not make out an infringement of the due process clause” *Kennecott Copper Corp. v. FTC*, 467 F.2d 67, 79 (10th Cir. 1972). *See also Pangburn v. Civil Aeronautics Board*, 311 F.2d 349, 356 (1st Cir. 1962) (“It is well settled that a combination in investigative and judicial functions within an agency does not violate due process.”); *Brinkley v. Hassig*, 83 F.2d 351, 357 (10th Cir. 1936) (noting that the FTC investigates charges of misconduct, files a charge, and then decides whether the proof sustains the charges it has issued). As the court stated in *Levers v. Berkshire*, 159 F.2d 689, 693 (10th Cir. 1947), “[i]t is of course true that the charge originated in, was investigated, prosecuted, heard, and decided by the agency charged with the administration of the Act. But this

adjudicatory plan is encompassed with the Congressional enactment, [and] is not repugnant to constitutional concepts”⁵⁷ Moreover, if a respondent disagrees with the final decision of the Commission, an appeal to a federal court of appeals is allowed. 5 U.S.C. § 702 (“A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.”).

For all the foregoing reasons, Respondent’s assertion that these proceedings violate due process by failing to separate investigative and prosecutorial functions from adjudicative functions is without merit and is rejected.

2. Discovery Objections

Respondent contends that Complaint Counsel engaged in “abusive discovery practices” in violation of Respondent’s due process rights. RB at 213. To support this charge, Respondent first revisits discovery disputes that were raised and litigated in motion practice during the pre-hearing phase of this case. RB at 213-217. Respondent’s various discovery complaints were duly considered in that context and, where meritorious, were remedied by court-ordered relief. *See, e.g.*, Order Granting in Part and Denying in Part Respondent’s Motion for Sanctions, March 21, 2014; *compare* Order Denying Respondent’s Motion for Sanctions for Unauthorized Dissuasion of Response to Subpoena *Duces Tecum*, April 9, 2014; Order Denying Respondent’s Motion to Sanction Complaint Counsel for Violation of Discovery Rules, April 7, 2014. The notion that these same discovery disputes amount to a denial of due process is without merit.

Respondent next contends that Complaint Counsel escalated costs in this matter by taking 20 fact witness depositions, in varying parts of the country, some of which Respondent attended only by telephone. According to Respondent, Complaint Counsel took advantage of this by asking leading questions, and then introducing those deposition transcripts, rather than live testimony at trial, thereby limiting Respondent’s opportunity for cross-examination.

⁵⁷ *Leer Electric Inc. v. Pennsylvania*, 597 F. Supp. 2d 470 (M.D. Pa. 2009), cited by Respondent, is inapposite. The federal district court in *Leer* held that the plaintiff state contractor sufficiently pled a claim for civil rights violations by the state, in part based on allegations of actual bias and intentional misconduct by the state in taking enforcement action to bar plaintiff from obtaining state contracts. Respondent makes no such assertions regarding the Commission. Moreover, *Leer* did not involve the FTC Act, or Section 554(d) of the APA, which, as analyzed above, allow the combination of functions to which Respondent objects.

Respondent argues that due process requires a meaningful opportunity to cross-examine and the opportunity for the fact-finder to observe the demeanor of witnesses. Because of these circumstances, Respondent asks that no “dispositive weight” be given to the testimony of any witness who did not appear live at trial. RB at 214-217. Complaint Counsel responds, among other things, that Respondent participated in each of the depositions, including by making objections and cross-examining deponents, and that Respondent stipulated to the admissibility of the deposition transcripts. CCRB at 27-28.

Based on the foregoing and the record in this case, Respondent has failed to demonstrate that it was denied due process with respect to the number or the conduct of the fact witness depositions. The Commission’s Rules permit introduction of deposition transcripts, notwithstanding their nature as hearsay, if “[r]elevant, material, and reliable” 16 C.F.R. §3.43(b). Respondent stipulated to the admissibility of the depositions. *See* JX-1A. Under these circumstances, the depositions are entitled to be, and have been, given appropriate weight.

3. Unfair Surprise

Respondent further contends that it was denied due process through “unfair surprise,” based on the participation in this case of Dr. Frederick Michel as Complaint Counsel’s rebuttal expert witness, and the denial of Respondent’s request to call a surrebuttal expert witness, Dr. Steven Grossman.

Respondent argues that Complaint Counsel failed to timely designate Dr. Michel as a rebuttal expert witness under the Commission’s Rules and that Dr. Michel’s opinions included matters that were part of Complaint Counsel’s case in chief. RB at 217-220. These arguments were considered and rejected by the Order issued, prior to trial, on Respondent’s Combined Motion for Sanctions to Exclude Expert Witness, and for Leave, issued on July 23, 2014 (“July 23 Order”). That Order held, *inter alia*, that Complaint Counsel timely provided Dr. Michel’s rebuttal expert report in accordance with the Rules and the Scheduling Order in this case; and that Dr. Michel’s rebuttal opinions constituted fair rebuttal. *Id.* at 2-4. Moreover, to minimize prejudice, the July 23 Order also granted Respondent’s request to modify the scheduling order to permit time for Respondent to take Dr. Michel’s deposition prior to the hearing. *Id.* at 4.

Furthermore, at the evidentiary hearing, the examination of Dr. Michel was strictly limited to the opinions offered in his rebuttal expert report. Tr. 2827-2828. Accordingly, Respondent has failed to demonstrate that it was deprived of due process rights with respect to Complaint Counsel's rebuttal expert witness, Dr. Michel.

Respondent further argues that it was denied the opportunity to present a surrebuttal expert witness, Dr. Steven Grossman, who would have responded to statements made by Complaint Counsel's expert witness, Dr. McCarthy, that Respondent contends are "false and scientifically incorrect." RB at 219. However, Respondent's arguments in support of calling Dr. Grossman as a surrebuttal expert witness were also evaluated and rejected in the July 23 Order, which noted that under Rule 3.31A(a), leave to call surrebuttal experts may be considered only where it is demonstrated that "material outside the scope of fair rebuttal is presented" by a rebuttal report. 16 C.F.R. § 3.31A(a); July 23, 2014 Order, at 3. Because Respondent failed to demonstrate that matters outside the scope of fair rebuttal had been presented, there was no valid basis for allowing a surrebuttal expert witness. Thus, denying Respondent's request to call Dr. Grossman for this purpose does not constitute a denial of due process.

I. REMEDY

1. Overview

Having concluded that Respondent violated the FTC Act in claiming, and providing others with the means and instrumentalities to claim, that ECM Plastics would fully biodegrade in a landfill within 9 months to 5 years, and that tests proved such claim, the FTC Act authorizes issuance of an order to cease and desist the unlawful conduct. 15 U.S.C. § 45(b) ("If upon such hearing the Commission shall be of the opinion that the . . . act or practice in question is prohibited by this Act, . . . it shall state its findings as to the facts and shall issue . . . an order requiring such person, partnership, or corporation to cease and desist from using . . . such act or practice."). As an administrative body, the Commission possesses only such powers as are granted by statute and may make only such orders as the FTC Act authorizes. *FTC v. National Lead Co.*, 352 U.S. 419, 428 (1957); *Arrow-Hart & Hegeman Electric Co. v. FTC*, 291 U.S. 587, 598 (1934). The purpose of a cease and desist order is to prevent the future

repetition of the violations found to exist, including by “creating stringent monetary incentives (in the form of civil penalties) for its observance.” *Litton Indus.*, 1981 FTC LEXIS 94, at *147; accord *Thompson Medical*, 1984 FTC LEXIS 6, at *405-06 (describing order as appropriate “to prohibit and prevent [the respondent] from engaging in deceptive acts or practices”). “Orders of the Federal Trade Commission are not intended to impose criminal punishment or exact compensatory damages for past acts, but to prevent illegal practices in the future.” *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952).

Respondent contends that remedial action in this case is not in the public interest because (1) ECM Customers were sophisticated entities who were not misled by ECM; and (2) ECM did not sell to end-use consumers. As to the first assertion, Respondent made substantially the same assertion to argue that its claims were not material to its Customers. The assertion was rejected, as stated in Section III.F., *supra*, because the evidence fails to support the conclusion that ECM Customers were “sophisticated” with respect to evaluating ECM’s biodegradation rate and testing claims. Moreover, as also noted in Section III.F., *supra*, there is direct evidence that ECM Customers believed ECM’s representations to be true, and therefore were deceived by ECM. F. 1508-1509, 1537. These facts readily distinguish this case from *In re Harad*, 50 F.T.C. 300 (Sept. 24, 1953), cited by Respondent, in which it was “assumed” that the medical doctors that were targeted by an advertisement for a medical device were sufficiently knowledgeable not to be misled thereby, and from *Arnold Stone v. FTC*, 49 F.2d 1017 (5th Cir. 1931), also cited by Respondent, in which the evidence showed that the defendant’s construction industry customers accurately understood “cast stone,” as sold by defendant, to refer precisely to the product defendant was selling, and therefore, no misrepresentation occurred.

Furthermore, as to Respondent’s second assertion, above, the fact that Respondent did not sell the ECM Additive directly to consumers is not determinative of whether the public interest is served by this action. A case affects the “public interest” where there is deception of the public. *Koch v. FTC*, 206 F.2d 311, 319 (6th Cir. 1953). ECM Customers, and downstream customers, although not ordinary “consumers,” are nonetheless members of the public, and protecting them from deception is in the public interest.

While it may not be necessary to demonstrate that end-use consumers were harmed by Respondent's deceptive claims in order for a remedial order to be in the public interest, the absence of any proof of such consumer harm in this case militates against a broad remedial order. Complaint Counsel introduced no consumer testimony. The evidence shows that ECM directly, and through its Customer, Island Plastic Bags, caused the claim that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years to be printed on millions of grocery bags sold to Island Plastic Bags' customer, Down-to-Earth ("DTE") and distributed in the state of Hawaii. F. 32, 35-36, 293, 297-301. While it is reasonable to infer that consumers were exposed to this claim, F. 302, consumers do not purchase the bags; rather, the bags are provided after consumers complete their grocery purchases. F. 297. In addition, there is no evidence that consumers would make, or did make, purchasing decisions based, in whole or in part, on the properties of bags provided to them by stores.⁵⁸ For example, Complaint Counsel does not point to any evidence suggesting that consumers chose to shop at DTE – or any other grocery stores carrying the bags with the 9 Months to 5 Years Claim – based in whole or in part on the claim that the grocery bags would biodegrade in a landfill within 9 months to 5 years. Moreover, DTE testified that it chose to include the claim on its bags because the technology was new and DTE's customers are well-informed. F. 1510. DTE also wanted to demonstrate that DTE was doing its part to help the environment. F. 1510. The evidence fails to show that DTE included the claim on its bags in order to induce grocery sales.⁵⁹

⁵⁸ Indeed, Complaint Counsel did not present evidence that any end-use consumers (as opposed to commercial enterprises) purchased any ECM Plastic based, in whole or in part, on any claim made by ECM. There is also no record evidence that any such end-use consumers "purchased" the grocery bags, shopping bags, restaurant bags, disposable dinnerware, packaging materials, or shipping materials that comprise many of the products which, based on the customer deposition testimony, are manufactured using the ECM Additive. *See, e.g.*, F. 11-12, 25, 31, 49-51, 56-59, 65-66, 71-73.

⁵⁹ Complaint Counsel asserts that "ECM's 'biodegradable plastic' claims have . . . reached millions of consumers through advertising for a host of products and packages – ranging from grocery bags to shampoo bottles, Frisbees, golf tees, highlighters, storage cases, shoe soles, mailers, zippers, plastic cutlery, straws, and more." CCFF 25. The exhibits upon which this proposed finding relies consist of photographs of items with "biodegradable" symbols – some of which are not ECM's logo – and copies of promotional materials belonging to various entities, many of which have no clear connection to ECM and/or do not appear to sell to the general public. *See, e.g.*, CCX 39 (website ad for biodegradable golf tees); CCX 40 (ad for biodegradable packaging); CCX 41 (ad for biodegradable bags and film); CCX 52 (labels for "certified" biodegradable bags and cases); CCX 56 (ad for biodegradable bags and cutlery); CCX 59 (ad for biodegradable medical supply bags); CCX 61 (ad for biodegradable bottle); CCX 63 (biodegradable cold packs); CCX 64 (ad for biodegradable mailers); CCX 65 (ad for biodegradable trash bin); CCX 79 (biodegradable zipper ad); CCX 96 (biodegradable straws); CCX 103 (biodegradable Frisbee); CCX 112 (biodegradable bag); CCX 126 (biodegradable highlighter). *See also* CCX 139

Respondent states that it has permanently discontinued the 9 Months to 5 Years Claim. The evidence shows that ECM began revising its Marketing Materials in or around October 2012, in response to the issuance of the revised Green Guides, to omit references to a biodegradation rate of “9 months to 5 years.” F. 238, 251-252. The evidence further shows that ECM permanently discontinued the 9 Months to 5 Years Claim in approximately November or December 2013, when it removed all such references to this time period from its website. F. 259. The Complaint was issued in October 2013. Moreover, at least some of ECM’s Customers believed that ECM Plastics would biodegrade in 9 months to 5 years, even after the change in ECM’s rate language to “some period greater than a year.” F. 1509. The fact that Respondent ceased making the 9 Months to 5 Years Claim in its Marketing Materials after November or December 2013, after issuance of the Complaint, does not bar a cease and desist order, where, as here, the public interest otherwise supports such an order. *See Fedders Corp. v. FTC*, 529 F.2d 1398, 1403 (2d Cir. 1976) (discontinuance of claim was not “voluntary,” but resulted from defendant’s awareness of the Commission’s investigation); *see also American Home Products Corp. v. FTC*, 695 F.2d 681, 703 n.38 (3d Cir. 1982) (holding that discontinuance of claims was not voluntary when claims ceased after proceedings were brought).

For the foregoing reasons, a cease and desist order barring the deceptive biodegradation rate and testing claims made in this case serves the public interest and is otherwise appropriate pursuant to Section 5(b) of the FTC Act. After consideration of all the arguments of the parties and the entire record of the case, the attached order, to be entered herewith (“Order”), will serve to prohibit and prevent Respondent from engaging in these deceptive trade practices in the future, is reasonably related to the unlawful acts or practices found to exist, and is sufficiently clear and precise. As more fully explained below, several portions of the proposed order

(biodegradable shoe soles manufactured by Italian firm). At most, the exhibits cited in support of Complaint Counsel’s Proposed Finding 25 demonstrate that ECM’s logo appeared on some products that are available for purchase by consumers, or are provided to consumers in connection with the purchase of something else, such as groceries or shipped goods. However, this is not relevant because the products in the record displaying the ECM logo do not set forth the claims that ECM Plastics will fully biodegrade in a landfill within 9 months to 5 years, or that tests prove such claim, which are the only Challenged Claims that have been found in this case to have been false or misleading.

submitted by Complaint Counsel (“Proposed Order”)⁶⁰ substantially fail to address the deceptive claims found to have been made in this case, and instead seek to restrain conduct as to which no deception has been found. Accordingly, those portions of the Proposed Order are rejected.

2. The Proposed Order

a. Part I.A. restraints on future “unqualified” biodegradable claims

Part I.A. of the Proposed Order provides as follows:

Respondent, and its officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, package, or service, in or affecting commerce, shall not represent, in any manner, directly or indirectly, expressly or by implication:

- A. That any product or package is degradable,⁶¹ or that any product, package, or service affects a product or package’s degradability, unless
 - i. the entire item will completely decompose into elements found in nature within one year after customary disposal; or
 - ii. the representation is clearly and prominently and in close proximity qualified by:
 - a. Either (1) the time to complete decomposition into elements found in nature; or (2) the rate and extent of decomposition into elements found in nature, provided that such qualification must disclose that the stated rate and extent of decomposition does not mean that the product or package will continue to decompose; and
 - b. If the product will not decompose in a customary disposal facility or by a customary method of disposal, both (1) the type of non-customary disposal facility or method and (2) the availability of such disposal facility or method to consumers where the product or package is marketed or sold and such representation is true, not misleading, and, at the time it is made, respondent possesses and relies upon competent and

⁶⁰ See Complaint Counsel’s Annotated Proposed Order, submitted with Complaint Counsel’s Post-Trial Brief.

⁶¹ “Degradable” is defined in the Proposed Order to include, *inter alia*, “biodegradable.”

reliable scientific evidence that substantiates the representation.

Proposed Order Part I.A.; *see also* Definitions para. 4, defining competent and reliable scientific evidence, for “unqualified” biodegradable claims, as technical protocols demonstrating “complete decomposition within one year and replicate, *i.e.*, simulate, the physical conditions found in landfills,”

i. Arguments of the parties

Complaint Counsel explains that Part I.A.i., set forth above, is designed to prohibit “unqualified” biodegradable claims (*i.e.*, representations of “biodegradable” without a qualification regarding the rate and extent of complete decomposition) unless competent and reliable scientific evidence demonstrates that the entire item will completely decompose into elements found in nature within one year after customary disposal (the “One Year Requirement”). CCB 92-93, 96. Complaint Counsel argues that such provisions are necessary to prevent Respondent “from making deceptive unqualified biodegradable claims suggesting that its additive will make plastics biodegrade within a year in landfills.” CCB at 95; Proposed Order at I.A.i.n.12. Complaint Counsel notes that, under Part I.A.ii, Respondent is free to make truthful, substantiated, “qualified” biodegradable claims for products “that will not completely biodegrade in a landfill within one year, [however] ECM must: (1) conspicuously disclose the substantiated time to complete biodegradation; or (2) conspicuously disclose, with appropriate qualifications, the rate and extent of biodegradation shown through competent and reliable scientific evidence.” Proposed Order at I.A.ii.n.11; CCB at 96.

Respondent asserts that the One Year Requirement in the Proposed Order is invalid for numerous reasons. Respondent argues that its unqualified biodegradable claims are neither false, nor unsubstantiated, and that the restrictions on such speech amount to an overbroad and unjustified prior restraint in violation of the First Amendment to the Constitution. RB at 188-195. Respondent further argues that enforcing the Proposed Order is not in the public interest, because, *inter alia*, by effectively restricting the labeling of products as “biodegradable” to those that completely biodegrade in a landfill within one year, the FTC is (1) favoring rapidly degrading technologies, which Respondent asserts emit harmful amounts of methane that are

worse for the environment; and (2) enforcing erroneous and unreasonable consumer “impressions” about the speed of biodegradation, over scientific facts. RB at 191, 197-198. Moreover, Respondent contends, in favoring rapidly degrading technologies, the FTC is intruding on the regulatory power of the U.S. Environmental Protection Agency (“EPA”) and exceeding the powers of the FTC. RB at 205-209. In addition, Respondent asserts that the One Year Requirement in the Proposed Order is, in effect, the Commission enforcing the revised Green Guides against Respondent and giving effect to a “rule” that has not been adopted through statutorily required rulemaking processes. RB at 209-210. Further, Respondent contends that Part I.A effectively forces Respondent to state a rate and an extent for biodegradation, but the evidence fails to show that there is any test that could sufficiently demonstrate such rate and that rates are inherently variable depending on landfill environments. Thus, Respondent argues, the Proposed Order imposes requirements that are virtually impossible to meet. RB at 201-202; RRB at 182-184.

Complaint Counsel acknowledges that the One Year Requirement reflects the Commission’s views as expressed in the revised Green Guides, but argues that the evidence shows that consumers perceive “biodegradable” claims to imply complete biodegradation within one year, which makes the One Year Requirement appropriate relief. *See* Transcript of Closing Arguments, October 22, 2014, Tr. 37. Complaint Counsel further replies that regardless of whether the One Year Requirement is inconsistent with environment policy, or with science, the provisions are still “reasonable” and in the public interest because Respondent deceptively implied that its products would completely biodegrade in a landfill in one year. CCRB at 23-25.

ii. Analysis

Part I.A. of the Proposed Order is based on the Complaint Counsel’s contention in this case that Respondent’s “unqualified” biodegradable claims, *i.e.*, claims that ECM Plastics are “biodegradable,” without stating a time period for complete biodegradation, such as the claim represented by ECM’s “biodegradable” logo, F. 239, violated the FTC Act by implying, falsely or without substantiation, that ECM Plastics would completely break down into elements found in nature, in a landfill, within one year (the “Implied One Year Claim”). However, Complaint

Counsel failed to prove that Respondent made the Implied One Year Claim. *See* Section III.D.4., *supra*. Moreover, the “unqualified” biodegradable claims actually made by Respondent, properly interpreted as a matter of both consumer perception and science, were not false or unsubstantiated. *See* Section III.E., *supra*. Because Complaint Counsel failed to prove its assertion that Respondent’s unqualified biodegradability claims were deceptive, there is no proper basis in law, fact, or fairness, for enjoining such conduct. *See American Home Products*, 695 F.2d at 710; *ITT Continental Baking Co. v. FTC*, 532 F.2d 207, 220-21 (2d Cir. 1976). Complaint Counsel offers no alternative proposal to redress the 9 Months to 5 Years Claim or the claim that tests prove the 9 Months to 5 Years Claim, which Complaint Counsel did prove were deceptive.

In *ITT*, the Commission found that the respondent misrepresented that its product, Wonder Bread, was “an extraordinary food for producing dramatic growth in children.” 532 F.2d at 221. On appeal, the court deleted provisions of the cease and desist order that prohibited the respondent from representing “[t]he nutritional properties of any [food] product in generalized terms such as ‘rich in nutrients,’ vitamins or iron fortified, ‘enriched,’ or other similar nutritional references, [without adequate substantiation]”; “[t]he comparative nutritional efficacy or value of the product without stating the brand, product or product category to which the comparison is being made”; and “[t]he essentiality of the product as a source of a particular nutritional value if there are other food product categories which are also sources of the same or similar nutritional values, [without adequate substantiation] . . .” because the provisions were not “reasonably related” to the unlawful conduct found to exist. 532 F.2d at 220-21. Noting that “[t]he courts may narrow FTC orders, . . . by deleting those portions for which a reasonable relationship to the offending conduct is lacking, the court reasoned:

[The Commission found] that Wonder Bread had *not* been misrepresented as nutritionally superior to other breads, or as necessary for children’s healthy growth and development, the very types of representations at which paragraphs 1(b) and 1(c) are aimed. The petitioners had not been charged with representing Wonder Bread’s nutritional value in “generalized terms” (the practice regulated by paragraph 1(a)); nevertheless the Commission did *exonerate* them of several accusations concerning Wonder Bread’s nutritional content. Moreover, while the petitioners had advertised another group of food products, Hostess Snack Cakes, as “fortified with vitamin and iron,” “vitamin fortified,” and containing “good nutrition”, the Commission *dismissed* all charges relating to this

advertising, including charges that the claim of “good nutrition” was misleading. *It is difficult to avoid concluding that paragraphs 1(a), (b) and (c) of the cease and desist order were framed to remedy wrongs which the Commission found not to have been committed.*

532 F.2d at 221 (emphasis added). Similar to *ITT*, Part I.A. of the Proposed Order is framed to remedy the alleged Implied One Year Claim, which, it has been determined, was not made.

Complaint Counsel notes that the Commission may order “provisions that are broader than the conduct that is declared unlawful” as a way to “fence-in” the violator. CCB at 94 n. 160. *See Telebrands*, 457 F.3d at 357 n.5. A common form of “fencing-in” relief is a “multi-product” prohibition that bars the respondent from using its deceptive trade practice to sell not only the product that was the subject of the enforcement action, but all products sold by the respondent. Such multi-product orders are justified where the respondent’s deceptive practice was serious or deliberate, easily transferrable to the sale of other products, and/or where there is a history of prior violations. *See, e.g., POM*, 2013 FTC LEXIS 6, at *153-57. *See also FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394 (1965) (all products); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392 (9th Cir. 1982); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 563-64 (2d Cir. 1984).

It has been held that fencing-in relief can include restraining the respondent from engaging in deceptive practices that are “like and related” to the violating practice “as a prophylactic and preventative measure.” *FTC v. Mandel*, 359 U.S. 385, 393 (1959). *See also Niresk Indus., Inc. v. FTC*, 278 F.2d 337, 343 (7th Cir. 1960) (holding that FTC orders may prohibit future use of “related and similar practices”). In the instant case, however, the unlawful practice was misrepresenting the time period in which complete biodegradation would occur. This is neither “similar” nor “related to” Respondent’s non-deceptive, unqualified biodegradable claim, which did not state or imply any time period. F. 232-244. *See American Home Products*, 695 F.2d 681. In *American Home Products*, the court rejected a proposed order that the respondent cease and desist from unsubstantiated non-comparative efficacy claims. “The only non-comparative claim of effectiveness or freedom from side effects, lacking a reasonable basis, which the Commission specifically found was the advertising message that Anacin offers relief from tension.” *Id.* at 703. The court dismissed the argument

that the provision was justified as fencing-in relief, noting, among other things, that the provision “encompasses deceptive practices which seem to be quite dissimilar to the deceptions actually found,” and that the deceptive “tension relief” claim was directly addressed by a separate – and uncontested – portion of the order. *Id.* at 710-11. The One Year Requirement in Part I.A. of the Proposed Order is even less justified in the instant case where, unlike in *American Home Products*, Complaint Counsel specifically failed to prove the claim that the proposed One Year Requirement is designed to redress. *See* Section III.D.4., *supra*. Complaint Counsel does not point to any case upholding a Commission order that directly, or by way of fencing-in, enjoined conduct that the government contended, but specifically failed to prove, was deceptive. As a matter of fundamental fairness, fencing-in relief must not include conduct that the government charged but could not prove.

Other factors also militate against the One Year Requirement. The ECM Additive is the only product sold by Respondent, F. 158, 163, and therefore there is no issue of transferability. Complaint Counsel does not contend, nor does the evidence show, any prior violations by Respondent. Further, Complaint Counsel has failed to demonstrate that the violations in this case are so “serious” or “deliberate” that, when considered as part of the totality of the circumstances, Respondent should be fenced-in with a restraint upon “biodegradable” claims that have specifically been found not to be deceptive.⁶² *See Sears*, 676 F.2d at 392 (holding that, in determining the propriety of fencing-in relief, courts look to the circumstances as a whole “and not to the presence or absence of any single factor”).⁶³

To be sure, those caught violating the FTC Act “must expect some fencing in” in order to prevent similar illegal practices in future advertisements. *Colgate-Palmolive*, 380 U.S. at

⁶² Complaint Counsel refers to decisions of the National Advertising Division of the Better Business Bureau (“NAD”) and certain European tribunals, in cases against some of ECM’s Customers to which ECM was not party, as evidence that Respondent “knew” the ECM Additive “did not work.” *See* CCF 103, CCB at 26, 96. The findings in these cases, in which ECM was not a party or represented, were not offered, or accepted, for the truth of the matters asserted therein, however. Tr. 1617-1624, 1647-1650. Thus, as a matter of fairness, these cases do not constitute prior “violations” by ECM, or notice that the ECM Additive “did not work.” Moreover, Respondent’s failure to change its marketing practices in response to findings of the NAD or foreign tribunals does not demonstrate that the violations found in this case are “serious” and “deliberate.”

⁶³ Respondent’s cessation of the offending practice and the absence of proof that any ordinary end-use consumer purchased any ECM Plastic containing the offending claims, also militate against a broad fencing-in order.

395. But “a court must still demand that there be some relation between the violations found and the breadth of the order. . . . An order is not entitled to enforcement if the court reviewing it finds that ‘the remedy selected has no reasonable relation to the unlawful practices found to exist.’ *Jacob Siegel Co. v. F.T.C.*, 327 U.S. 608, 613, 66 S.Ct. 758, 760, 90 L.Ed. 888 (1946).” *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964).

Part I.A. of the Proposed Order seeks to restrain unqualified biodegradable claims, which have been determined not to be deceptive or unlawful, and such claims are not sufficiently similar or related to Respondent’s deceptive biodegradation rate claims to justify the provisions of Part I.A. as fencing-in relief. *See Country Tweeds*, 326 F.2d at 148-49. As the Supreme Court has stated, “[o]ne cannot generalize as to the proper scope of these orders. It depends on the facts of each case and a judgment as to the extent to which a particular violator should be fenced in.” *Mandel*, 359 U.S. at 392. The judgment in the present case is that the One Year Requirement is not reasonably related to the violations found to exist and is not justified as fencing-in relief.⁶⁴ Accordingly, Part I.A. of the Proposed Order is rejected.⁶⁵

b. Part I.B. restraints on future environmental benefit claims

Part I.B. of the Proposed Order prohibits Respondent from representing that any ECM “product, package, or service offers any environmental benefit, unless the representation is true, not misleading, and, at the time it is made, [R]espondent possesses and relies upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, that substantiates the representation.” Proposed Order, Part I.B.

⁶⁴ Complaint Counsel states that there is “wide discretion” to craft a remedy, and such discretion is subject only to two constraints: (1) that the order bear a “reasonable relation” to the unlawful practices, and (2) be sufficiently clear and precise that its requirements can be understood. CCB at 92. It is, of course, well established that Congress, through the FTC Act, has granted the Commission “wide discretion in its choice of a remedy deemed adequate to cope with . . . unlawful practices” and that “the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist.” *Jacob Siegel*, 327 U.S. at 611-13. However, the “reasonable relation” test is an outside limit on the permissible exercise of the FTC’s discretion, rather than a standard for determining what remedy will serve the purpose of prohibiting and preventing the recurrence of deceptive trade practices.

⁶⁵ Because the One Year Requirement is not included in the Order, it is not necessary or appropriate to analyze or determine the merits of Respondent’s arguments against the One Year Requirement, summarized in Section III.H.2.a.i, above.

The Complaint does not specifically charge, the parties did not litigate, and Complaint Counsel sought no findings as to whether or not Respondent misrepresented any “environmental benefit.” Although it is unclear, Complaint Counsel appears to justify this provision as fencing-in relief. Proposed Order at 6 n.15. The facts of this case militate against a broad remedial order that would reach any “environmental benefit” claim, including that: Respondent has permanently ceased the claim found to have violated the FTC Act; there is no evidence of economic harm to ordinary consumers; Respondent has no prior violations; and there is no issue of transferability. Moreover, the term “environmental benefit” is vague, undefined by the Proposed Order, and overly broad in light of the misrepresentations found to have been made in this case. *See Country Tweeds*, 326 F.2d at 148-49 (rejecting as vague, overbroad and unjustified prohibition against “misrepresenting in any manner the quality of cashmere or other fabric in their merchandise” as fencing-in remedy for the respondent’s misrepresenting the quality of their cashmere through the misuse of test results). Accordingly, Part I.B. of the Proposed Order is not included in the Order.

c. Proposed Definition of competent and reliable scientific evidence

Paragraph 4 of the Definitions section of the Proposed Order defines “competent and reliable scientific evidence” as:

tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that a representation is true.

Proposed Order, Definitions para. 4.

The evidence demonstrates that competent and reliable scientific evidence is necessary to support the biodegradability claims made in this case, and the foregoing definition is consistent with that evidence. *See* F. 704-705. In addition, Commission orders requiring respondents to substantiate claims with competent and reliable scientific evidence, as defined above, are typical and have been consistently upheld by the appellate courts. *E.g., In re Daniel*

Chapter One, 2010 FTC LEXIS 11, *rev. denied*, 405 Fed. Appx. 505, 2010 U.S. App. LEXIS 25496 (D.C. Cir. 2010); *Telebrands*, 140 F.T.C. at 347, *aff'd*, 457 F.3d 354; *Kraft*, 1991 FTC LEXIS 38, at *59-60, *aff'd*, 970 F.2d 311 (7th Cir. 1992). Such a requirement in this case serves the purpose of preventing future violations, is reasonably related to the violation found to exist, is sufficiently clear and precise, and is amply supported by legal precedent and the facts of this case. Accordingly, the definition is incorporated into the Order.

Complaint Counsel's Proposed Order also expands upon the definition of "competent and reliable scientific evidence" by adding the following:

- A. For unqualified biodegradability claims, any scientific technical protocol (or combination of protocols) substantiating such claims must assure complete decomposition within one year and replicate, *i.e.*, simulate, the physical conditions found in landfills, where most trash is disposed.
- B. For qualified biodegradability claims, any scientific technical protocol (or combination of protocols) substantiating such claims must both:
 - i. assure the entire product will (1) completely decompose into elements found in nature in the stated timeframe or, if not qualified by time, within one year; or (2) decompose into elements found in nature at the rate and to the extent stated in the representation; and
 - ii. replicate, *i.e.*, simulate, the physical conditions found in the type of disposal facility or method stated in the representation or, if not qualified by disposal facility or method, the conditions found in landfills, where most trash is disposed.

For example, results from ASTM (American Society for Testing and Materials) International D5511-12, *Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials under High Solids Anaerobic Digestion Conditions*, or any prior version thereof, are not competent and reliable scientific evidence supporting unqualified claims, or claims of outcomes beyond the parameters and results of the actual test performed.

Proposed Order, Definitions para. 4A, 4B.

The above-quoted portions of the proposed definition of competent and reliable scientific evidence are not justified by the record in this case. As noted above, the evidence

failed to prove the charge that Respondent, in representing that ECM Plastics were biodegradable, represented that ECM Plastics would completely decompose into elements found in nature, in a landfill, within one year, and Respondent will not be required to substantiate a claim that has not been made. In addition, the greater weight of the expert testimony establishes that experts in the relevant scientific fields do not require proof of complete decomposition within one year in order to substantiate that something is “biodegradable.” See Section III.E.3., *supra*. Accordingly, to the extent that the provisions of 4A and 4B of the Proposed Order would require Respondent to prove that ECM Plastics will completely decompose into elements found in nature, in a landfill, within one year, in order to claim that ECM Plastics are “biodegradable,” the definition is not justified by the findings in the case and is rejected. Those portions of 4A and 4B affecting substantiation for any future claims as to a time period for complete biodegradation are accepted with some modifications, as described *infra*.

Moreover, the proposed requirement that Respondent substantiate unqualified “biodegradable” claims with proof of complete decomposition in a landfill within one year is unprecedented as a matter of law. Complaint Counsel cites no statute, rule, or adjudicative order that has expanded the definition of competent and reliable scientific evidence to require for “biodegradable” claims that the advertiser substantiate complete biodegradation in a landfill within one year. The Green Guides, upon which the Proposed Order is patterned, and which Complaint Counsel cites in support of the Proposed Order (Proposed Order at 2 nn.2, 3, and at 4 n.8) are not law, and expressly do not “bind the FTC or the public.” 16 C.F.R. § 260.1.⁶⁶ Again, as analyzed and determined above, Complaint Counsel failed to prove that a “within one year standard” is appropriate.

Complaint Counsel’s assertion that consent orders are precedent for the provisions of the Proposed Order (Proposed Order at 2 nn.2, 3) is without merit. It is well established that consent orders do not constitute legal precedent. “[T]he circumstances surrounding . . .

⁶⁶ Furthermore, the Green Guides acknowledge that “[i]n any such enforcement action, the Commission must prove that the challenged act or practice is unfair or deceptive in violation of Section 5 of the FTC Act.” 16 C.F.R. § 260.1 In the instant case, such enforcement action has failed to demonstrate that Respondent’s unqualified biodegradable claims were deceptive in violation of the FTC Act, or to demonstrate that Respondent represented that ECM Plastics would completely biodegrade in a landfill within one year.

negotiated [consent decrees] are so different that they cannot be persuasively cited in a litigation context.” *United States v. E. I. du Pont de Nemours & Co.*, 366 U.S. 316, 331 n.12 (1961); *see POM*, 2012 FTC LEXIS 106, at *705 (Initial Decision); *see also In re Giant Food, Inc.*, 61 F.T.C. 326, 1962 FTC LEXIS 84, at *63 (July 31, 1962) (“consent order . . . lacks the precedent value of a litigated case”); *In re Federal Employees Distributing Co.*, 56 F.T.C. 550, 1959 FTC LEXIS 301, at *58 (Nov. 23, 1959) (“consent order under agreement of parties . . . is not a precedent in other cases for any purpose.”). Indeed, as confirmed by the express terms of the consent orders cited by Complaint Counsel, a consent order “is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated.” *See, e.g., In re Gorell Enters.*, No. C-4360, 2012 FTC LEXIS 96, at *1 (May 16, 2012); *In re Down to Earth Designs, Inc.*, No. C-4443, 2014 FTC LEXIS 46, Consent Order at *1 (Mar. 18, 2014). For these reasons as well, the proposed requirement that Respondent substantiate unqualified biodegradable claims with proof of complete decomposition in a landfill within one year, is rejected.

3. The Order

In order to prohibit and prevent the deceptive claims found to have been made in this case, the Order includes this provision: “[R]espondent, and its officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, package, or service, in or affecting commerce, shall not represent, in any manner, directly or indirectly, expressly or by implication, that any product or package will completely biodegrade within any time period, or that tests prove such representation, unless such representation is true, not misleading, and, at the time it is made, [R]espondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.” Order, Part I. Although this provision will encompass all false or unsubstantiated biodegradation rate claims, and not just the 9 Months to 5 Years Claim, Respondent has maintained throughout this proceeding, and it has been found as a matter of fact, that there is presently no single test that can substantiate the precise rate of biodegradation of plastics in a landfill. F. 712-715. Accordingly, based upon the scientific record in this case, it is appropriate to prohibit false or unsubstantiated biodegradation rate claims, as provided in

the Order, in order to prevent deceptive claims in the future. Moreover, barring all biodegradation rate claims, unless and until such rate can be properly substantiated as provided in the Order, will give clear guidance to Respondent, as well as other similarly situated entities, as to how ECM Plastics may be marketed.

As noted above, the Order defines competent and reliable scientific evidence as “tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that a representation is true.” In addition, in accordance with the findings in this case, the definition set forth in the Order further requires that:

for any representation that complete biodegradation will occur within any time period, or that tests prove such representation, any scientific technical protocol (or combination of protocols) substantiating such representations must both:

- i. substantiate that the entire product will completely decompose within the time period stated in the representation; and
- ii. replicate, *i.e.*, simulate, the physical conditions found in the type of disposal facility or method stated in the representation or, if not qualified by disposal facility or method, the conditions found in landfills, where most trash is disposed.

Order, Definitions Paragraph 2. The foregoing definition of competent and reliable scientific evidence incorporates portions of the definition proposed by Complaint Counsel, in paragraphs 4A and 4B of the Proposed Order that specify the type of substantiation required for future biodegradation rate claims and is consistent with the evidence and findings in this case.

However, the Order does not include Complaint Counsel’s proposal that “results from ASTM (American Society for Testing and Materials) International D5511-12, *Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials under High Solids Anaerobic Digestion Conditions*, or any prior version thereof, are not competent and reliable scientific evidence” The Order makes clear what substantiation is required in the future. Therefore, it is unnecessary to also specify a test that may not constitute adequate substantiation.

Part II of the Order, which is based upon Part II of the Proposed Order with modifications, prohibits Respondent from providing “others the means and instrumentalities with which to make, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names, any false, unsubstantiated, or otherwise misleading representation that any product or package will completely biodegrade within any particular time period, or that tests prove such representation.” Order, Part II. These provisions are consistent with the evidence and findings and will prevent future violations by Respondent.

Parts III-VII of the Order incorporate the corresponding parts of the Proposed Order. These provisions impose certain record-keeping, notification, and reporting requirements, and set forth the duration of the order. Such provisions properly serve to facilitate administration of the Order, and therefore have been included in the Order.

4. Conclusion

The Order entered herewith will serve to prevent Respondent from engaging in deceptive practices in the future, is reasonably related to the unlawful acts or practices found to exist, and is sufficiently clear and precise.

IV. SUMMARY OF CONCLUSIONS OF LAW

1. Complaint Counsel bears the burden of proving jurisdiction and liability by a preponderance of evidence.
2. Respondent is a corporation within the meaning of Sections 4 and 5 of the Federal Trade Commission Act (“FTC Act”). 15 U.S.C. §§ 44, 45.
3. Respondent’s sales of “MasterBatch Pellets” (the “ECM Additive”), as alleged in the Complaint, are and have been “in or affecting commerce,” as required by the FTC Act, 15 U.S.C. § 45(a)(1).
4. The FTC has jurisdiction over the conduct challenged in the Complaint, pursuant to Sections 4 and 5 of the FTC Act.
5. An advertisement is deceptive if it contains a representation or omission of fact that is likely to mislead a consumer acting reasonably under the circumstances, and that representation or omission is material to a consumer’s purchasing decision.
6. An advertisement is deemed to convey a claim if consumers, acting reasonably under the circumstances, would interpret the advertisement to contain that message.
7. Whether an advertisement communicated a claim to reasonable consumers is a question of fact. This question of fact may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey.
8. The primary evidence of the representations that an advertisement conveys to reasonable consumers is the advertisement itself.
9. Complaint Counsel has proven that Respondent claimed that ECM Plastics are biodegradable, including in a landfill; that ECM Plastics would completely biodegrade in a landfill in a time period ranging from 9 months to 5 years; and that tests proved such claims.
10. Complaint Counsel failed to prove its contention that Respondent’s claims of (1) “biodegradable” or (2) “biodegradable” in “some period greater than a year” impliedly claimed that ECM Plastics will completely biodegrade into elements found in nature, in a landfill, within one year (the “Implied One Year Claim”). Rather, to find such an implied claim would be to “inject novel meanings into ads,” which is improper.
11. To prove its Implied One Year Claim, Complaint Counsel bears the burden of proving that a significant minority of reasonable consumers would interpret ECM’s claims of (1) “biodegradable” or (2) “biodegradable” in “some period greater than a year” to be conveying the message that ECM Plastics will completely biodegrade into elements found in nature, in a landfill, within one year.

12. The plain language used in Respondent's Marketing Materials and logo does not state that ECM Plastics will completely breakdown into elements found in nature, in a landfill, within one year. Moreover, there are no additional elements of the materials at issue, such as the juxtaposition of phrasing or associated images, that support a finding that the language (1) "biodegradable" or (2) "biodegradable" in "some period greater than a year" is reasonably interpreted to be conveying the Implied One Year Claim.
13. Based on a facial analysis alone, Respondent's (1) "biodegradable" and (2) "biodegradable" in "some period greater than a year" claims do not, in fact, convey the message that ECM Plastics completely biodegrade into elements found in nature, including in a landfill, within one year.
14. It is appropriate to infer that consumers interpret words to mean what they say.
15. As the primary evidence of the meaning of Respondent's representations, the fact that the advertisements themselves do not support the Implied One Year Claim is given substantial weight.
16. When extrinsic evidence has been introduced, that evidence must be considered in reaching a conclusion about the meaning of the advertisement.
17. Extrinsic evidence includes, but is not limited to, evidence of the common usage of terms, and reliable results from methodologically sound consumer surveys.
18. The common meanings of "biodegradable," based on the dictionary definitions, are: "capable of being slowly destroyed and broken down into very small parts by natural processes, bacteria, etc." or "capable of being broken down especially into innocuous products by the action of living things (as microorganisms)." *Merriam-Webster.com, supra. Thompson Medical*, 1984 FTC LEXIS 6, at *359. Nothing in the foregoing definitions supports a conclusion that a significant minority of reasonable consumers would interpret "biodegradable," to mean completely breakdown into elements found in nature, in a landfill, within one year.
19. Complaint Counsel has failed to prove that the Google survey, procured for this litigation by Complaint Counsel's expert witness, Dr. Shane Frederick, drew valid samples from the appropriate population, asked appropriate questions in ways that minimized bias, and analyzed results correctly, or that the Google survey should be given any meaningful weight on the issue of whether a significant minority of reasonable consumers would interpret Respondent's biodegradable claims to be communicating a message that ECM Plastics will completely break down into elements found in nature, in a landfill, within one year.
20. Complaint Counsel's Google survey fails to comport with generally accepted standards for survey research, as well as the legal standards used by the Commission, and is insufficiently reliable or valid to draw any material conclusions.

21. Complaint Counsel's Google survey is not of sufficient methodological quality to constitute probative evidence in litigation, under the Commission's standards or the standards applicable to federal courts in general. For purposes of this adjudication, the Google survey is weak, at best.
22. The 2006 survey by the American Plastics Council ("APCO" survey) and 2010 survey performed by Synovate ("Synovate" survey), upon which Complaint Counsel relies to support the Implied One Year Claim, are both so seriously flawed that, for the purpose of determining the message conveyed by Respondent's biodegradable claims, the surveys are either invalid or, at best, entitled to little weight.
23. Dr. Frederick's theory of "convergent validity" of the Google, APCO, and Synovate surveys is inapplicable to bolster the probative value of these three flawed surveys. For purposes of the weight to be given to the Google, APCO, and Synovate surveys on the issue of whether Respondent made the alleged Implied One Year Claim, the whole is no greater than the sum of its parts.
24. Results from survey questions designed and implemented for this litigation by Respondent's expert, Dr. David Stewart, weigh against the conclusion that Respondent's "biodegradable" representation implied complete biodegradation in a landfill within one year. Based on Dr. Stewart's survey, consumers interpret the term "biodegradable" to mean the process by which a product breaks down or decays; and consumers understand that the time for this process varies depending on the materials involved and that the process of biodegradability is not always, or even often, a rapid process.
25. Two approaches have been used to prove that an advertisement is deceptive: (1) the "falsity" theory, or (2) the "reasonable basis" or "substantiation" theory.
26. Respondent must possess and rely on "competent and reliable scientific evidence" in support of its claims.
27. "Competent and reliable scientific evidence" means tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
28. The scientific evidence in this case establishes that the term "biodegradable" refers to the biological process by which microorganisms such as bacteria and fungi use the carbon found in organic materials as a food source and that scientific literature defining biodegradation does not require completion or impose a time restraint.
29. Complaint Counsel failed to prove that, for purposes of evaluating whether Respondent's claims are false or unsubstantiated, the term "biodegradable" means that

an item must completely break down and decompose into elements found in nature within one year after customary disposal.

30. Complaint Counsel failed to prove that, in order to claim that a product is biodegradable, the relevant scientific community demands competent and reliable scientific evidence that assures complete decomposition within one year in a landfill environment.
31. ASTM D5511 tests can provide competent and reliable scientific evidence of biodegradability of plastics in a landfill environment.
32. The expert testimony convincingly establishes that ECM Plastics are not fully biodegradable in a period of 9 months to 5 years in a landfill, and that tests do not prove such claims.
33. Complaint Counsel has met its burden of proving that the claims that ECM Plastics would completely biodegrade, including in a landfill, in a time period ranging from 9 months to 5 years, and that tests proved such claim, are both false and unsubstantiated.
34. Respondent has met its burden of producing the scientific evidence upon which it relies, including numerous ASTM D5511 tests conducted by independent laboratories, to substantiate its representations.
35. Complaint Counsel has not met its burden of showing that the ASTM D5511 tests upon which Respondent relies do not meet the standards demanded by the relevant scientific community or are so fatally flawed as to not constitute reliable and competent scientific evidence.
36. The tests upon which Respondent relies constitute competent and reliable scientific evidence demonstrating that plastics manufactured with the ECM Additive are biodegradable, including in a landfill.
37. Complaint Counsel has not met its burden of proving, pursuant to the falsity theory, that tests do not prove the biodegradability of ECM Plastics, or that the studies Respondent possessed do not pass muster in the view of the relevant scientific communities.
38. Complaint Counsel has not met its burden of proving, pursuant to the reasonable basis theory, that Respondent's substantiation for its claims that ECM Plastics are "biodegradable," including in a landfill, is inadequate, or that the studies upon which Respondent relies do not pass muster in the view of the relevant scientific communities.
39. Complaint Counsel has not met its burden of proving that the claims that ECM Plastics are biodegradable, including in a landfill, and that tests proved such claims, are false or unsubstantiated.

40. Complaint Counsel has proven that Respondent's false and unsubstantiated claims that ECM Plastics will fully biodegrade in a landfill in 9 months to 5 years, and that tests prove such claim, are likely to affect the purchasing decisions of ECM Customers, and downstream customers, and that therefore these claims constitute material misrepresentations.
41. Because Complaint Counsel has demonstrated Respondent made material false and unsubstantiated claims that ECM Plastics will fully biodegrade in a landfill in 9 months to 5 years, and that tests prove such claim, Complaint Counsel has met its burden of proving the charge that Respondent committed a deceptive trade practice in violation of Section 5 of the FTC Act.
42. Complaint Counsel has proven that Respondent provided its Customers with marketing materials that included false and unsubstantiated claims that ECM Plastics will fully biodegrade in a landfill in 9 months to 5 years, and that tests prove such claim, and encouraged its Customers to use these materials for its Customers' marketing of ECM Plastics to their own customers. Accordingly, Complaint Counsel has met its burden of proving the charge that Respondent provided the means and instrumentalities for deceptive marketing claims to be conveyed to others in the ECM supply chain.
43. Respondent has failed to prove that its due process rights have been violated in this case.
44. Having concluded that Respondent violated the FTC Act, that Act authorizes an order requiring Respondent to cease and desist from such violating acts or practices.
45. Although Respondent ceased making the 9 Months to 5 Years Claim as of late 2013, after issuance of the Complaint, this fact does not bar a cease and desist order, where, as here, the public interest otherwise supports such an order.
46. Because Complaint Counsel failed to prove its assertion that Respondent impliedly claimed that ECM Plastics would completely biodegrade in a landfill within one year, or that Respondent's "unqualified" biodegradability claims were otherwise deceptive, Complaint Counsel is not entitled to its proposed order barring Respondent from making unqualified biodegradable claims unless Respondent can substantiate that "the entire item will completely decompose into elements found in nature within one year after customary disposal."
47. The facts of this case militate against a broad remedial order, including that: Respondent has permanently ceased the claim found to have violated the FTC Act; there is no evidence of economic harm to ordinary consumers; Respondent has no prior violations; and there is no issue of transferability.
48. The Order entered herewith will serve to prevent Respondent from engaging in deceptive practices in the future, is reasonably related to the unlawful acts or practices found to exist, and is sufficiently clear and precise.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
2. “Commission” shall mean the Federal Trade Commission.
3. “Competent and reliable scientific evidence” shall mean tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that a representation is true. Specifically, for any representation that complete biodegradation will occur within any time period, or that tests prove such representation, any scientific technical protocol (or combination of protocols) substantiating such representations must both:
 - iii. substantiate that the entire product will completely decompose within the time period represented; and
 - iv. replicate, *i.e.*, simulate, the physical conditions found in the type of disposal facility or method stated in the representation or, if not qualified by disposal facility or method, the conditions found in landfills, where most trash is disposed.
4. “Landfill” means a municipal solid waste landfill that receives household waste. “Landfill” does not include landfills that are operated as bioreactors or those that are actively managed to enhance decomposition.
5. “Means and instrumentalities” shall mean any information, including, but not necessarily limited to, any advertising, labeling, or promotional, sales training, or purported substantiation materials, for use by trade customers in their marketing of any product, package, or service, in or affecting commerce.
6. Unless otherwise specified, “respondent” shall mean ECM BioFilms, Inc., a corporation, and its successors and assigns.

I.

IT IS ORDERED that respondent, and its officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, or other

device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, package, or service, in or affecting commerce, shall not represent, in any manner, directly or indirectly, expressly or by implication, that any product or package will completely biodegrade within any time period, or that tests prove such representation, unless such representation is true, not misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent, and its officers, agents, representatives, and employees, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, package, or service in or affecting commerce, shall not provide to others the means and instrumentalities with which to make, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names, any false, unsubstantiated, or otherwise misleading representation that any product or package will completely biodegrade within any particular time period, or that tests prove such representation.

III.

IT IS FURTHER ORDERED that respondent shall, for five (5) years after the last date of dissemination of any representation covered by this Order, maintain and upon request make available to the Commission for inspection and copying:

- A. All advertisements, labeling, packaging and promotional materials containing the representations specified in Parts I and II;
- B. All materials that were relied upon in disseminating the representations specified in Parts I and II;
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and
- D. All acknowledgments of receipt of this Order obtained pursuant to Part IV.

IV.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this Order to all current and future subsidiaries, current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities relating to the subject matter of this Order. Respondent shall secure from each such person a

signed and dated statement acknowledging receipt of the Order, with any electronic signatures complying with the requirements of the E-Sign Act, 15 U.S.C. § 7001 *et seq.* Respondent shall deliver this Order to current personnel within thirty (30) days after the effective date of this Order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

V.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this Order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge.

Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: “ECM BioFilms, Inc., Docket 9358.”

VI.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after the effective date of this Order file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form in which respondent has complied with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent shall submit additional true and accurate written reports. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: “ECM BioFilms, Inc., Docket No. 9358.”

VII.

This Order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this Order that terminates in less than twenty (20) years;
- B. This Order's application to any respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Part as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

Date: January 28, 2015

EXHIBIT B

316

1 **Q. Was that based on your review of the raw data?**
 2 A. If the standard deviation was available, that's
 3 when I took a look at it.
 4 **Q. Do you recall testifying back in June to me that**
 5 **you didn't look at the raw data before you wrote your**
 6 **report?**
 7 A. That is correct.
 8 **Q. And you hadn't looked at the raw data before**
 9 **you -- before you testified in June; correct?**
 10 A. That is correct.
 11 **Q. And you hadn't run any statistical models when**
 12 **you testified in June.**
 13 A. That is correct.
 14 **Q. So you're telling me now that between the time**
 15 **of your testimony and your testimony today you've run**
 16 **statistical calculations.**
 17 A. Just let me be clear. Whenever a standard
 18 deviation was provided, I took that number and in my
 19 head I multiplied it by two.
 20 **Q. So you did mental math; is that what you're**
 21 **saying?**
 22 A. Yes.
 23 **Q. You're aware that the raw data was available to**
 24 **you for these tests; right?**
 25 A. I am aware, yes.

317

1 **Q. You know that Dr. Morton Barlaz performed a**
 2 **statistical analysis of many of these tests where the**
 3 **raw data was available; correct?**
 4 A. Dr. Barlaz reported that he did one statistical
 5 analysis on those -- on the raw data. Yes.
 6 **Q. One statistical analysis which actually**
 7 **incorporated some a dozen or so tests; correct?**
 8 A. That is correct.
 9 **Q. Did you review his statistical analysis?**
 10 A. No. But I reviewed the data he relied on to
 11 make that statistical analysis.
 12 **Q. And you reviewed that data after you testified**
 13 **in June?**
 14 A. Yes.
 15 **Q. Did you -- did you write down any of your**
 16 **calculations that you claim to have performed on the**
 17 **statistics?**
 18 A. I didn't do any calculations. I looked at the
 19 data.
 20 **Q. You just looked at the data.**
 21 A. That is correct.
 22 **Q. And -- but you just said you didn't calculate --**
 23 **sorry. Excuse me.**
 24 **You just said you didn't run any calculations;**
 25 **right?**

318

1 A. I think we're talking about two different
 2 things. That's why we're getting confused, so could you
 3 ask me the question again.
 4 **Q. Let's ask it -- let me be more precise, and I do**
 5 **apologize.**
 6 **You testified that you had access to the raw**
 7 **data and you looked at it; correct?**
 8 A. That is correct.
 9 **Q. Did you calculate -- in either of those**
 10 **studies, based on the triplicate data, did you**
 11 **calculate the mean carbon dioxide in milliliters for**
 12 **the substrate?**
 13 A. There are some studies that I looked at where I
 14 did some mathematical calculations where I calculated
 15 the actual average methane generation, and I reported
 16 that in the report.
 17 **Q. So the answer to the --**
 18 A. I also --
 19 **Q. I apologize. You can finish.**
 20 A. I also told you that I did in my head, whenever
 21 your client provided a test that had a standard
 22 deviation, I looked at the standard deviation, and in my
 23 mind I multiplied it by two. That's the only
 24 statistical things that I did.
 25 **Q. So the answer to my question was no, you did not**

319

1 **calculate a mean carbon dioxide in milliliters --**
 2 A. No.
 3 **Q. -- for the substrate.**
 4 A. No.
 5 **Q. An and you didn't provide us with any of that**
 6 **information that you -- the statistical analysis --**
 7 **JUDGE CHAPPELL: Hold on a second.**
 8 **I just want to make sure the record is clear.**
 9 **You asked the witness, "So the answer to my question was**
 10 **no," and he said, "No." Did he mean yes?**
 11 **MR. ARHANGELSKY: Thank you, Your Honor.**
 12 **BY MR. ARHANGELSKY:**
 13 **Q. The question was -- the answer was, you did not**
 14 **calculate mean CO2 in milliliters; correct?**
 15 A. Correct.
 16 **Q. Thank you.**
 17 **And you didn't provide us with any copies of any**
 18 **statistical analyses that you performed.**
 19 A. That is correct.
 20 **Q. You didn't give us anything in writing**
 21 **concerning these mental calculations that you**
 22 **performed.**
 23 A. No, I didn't.
 24 **Q. Did you calculate the mean methane content in**
 25 **milliliters for the inoculum?**

EXHIBIT C

1 A. That is correct.
 2 **Q. It would be a substantial hardship because of**
 3 **the EPA's position in the market?**
 4 **I'm sorry. Please.**
 5 A. I don't know what exactly that means.
 6 **Q. Did you testify in June that you recommended**
 7 **to your counsel that EPA perform tests of ECM's**
 8 **product?**
 9 A. I didn't recommend. I said we could try and do
 10 it.
 11 **Q. I'll represent that I'm displaying the**
 12 **transcript from your deposition. This is pages 38 and**
 13 **39 of your transcript.**
 14 **At the bottom of the page 39, you were asked,**
 15 **"Were you asked to perform any of those tests in this**
 16 **case?"**
 17 **Your response was: "No."**
 18 **The next question was: "Did you ask to perform**
 19 **any of those tests?"**
 20 **And your response was: "I suggested one time**
 21 **that it may be beneficial to do it, but that was it."**
 22 **Is that your response?**
 23 A. That is correct.
 24 **Q. And then just below that, you suggested to your**
 25 **counsel that you would run a BMP test; correct?**

1 A. That's what it -- I can't read it there, so if
 2 that's what it says --
 3 JUDGE CHAPPELL: Hang on.
 4 If you're going to ask him about this, he said
 5 he can't read it, so make sure he can read it, and then
 6 proceed.
 7 MR. ARHANGELSKY: Excuse me, Your Honor.
 8 Thank you, Your Honor. I apologize.
 9 JUDGE CHAPPELL: And I'm not saying you have to
 10 give him a copy, but at least blow it up, you know,
 11 make sure the witness can read what you're asking him
 12 about. It's your option.
 13 MR. ARHANGELSKY: Thank you, Your Honor.
 14 BY MR. ARHANGELSKY:
 15 **Q. Are you able to read it now?**
 16 A. Yeah.
 17 **Q. The question on --**
 18 JUDGE CHAPPELL: Is there an objection?
 19 MR. DeCASTRO: There is, Your Honor. I'm trying
 20 to determine if this is a proper basis for impeachment
 21 because it doesn't appear to me that Dr. Tolaymat is
 22 giving an inconsistent answer with the opposing
 23 counsel's questions.
 24 JUDGE CHAPPELL: We have an objection for lack
 25 of proper foundation. What's your response?

1 MR. ARHANGELSKY: Your Honor, that's fine. I'll
 2 ask him more directly. I'll waive the question and I'll
 3 ask him directly.
 4 JUDGE CHAPPELL: All right.
 5 BY MR. ARHANGELSKY:
 6 **Q. Dr. Tolaymat, did you recommend to your counsel**
 7 **that you would perform a BMP test at EPA's**
 8 **headquarters?**
 9 A. I suggested that we can do. I did not
 10 recommend.
 11 MR. ARHANGELSKY: Thank you. I have no further
 12 questions.
 13 JUDGE CHAPPELL: Anything further?
 14 MR. DeCASTRO: Nothing further, Your Honor.
 15 JUDGE CHAPPELL: Thank you, sir. You're
 16 excused.
 17 THE WITNESS: Thank you, Your Honor.
 18 JUDGE CHAPPELL: Next witness.
 19 This is off the record.
 20 (Discussion off the record.)
 21 JUDGE CHAPPELL: Let's go back on the record.
 22 MS. JOHNSON: Good afternoon, Your Honor.
 23 Katherine Johnson for complaint counsel.
 24 We'd like to call Dr. Stephen McCarthy.
 25 - - - - -

1 Whereupon --
 2 STEPHEN McCARTHY
 3 a witness, called for examination, having been first
 4 duly sworn, was examined and testified as follows:
 5 DIRECT EXAMINATION
 6 BY MS. JOHNSON:
 7 **Q. Good afternoon, Dr. McCarthy.**
 8 **Can you please introduce yourself to the court.**
 9 A. I'm Stephen McCarthy. I'm a professor from the
 10 University of Massachusetts Lowell in the plastics
 11 engineering department.
 12 **Q. Dr. McCarthy, did you say that you are a**
 13 **professor?**
 14 A. That's correct.
 15 **Q. And where are you a professor?**
 16 A. At the University of Massachusetts Lowell in
 17 Lowell, Massachusetts.
 18 **Q. And how long have you been a professor there?**
 19 A. 30 years.
 20 **Q. And prior to being a professor at the**
 21 **University of Massachusetts Lowell, where were you?**
 22 **What were you doing?**
 23 A. Immediately before, I was getting my Ph.D.
 24 Then before that, I worked as an advanced
 25 engineer for Owens-Corning Fiberglas in Columbus, Ohio.

360

1 And then before that, I was a -- getting my
 2 master's degree at Princeton University.
 3 And before that, I was getting my bachelor's
 4 degree at Southeastern Massachusetts University.
 5 **Q. And your bachelor's degree, what was -- what is**
 6 **your bachelor's degree in?**
 7 A. It's in textile chemistry.
 8 **Q. And could you explain for the court what textile**
 9 **chemistry is.**
 10 A. Sure. It's basically a chemistry degree with a
 11 concentration in textiles. And it was at that point in
 12 learning about the synthetic textiles that are
 13 basically the same as polymers that I got interested in
 14 plastics.
 15 **Q. And from there, you went on to complete a**
 16 **master's degree?**
 17 A. That is correct.
 18 **Q. And what is your master's degree in?**
 19 A. It's in chemical engineering at Princeton
 20 engineering -- Princeton University.
 21 **Q. And what -- could you describe for the court**
 22 **what chemical engineering entails.**
 23 A. So chemical engineering, you know, there's a lot
 24 of reactor design, unit operations, transport
 25 phenomenon, thermodynamics, heat transfer, as well as

361

1 there was a concentration in polymer engineering.
 2 **Q. So you -- you were explaining your degree in**
 3 **chemical engineering.**
 4 **And after you completed your degree in chemical**
 5 **engineering -- oh, did you have a -- excuse me -- a**
 6 **specific focus while you were completing your master's?**
 7 A. Yeah. My work was -- my thesis work was in
 8 polymers and actually diffusion of different dyes in
 9 Nomex fibers.
 10 **Q. Then after you completed your master's degree at**
 11 **Princeton, you went to a Ph.D. program?**
 12 A. Well, I spent a year at Owens Corning Fiberglas
 13 in Columbus, Ohio, and it was there that I -- rather
 14 than getting an MBA and climbing the corporate ladder, I
 15 decided to get a Ph.D. and go into research.
 16 **Q. And what area of research are you in?**
 17 A. Currently?
 18 **Q. Oh. Yes, currently.**
 19 A. Currently, a majority of my research is in
 20 biodegradable polymers.
 21 **Q. And what -- is that different than the focus**
 22 **that you had at -- during your Ph.D. program?**
 23 A. Yeah. My Ph.D. program was more in just basic
 24 polymer engineering, you know, mechanical properties,
 25 physical properties. My actual dissertation was in

362

1 shear yielding and diffusion through shear bands in
 2 different polymer plants.
 3 **Q. Can you -- we -- we've been talking about your**
 4 **background in polymers.**
 5 **Can you explain for the court what a polymer**
 6 **is?**
 7 A. Sure. A polymer is a long macromolecule, so
 8 it's a chain of typically carbon atoms that are
 9 connected together in very, very long chains. And
 10 these -- there's all different types of these polymers.
 11 There are natural polymers.
 12 For example, DNA is a polymer. Cellulose is a
 13 polymer. Cornstarch is a polymer.
 14 So there's all sorts of different polymers, as
 15 well as recently we have synthetic polymers, and so
 16 there's a large amount of synthetic polymers that we
 17 typically refer to as plastics.
 18 **Q. And how do you synthesize a polymer?**
 19 A. Okay. So there's really two different -- should
 20 I get my --
 21 MS. JOHNSON: Oh, Your Honor, we have a
 22 demonstrative that we would like to use.
 23 (Pause in the proceedings.)
 24 I apologize for the interruption, Your Honor.
 25 We have a demonstrative, as well as we would

363

1 like to provide Dr. McCarthy with an easel so he can
 2 illustrate for you how polymer chains look.
 3 May we approach the witness, Your Honor, and
 4 provide the demonstrative and the easel?
 5 JUDGE CHAPPELL: All right. But it's up to you
 6 to make sure this makes sense on the record.
 7 Go ahead.
 8 MS. JOHNSON: Thank you, Your Honor.
 9 (Pause in the proceedings.)
 10 Would it be easier if he drew on a piece of
 11 paper?
 12 I'm sorry. May I approach the witness,
 13 Your Honor?
 14 JUDGE CHAPPELL: Yes. I'm glad you got the
 15 noisy version of whatever that is.
 16 And I believe there's no question pending at the
 17 moment. If there is, you need to restate it.
 18 BY MS. JOHNSON:
 19 **Q. I believe we were talking about how polymers are**
 20 **polymerized.**
 21 **Can you explain for the court the process of**
 22 **polymerization?**
 23 A. Yes.
 24 So there are two main classes of synthetic
 25 polymers. One is an addition polymerization polymer.

364

1 And this chain can represent the polymer chain, so there
 2 would be carbons here, so this would be sort of for
 3 polyethylene, an ethylene polymer (indicating).
 4 Ethylene monomer has a double bond, and then
 5 this polymerization takes place through the double bond
 6 and it extends for, you know, hundreds of thousands of
 7 these units of these atoms.
 8 And that polymerization takes place where one
 9 chain grows to a full length and then the next chain
 10 grows, and so by the end you just have full polymer and
 11 monomer units, full length. And these polymers are very
 12 different than polymers that exist in nature.
 13 So the second group of polymers are condensation
 14 polymers, and an example of that is a polyester. In a
 15 polyester you have a carboxylic group, so it's -- so
 16 you'd have a carboxylic acid that reacts with an
 17 alcohol, and you extract water to get to the
 18 polymerization. That's why it's called a condensation
 19 polymerization.
 20 And so these white balls here would represent
 21 oxygen, so the oxygen -- as you see, this oxygen unit is
 22 located in the chain of the polymer, and so that's very
 23 different in that that is similar to polymers that exist
 24 in nature.
 25 So, for example, cellulose, pullulan, amylose

365

1 all have oxygen in the main chain. As a matter of fact,
 2 polyhydroxybutyrate --
 3 **Q. Well, why don't we -- that's a lot of**
 4 **information, so let's break it down into smaller**
 5 **pieces.**
 6 A. Yeah.
 7 **Q. Before we do that, I wanted to ask whether --**
 8 **did complaint counsel ask you to prepare a written**
 9 **report of your opinions that you'll be stating in this**
 10 **case?**
 11 A. Yes, they did.
 12 **Q. And I'm holding in my hand Complaint Counsel's**
 13 **Exhibit 891.**
 14 **Your Honor, may I approach the witness?**
 15 JUDGE CHAPPELL: Go ahead.
 16 BY MS. JOHNSON:
 17 **Q. Dr. McCarthy, what is Complaint Counsel's**
 18 **Exhibit 891?**
 19 A. This is my expert report.
 20 **Q. And this is the report that you prepared in this**
 21 **case?**
 22 A. That is correct.
 23 **Q. I just want to turn to page 10 of**
 24 **Complaint Counsel's 891.**
 25 A. Okay.

366

1 **Q. Is this a depiction of a -- of what you were**
 2 **just discussing?**
 3 A. That's exactly right. Yeah. This is the
 4 ethylene units with the double bonds and then
 5 polymerized so that you have all carbons along the back
 6 chain, along the backbone.
 7 **Q. Are you prepared to give an opinion today in**
 8 **this case?**
 9 A. Yes.
 10 **Q. And what opinions did complaint counsel ask you**
 11 **to -- or what matters did complaint counsel ask you to**
 12 **opine on?**
 13 A. Whether the ECM additive would, at a loading of
 14 1 percent, cause the 99 percent of the conventional
 15 nonbiodegradable plastic to biodegrade in -- completely
 16 in less than a year, also to biodegrade completely in
 17 less than five years, also whether they would
 18 appreciably show an increase in biodegradable -- in
 19 biodegradation rate compared to the untreated sample,
 20 and whether there's conclusive scientific evidence for
 21 those claims.
 22 **Q. And does your expert report contain your**
 23 **opinions on that matter?**
 24 A. Yes, it does.
 25 **Q. And when you prepared your expert report, did**

367

1 **you provide complaint counsel a list of materials that**
 2 **you considered in preparing your opinion?**
 3 A. Yes, I did.
 4 **Q. I have in my hand -- not the right version --**
 5 **Complaint Counsel's --**
 6 JUDGE CHAPPELL: If you need a moment to make
 7 sure you've got the right documents, go ahead.
 8 MS. JOHNSON: Thank you, Your Honor. I do
 9 believe that I have the correct one now.
 10 I have Complaint Counsel's 942.
 11 Your Honor, may I approach the witness?
 12 JUDGE CHAPPELL: All right.
 13 BY MS. JOHNSON:
 14 **Q. Dr. McCarthy, what does -- what is**
 15 **Complaint Counsel's 942?**
 16 A. This is the exhibit with the list of the
 17 documents that I reviewed to support my expert report.
 18 **Q. Did you -- other than these, these documents**
 19 **that are identified on Exhibit A -- or -- excuse me --**
 20 **on Complaint Counsel's 942, what else factored into how**
 21 **you rendered your opinion?**
 22 A. The other things that I considered were
 23 basically the research that I've conducted in
 24 biodegradable polymer, especially in the blends, and the
 25 biodegradation testing.

368

1 A lot of papers are listed in my vita and all of
2 the master's thesis and dissertations.

3 In addition to that, probably the most
4 significant would be the papers that I see on a weekly
5 basis as my -- in my position as editor for the
6 Journal of Polymers and the Environment, which deals
7 with a lot of biodegradable polymer synthesis, blending
8 and biodegradation testing.

9 In addition to that, probably the conferences
10 that I've attended where I've been an invited speaker,
11 and some of them I've also organized, and the lectures
12 that I've heard from other leading scientists in
13 biodegradable polymers.

14 And finally, probably the patents that I have in
15 biodegradable polymers and blends.

16 **Q. Now, you mentioned a number of things.**

17 **Are these items included in your expert report?**

18 A. They're included in the vita. Yeah.

19 **Q. And your CV is attached to your expert report?**

20 A. That is correct, yeah.

21 **Q. Can you tell me where in your report I would
22 find it?**

23 A. Okay.

24 So the first of what I mentioned were the
25 publications. Those start on page 45.

369

1 **Q. Okay. So let's turn to page 45 of your expert
2 report.**

3 **And how did your publications factor in to the
4 opinions that you will be giving today?**

5 A. So a lot of my research is in dealing with the
6 biodegradable blends and also in testing these, the
7 biodegradability of the blends and various materials.

8 **Q. And these are -- the publications that you've
9 identified in your CV are publications in peer-reviewed
10 journals?**

11 A. That is correct.

12 **Q. Do these reflect the research that you were
13 talking about earlier?**

14 A. Yes. Yeah.

15 **Q. And how many of these publications deal with --
16 deal -- or excuse me -- are in the area of degradable
17 polymers?**

18 A. In biodegradable polymers, over 60.

19 **Q. Are there any of your peer-reviewed articles
20 that deal specifically with biodegradable blends?**

21 A. Yes.

22 **Q. Are there any that -- which ones would that --
23 which publications would those be?**

24 A. Do you want me to go through each, each one
25 or -- each of the ones that are just biodegradable

370

1 blends?

2 **Q. Yes.**

3 A. Okay. So let's see.

4 The Processing and Blends of Biopolymers around
5 2008.

6 Biodegradable Polymer Blends for Medical
7 Applications.

8 Advances in Properties and Biodegradability of
9 Co-Continuous, Immiscible, Biodegradable Polymer Blends
10 from 1999.

11 **Q. So there are a number of different --**

12 A. Yes.

13 **Q. -- publications that --**

14 A. Quite a few.

15 **Q. Other than your research that's resulted in
16 peer-reviewed public -- published journal articles, you
17 mentioned a few other things that factored into and form
18 the basis of your opinion that were reflected in your
19 CV.**

20 **Can you tell us where those other things can be
21 found?**

22 A. So, for example, on page 38, editor of the
23 Journal of Polymers and the Environment, 1991 to
24 present.

25 **Q. Can you explain for the court what your role is**

371

1 **at the -- as editor of the Journal of Biodegradable
2 Polymers?**

3 A. Sure.

4 So this polymer -- I mean, this journal is --
5 deals mainly with biodegradable polymer synthesis,
6 blending, and as well as testing of biodegradability of
7 various polymers and blends. And I receive about thirty
8 submissions per week relating to this journal.

9 And based on those thirty, I go through them and
10 narrow them down to probably five or six that seem
11 suitable for the journal. And then those are sent out
12 to a peer-reviewed process where there are three
13 referees that review the paper and then either accept
14 the paper, accept it with revisions or reject the
15 paper -- accept it with minor revisions or accept it
16 with major revisions or reject the paper.

17 And then based on those reviews, I either
18 reject the paper or send it back to the author for
19 corrections. Or if it's accepted -- if all of them say
20 accepted without corrections, which hardly ever happens,
21 then I would accept it.

22 **Q. So what -- explain for the court what kinds of
23 things you take into account when evaluating a paper for
24 a -- that's been submitted to determine whether to
25 forward it on to the peer -- through the peer review**

372

1 **process.**

2 A. So one of the things I look at is, basically it
3 has to be -- it has to deal with a -- you know,
4 biodegradable polymers. And there are a number that
5 sort of submit that are not in that realm.

6 And then there basically is whether it's
7 something that's novel. There are some papers that just
8 have a repeat of research that's already been done, so
9 those aren't acceptable either.

10 So it's really the ones that are novel and the
11 ones that have adequate scientific merit either in the
12 biodegradation testing data or, you know, that they're
13 truly novel materials.

14 **Q. So it's a regular part of your professional**
15 **activities to evaluate scientific data to see if they**
16 **support submissions dealing with degradable polymers?**

17 A. Yes. Yeah. Every week.

18 **Q. A little bit earlier, I asked you to explain to**
19 **the court what a polymer is. We should probably also**
20 **explain to the court what biodegradation is.**

21 **When we're talking about biodegradable polymers,**
22 **what do we mean?**

23 A. So biodegradation typically is the breakdown of
24 the polymer chain through actions through the --
25 typically it's enzymes that are produced by

373

1 microorganisms, so it's a biological activity that
2 causes the breakdown in the chain, which is a very
3 natural process. I mean, that's how cellulose is broken
4 down. That's the way a lot of things are broken down in
5 nature.

6 **Q. And is there a difference between biodegradation**
7 **and degradation?**

8 A. Well, sure. Degradation could mean something
9 just like thermal degradation or photodegradation or
10 even mechanical degradation through shearing, which is
11 more of a disintegration rather than a complete
12 mineralization.

13 **Q. And earlier you were explaining to the court**
14 **the different ways that polymers are formed or**
15 **synthesized.**

16 A. Yeah.

17 **Q. And I think you had talked about addition**
18 **polymerization.**

19 **What kinds of polymers are formed through**
20 **addition polymerization?**

21 A. Well, a lot of conventional polymers that we
22 know about: polyethylene, polypropylene,
23 polyvinylchloride, polystyrene.

24 **Q. And there's another way to polymerize -- to make**
25 **a synthetic polymer?**

374

1 A. Right. The way I was explaining of making the
2 polyesters or the condensation polymerization that are
3 made of polyesters where a lot of the commercial
4 biodegradable polymers today are aliphatic polyesters.
5 We have this group that's subject to degradability
6 which is similar to these linkages that occur in
7 nature.

8 **Q. So let's back up to the polyethylene that's**
9 **formed through addition polymerization.**

10 A. Sure.

11 **Q. Can you explain to the court what that would**
12 **look like. And I think there might have been a**
13 **depiction that we were looking at earlier on page 10.**

14 A. Yeah. Yeah, it's on page 10.

15 So basically the -- the polyethylene on the
16 lower right-hand corner would be a backbone of just
17 carbon, but it's not straight like that. It's more
18 tetrahedral like in this model (indicating). That's why
19 I brought in the three-dimensional model.

20 So it's straight carbon along the whole backbone
21 and then the hydrogens off to the side.

22 **Q. Now, this depicts an ethylene. I assume that**
23 **some of the other polymers look different.**

24 **Can you describe how -- how they're -- how they**
25 **would be different, such as a polypropylene?**

375

1 A. Yes.

2 So a polypropylene unit, one of the hydrogens
3 would be replaced by a methyl group, and then that unit
4 would be then repeated. And with polypropylene you have
5 an effect of tacticity, so you could have -- the most
6 common polypropylene is isotactic polypropylene where
7 all of the methyl groups are on the same side, so that's
8 the most common form.

9 Atactic polypropylene that's not crystalline is
10 not very useful.

11 Syndiotactic polypropylene is used a lot in
12 medical applications.

13 **Q. Now, are the polymers that are formed through**
14 **addition polymerization considered biodegradable?**

15 A. No. They're -- the ones that I mentioned
16 are -- have this carbon backbone, and that doesn't have
17 any of these linkages that can be broken by the
18 enzymes.

19 And it's basically because the polymers haven't
20 existed long enough to have microorganisms develop
21 enzymes to break them down. I think eventually with
22 enough of these polymers being littered and put in
23 landfills there may be enzymes eventually developed,
24 similar to the way the enzymes develop these -- I mean,
25 the bacteria developed enzymes for cellulose and starch

30 (Pages 372 to 375)

376

1 and things of that nature.
 2 **Q. And for the polymers -- well, actually, can you**
 3 **give us some examples of polymers that are formed**
 4 **through condensation polymerization?**
 5 A. Yes.
 6 So the ones that are biodegradable are, say,
 7 polycaprolactone, polylactic acid, polydioxanone and
 8 polycaprolactone.
 9 There's also a common polymer, PET, polyethylene
 10 terephthalate, that we use in our soda bottles that is
 11 not biodegradable. But there is a technology where if
 12 you copolymerize the PET with one of these aliphatic
 13 polyesters and you don't have more than 50 percent of
 14 the PET, then it is biodegradable. And those are
 15 commercial products today.
 16 **Q. So let's -- just in case it wasn't clear,**
 17 **because there was a lot of scientific explanation in**
 18 **there --**
 19 A. Yeah.
 20 **Q. -- the polyethylene terephthalate, which is the**
 21 **PET, that is not considered biodegradable.**
 22 A. That's correct.
 23 **Q. And why is that?**
 24 A. It's probably because of the benzene rings in
 25 the terephthalic acid. Because you have a benzene ring

377

1 repeat every time, it is probably hard for the
 2 microorganisms to break it down.
 3 But it turns out if you just put -- if you
 4 randomly polymerize it with aliphatic polyesters, then
 5 those will break down, and then the PET linkages will
 6 be short enough so that those are able to be degraded.
 7 And Eastman proved that using carbon-14 labeling.
 8 **Q. So you just said that if the chain is short**
 9 **enough, it can be broken down, and why is that?**
 10 A. It probably has to do with the solubility. Once
 11 the length gets low enough, it's probably soluble and
 12 easier for the bacteria to ingest it.
 13 And that's why it was so important for the
 14 carbon-14 labeling of the benzene ring to actually --
 15 because it was doubted that that would ever be able to
 16 be biodegraded by bacteria.
 17 **Q. So if I understand your testimony so far, there**
 18 **are naturally occurring polymers.**
 19 A. Yeah.
 20 **Q. There are -- and there's synthetic polymers.**
 21 A. Yes.
 22 **Q. And some synthetic polymers are biodegradable.**
 23 A. Right. Because they resemble the naturally
 24 occurring polymers in some way. Yeah.
 25 **Q. And then there are some that are**

378

1 **nonbiodegradable.**
 2 A. Right. That -- that don't have organisms that
 3 are able to break them down.
 4 **Q. What other things factor into whether a polymer**
 5 **is biodegradable?**
 6 A. Well, the main thing is the backbone and whether
 7 there's a linkage in the backbone that can be then
 8 broken down.
 9 And then after that, probably the most important
 10 is the crystallinity. It turns out that the higher the
 11 crystallinity of the polymer, the more difficult it is
 12 to be broken down.
 13 **Q. Can you explain for the court what you mean by**
 14 **"crystallinity"?**
 15 A. Sure.
 16 So crystallinity is the formation of a true
 17 solid, so it would be a transition such as going from
 18 water to ice.
 19 So ice is a true solid, in a thermodynamic
 20 sense, so when these polymers crystallize, they give off
 21 a lot of heat. And in order to get them to melt, you
 22 have to put in all that heat, so they're at a much lower
 23 energy state and they're very packed close together, and
 24 it's a very ordered, packed region that's a true solid.
 25 It's a crystal lattice.

379

1 **Q. And why does that affect the ability of**
 2 **microorganisms to break down, break down the polymer?**
 3 A. Right.
 4 So the ability of the polymer -- of the enzymes
 5 to get to the crystal is diminished because the crystal
 6 is so tightly packed, as well as the chains in there are
 7 at a much lower energy, so you have to put in a lot of
 8 energy to get them to degrade, and so it's just much
 9 harder.
 10 **Q. And other than crystallinity, what other things**
 11 **affect the biodegradability of polymers?**
 12 A. So one thing that's important is the glass
 13 transition temperature.
 14 So, for example, if you look at a polylactic
 15 acid, the glass transition temperature is 60 degrees
 16 centigrade, and so it degrades at a much higher rate
 17 above 60 than below 60.
 18 **Q. Can you explain what glass transition**
 19 **temperature is?**
 20 A. Okay. That's kind of a hard one.
 21 So it's the -- it's sort of a temperature where
 22 it's not a thermodynamic change that the polymer is
 23 still a liquid, but below that temperature, the
 24 viscosity is so high that it appears to us to be a
 25 solid, so it's similar to window pane glass.

380

1 So window pane glass is actually a liquid in a
 2 thermodynamic state, but the viscosity is so high that
 3 it appears to us to be a solid, so hence the term
 4 "glass transition temperature."
 5 And so something like polystyrene, for example,
 6 typically is amorphous, but the glass transition
 7 temperature is 100 degrees centigrade, so when we use it
 8 at room temperature, it appears like a solid, but in
 9 fact it is a liquid.
 10 **Q. Thermodynamic?**
 11 A. Thermodynamically, yes.
 12 **Q. And the glass transition temperature is what in**
 13 **relation to the appearance of it being a solid or a**
 14 **liquid to us?**
 15 A. So if you're above the -- so if your glass
 16 transition temperature were below room temperature, so
 17 say it was 0 degrees C, then at room temperature we
 18 would perceive it as a rubbery, liquidy type material.
 19 If the glass transition temperature is much
 20 higher than room temperature, then at room temperature
 21 it appears to us to be a solid, glassy material.
 22 **Q. And what about the glass transition temperature**
 23 **affects the ability of the polymer to be biodegraded?**
 24 A. It's just easier for the degradation to --
 25 degradation occurs much faster above the glass

381

1 transition temperature.
 2 **Q. Other than the crystallinity and the glass**
 3 **transition temperature, are there other factors that**
 4 **play a role in the biodegradability of polymers?**
 5 A. You mean in terms of like the disposal or just
 6 in terms of properties of the polymer?
 7 **Q. Just in terms of properties of the polymer.**
 8 A. Those I think would be the primary ones.
 9 **Q. And when you were describing the formation of**
 10 **polymers through addition polymerization, you talked**
 11 **about chain length.**
 12 **Does chain length play a role in the ability --**
 13 **the biodegradability of a polymer?**
 14 A. Yes. Yes, chain length does play a role.
 15 The -- basically the chain length is typically
 16 measured in molecular weight that is sort of a
 17 distribution of molecular weights. There are some
 18 polymers such as metallocene polymerized polymers where
 19 the molecular weight distribution is very narrow, and
 20 there are others where it's very broad. But definitely
 21 the higher the average molecular weight, the more
 22 difficult it would be to degrade.
 23 **Q. And why is it -- how does the molecular weight**
 24 **affect the -- in what way does the molecular weight**
 25 **affect the ability of it to be biodegraded?**

382

1 A. So basically the longer it is, the more
 2 degradation.
 3 So typically the way biodegradation works is,
 4 you have a microorganism that would then have an
 5 extracellular enzyme that would then break down the
 6 molecular chain into pieces that were small enough that
 7 it then could ingest.
 8 And so you can imagine, if we start with a
 9 longer chain, it would take more time to break it down
 10 to that point than if we started with a shorter chain.
 11 **Q. And for the polymers that are formed through**
 12 **addition polymerization, there's -- there is no place**
 13 **for -- how would a microorganism break down, secrete an**
 14 **extracellular enzyme to break down a --**
 15 A. There's no evidence of one doing that.
 16 **Q. Is there some evidence that these long-chain**
 17 **polymers can be broken down?**
 18 A. The ones that are referred to as the
 19 polyethylene, polypropylene?
 20 **Q. Yes.**
 21 A. There is some evidence, for example, the
 22 Albertsson paper, that by oxidation and chemical
 23 biodegradation that there is some small amount of
 24 biodegradation at -- using carbon-14 labeling over a
 25 long period of time. It's a really small amount over

383

1 the years that they measured.
 2 **Q. Other than the Albertsson article, are you aware**
 3 **of other literature that discusses the biodegradability**
 4 **of polymers such as polyethylene?**
 5 A. There are -- I mean, there are some literature
 6 reviews of short molecular weight polyethylenes, so on
 7 the order of 500 molecular weight, that that is
 8 biodegradable.
 9 And it's interesting that that chain length is
 10 about the largest chain length in crude oil, and so it
 11 could be that there are organisms that have been got --
 12 that were -- have gotten adjusted to biodegrading these
 13 long chains in crude oil, and so it's possible that that
 14 500 molecular weight is due to that.
 15 **Q. Dr. McCarthy, can you explain in -- how you**
 16 **understand or what you understand the ECM additive to**
 17 **be?**
 18 A. Okay. My understanding is that
 19 complaint counsel has told me that the ECM additive was
 20 a biodegradable polymer and possibly poly- -- possibly
 21 the majority of it being polycaprolactone.
 22 **Q. And polycaprolactone is -- is -- is known to be**
 23 **biodegradable?**
 24 A. Yes. That's a known biodegradable polymer.
 25 It's a polyester.

1 **Q. Now, earlier you identified -- we -- I asked you**
 2 **to identify the four -- or excuse me -- the claims that**
 3 **complaint counsel asked you to opine on.**
 4 **Do you have an opinion in this case about**
 5 **whether -- about those claims?**
 6 A. Yes.
 7 **Q. And what -- let's go to the first claim. I**
 8 **think they're in -- identified in your report.**
 9 **Well, maybe I should ask you.**
 10 **Are the claims that you are discussing -- did**
 11 **you lay them out in your report?**
 12 A. Yes. On page 5.
 13 **Q. On page?**
 14 A. 5.
 15 **Q. Page 5 of your report.**
 16 A. Yeah.
 17 **Q. And for the first -- and where on page 5?**
 18 A. Towards the bottom.
 19 **Q. What paragraph?**
 20 A. Right there. Yep.
 21 **Q. So for the first claim that complaint counsel**
 22 **asked you to opine on, can you tell -- state for the**
 23 **court what your opinion is?**
 24 A. Yeah. My opinion is that it's false, that the
 25 ECM additive does not cause the nonbiodegradable plastic

1 to biodegrade completely in less than one year.
 2 **Q. And for the second claim -- or do you have any**
 3 **other opinions about that claim?**
 4 A. And also don't find any substantial scientific
 5 evidence to support that claim.
 6 **Q. And for the second claim that ECM plastics will**
 7 **completely break down and return to nature in nearly all**
 8 **landfills within nine months to five years, do you have**
 9 **an opinion about that claim?**
 10 A. Yes. I also believe that that's false.
 11 **Q. Do you have any other opinions about that**
 12 **claim?**
 13 A. Yeah. That there's no scientific evidence to
 14 support that is true.
 15 **Q. And for the claim identified in (c), that ECM**
 16 **plastics will completely break down and return to nature**
 17 **in most landfills within one to five years, do you have**
 18 **an opinion about that claim?**
 19 A. Yeah. It's my opinion that that is false.
 20 **Q. And do you have any other opinions about that**
 21 **claim?**
 22 A. Yes. That there is no substantial scientific
 23 literature to support that as true.
 24 **Q. Do you have any other opinions about that**
 25 **claim?**

1 A. So the appreciable -- within -- this is the
 2 five years? No, I don't.
 3 **Q. Let's just go -- step back.**
 4 **You said you believe that the claim -- or it's**
 5 **your opinion that the claim in subparagraph (c) is**
 6 **false.**
 7 A. Right.
 8 **Q. And then --**
 9 A. There's no scientific data to support that.
 10 **Q. Scientific data. Okay. Thank you.**
 11 A. Yeah.
 12 **Q. And then for the claim identified in**
 13 **paragraph (d), do you have any opinions about that**
 14 **claim?**
 15 A. Yeah. My opinion is that that claim is false,
 16 that the ECM plastics will not completely break down in
 17 an appreciably faster rate than the conventional
 18 plastics without the ECM additive.
 19 **Q. And do you have any other opinions about that**
 20 **claim?**
 21 A. Yeah. That there's not any scientific data to
 22 support that that is true.
 23 **Q. So I want to talk about -- we talked a little**
 24 **bit about the basis of your opinions.**
 25 **Did the things that we discussed earlier form**

1 **the basis of the opinions that you just related to the**
 2 **court?**
 3 A. Yes.
 4 **Q. And those were -- if you just want to just**
 5 **summarize all the things that form the basis of your**
 6 **opinion?**
 7 A. So there was materials that were supplied by me,
 8 by complaint counsel. There was all the literature that
 9 I have performed and my students have performed, the
 10 papers that I've written, the master's thesis and
 11 dissertations that I've supervised, the journal articles
 12 that I've reviewed both as part of my job as editor as
 13 well as reviewing literature for other things, and the
 14 conferences that I've been to and participated in and
 15 listened to other people.
 16 **Q. So why is it that adding 1 percent of a**
 17 **biodegradable polymer to 99 percent conventional plastic**
 18 **does not render the plastic biodegradable?**
 19 A. So there's -- the -- the -- one answer, in my
 20 opinion, is that the -- that 1 percent of the additive
 21 does not change the basic carbon bonds within the
 22 polyethylene, and so if it doesn't change those carbon
 23 bonds, then it wouldn't make it more biodegradable.
 24 So just the fact that it is -- that it may be
 25 biodegradable would not make it more biodegradable.

388

1 All of the literature for the polyethylene,
 2 you know, the Albertsson paper, et cetera, occur in a
 3 compost environment, so in an aerobic environment, and
 4 they rely on oxidation of the polyethylene. And in a
 5 landfill environment there would be an absence of
 6 oxidation, so the rate of oxidation would be orders of
 7 magnitude lower.
 8 And the -- if we assume that the
 9 polycaprolactone that is used for the additive is
 10 supposed to attract microorganisms that then will
 11 degrade the polyethylene, well, there's a flaw in that
 12 theory in that the polycaprolactone attracts organisms
 13 that degrade it by hydrolysis, and there are no linkages
 14 in the polyethylene chain that would be susceptible to
 15 hydrolysis, so these enzymes could not work on
 16 polyethylene.
 17 **Q. So let's just talk a little bit about the**
 18 **difference between the oxidation and hydrolysis.**
 19 **And how does hydrolysis result in**
 20 **biodegradation?**
 21 A. So as I mentioned these polyesters that are
 22 really the bulk of the biodegradable polymers that are
 23 accepted today, they are -- this condensation
 24 polymerization is reversible, so with the addition of
 25 water in this ester linkage you will then convert it to

389

1 a carboxylic acid and an alcohol, and so that reaction
 2 already is possible.
 3 The enzymes from the microorganisms just
 4 catalyze it, so they allow it to happen at much, much
 5 higher rates at room temperature.
 6 **Q. And you said there's some evidence that under**
 7 **some conditions polyethylene can be degraded in aerobic**
 8 **environments at very slow rates?**
 9 A. Yeah. In the Albertsson paper.
 10 So if you were to subject it to heat and cause
 11 oxidation of it and break it down into some fragments of
 12 low molecular weight, there is some evidence that small
 13 amounts of it will degrade over long periods of time.
 14 And they used carbon-14 labeling because it took so
 15 long, and it was very small amounts.
 16 **Q. How does oxidation promote biodegradation in**
 17 **traditionally nonbiodegradable polymers such as**
 18 **polyethylene?**
 19 A. Well, it would be a matter of using the
 20 oxidation to break the chain down into shorter segments
 21 such that then the microorganisms -- because again, if
 22 the polyethylene gets down to 500 molecular weight, then
 23 it would be -- look like the crude oil, and there are
 24 microorganisms that can degrade it.
 25 **Q. So the process of breakdown that you're talking**

390

1 **about when it's a small enough chain is something that**
 2 **happens inside the bacteria or fungi?**
 3 A. Once it's that low. But when it -- to get it
 4 down to being that low, it has to be caused by external
 5 means, such as, you know, there are some pro-oxygen
 6 additives that cause that, heat, sunlight, things of
 7 that nature, but it's not anything the microorganisms do
 8 to oxidize it.
 9 **Q. So there are no biological means to break down a**
 10 **high molecular weight polymer like polyethylene into**
 11 **smaller -- smaller molecular chains.**
 12 A. No.
 13 **Q. Is there any -- would your analysis change if we**
 14 **were not talking about polycaprolactone but we were**
 15 **talking about a different biodegradable polymer?**
 16 A. And like a similar polyester?
 17 **Q. Well, what kinds of biodegradable polymers are**
 18 **out there?**
 19 A. They're mostly polyesters and -- there are
 20 some -- a few polyethylenes, so yeah, they wouldn't
 21 change it.
 22 **Q. So whether it's 1 percent polycaprolactone or**
 23 **1 percent of polyhydroxybutyrate, it's --**
 24 A. It wouldn't change. 1 percent PLA or 1 percent
 25 starch wouldn't change it.

391

1 **Q. You also stated that you -- that it was your**
 2 **opinion that the claim that adding 1 percent ECM**
 3 **additive to a plastic is also not supported by**
 4 **scientific data.**
 5 A. That is correct.
 6 **Q. And what formed the basis of that opinion?**
 7 A. Basically the view of the testing that I've
 8 seen.
 9 **Q. Can you explain to the court what types of**
 10 **things you look for in evaluating the testing.**
 11 A. So in terms of the testing, one of the things
 12 we want to make sure of that is -- is that the -- that
 13 the conditions of the test simulate the disposal method
 14 so that the temperature, humidity, the microorganisms
 15 all simulate what is -- appears in the disposal method.
 16 Also the -- the -- if you're looking at --
 17 there should be a control that is a negative control
 18 and a control that is a positive control that are the
 19 same for every test so that you then -- then you can
 20 compare the biological activity from test to test.
 21 Also, if you're adding the additive to a type of
 22 plastic at 1 percent and you're comparing it to an
 23 untreated, that those plastics need to be identical, and
 24 so you can't test it with high-density polyethylene and
 25 then claim that it's -- will work on polypropylene or

392

1 all plastics.
 2 And then there's the loading rate. If you were
 3 test it -- I've seen testing where the testing was done
 4 at 5 percent or higher, and those -- it's not applicable
 5 to use those loading rates to then conclude that it
 6 would work at 1 percent.
 7 Some of the other things would be the amount of
 8 plastic in the -- in the test method relative to the
 9 amount of inoculum.
 10 So if you had a test method that had low amounts
 11 of plastic relative to the amount of inoculum, there's a
 12 high chance for background noise from the inoculum, so
 13 you might have a lot of degradation that occurs from the
 14 inoculum that you would interpret as degradation coming
 15 from the plastic material.
 16 And also the -- sort of the type -- the plastic
 17 form, you know, whether it's a thin film, whether it's a
 18 powder or whether it's a solid ball. All of these will
 19 affect the degradation rate. You know, the more surface
 20 area per unit weight, the higher the biodegradation rate
 21 you would get.
 22 JUDGE CHAPPELL: We're getting ready to take our
 23 lunch break.
 24 How much more time do you need for your direct?
 25 MS. JOHNSON: Probably another hour,

393

1 Your Honor.
 2 JUDGE CHAPPELL: All right.
 3 We're going to reconvene at 2:15.
 4 We're in recess.
 5 (Whereupon, at 1:09 p.m., a lunch recess was
 6 taken.)
 7
 8
 9
 10
 11
 12
 13
 14
 15
 16
 17
 18
 19
 20
 21
 22
 23
 24
 25

394

1 AFTERNOON SESSION
 2 (2:21 p.m.)
 3 JUDGE CHAPPELL: We're back on the record.
 4 Where is our witness?
 5 MS. JOHNSON: Your Honor, we'd like to call
 6 Dr. McCarthy back to the stand.
 7 JUDGE CHAPPELL: Yeah, we don't need to do that
 8 after a break. He can take the stand.
 9 It also occurs to me that once again we need to
 10 talk about scheduling.
 11 Based on what you told me before the break,
 12 this witness will be finished sometime tomorrow.
 13 Tomorrow is Thursday. You're going to need another
 14 witness to call. We're not going to take a break and
 15 wait on another witness. I'm already waiting on some
 16 guy from New Zealand, and I'm not happy about that, but
 17 I've already agreed to that.
 18 And this is my position. You can get with the
 19 respondent, work with them, let them start their case,
 20 and then bring your witness in later, whatever you need
 21 to do. But we're not going to take two or three days
 22 off to wait on somebody.
 23 MS. JOHNSON: Yes, Your Honor. We'll make --
 24 we'll see if we can make arrangements with respondents.
 25 This is going a little bit faster than we anticipated.

395

1 But of course, we still don't know how long it will take
 2 for any cross or redirect, so that might get us through
 3 the end of the day tomorrow.
 4 But I think we had already anticipated that
 5 there would be one other day that we would not be
 6 filling with testimony. Originally, the --
 7 JUDGE CHAPPELL: No one had told me about that.
 8 MS. JOHNSON: We were --
 9 JUDGE CHAPPELL: The day we were not having
 10 testimony was the middle of next week. That was the
 11 only day.
 12 MS. JOHNSON: Yes, Your Honor. I thought we
 13 had -- when we laid out the schedule in which had -- we
 14 had Dr. Frederick coming next week, we were also
 15 scheduled to have the 7th -- no court on the 7th, so we
 16 would have only had -- well, we would have had one fewer
 17 day.
 18 JUDGE CHAPPELL: Well, you can either call him
 19 tomorrow or whatever you want to do, but we're not
 20 taking two trial days off in the middle of the case.
 21 MS. JOHNSON: Yes, I understand, Your Honor.
 22 It's not possible to call Dr. Frederick. His travel
 23 arrangements have already been made, and he's going to
 24 be here on Monday on the 11th, so we'll --
 25 JUDGE CHAPPELL: Because the way this is going,

1 we're going to be taking a long break waiting for the
 2 27th already. And it's my job to move this along
 3 whenever possible, and this is whenever possible.
 4 And I don't know, Mr. Emord, are you going to be
 5 able to start your case?
 6 MR. EMORD: Well, we certainly will endeavor
 7 diligently to do that, Your Honor. Of course, we
 8 haven't had any opportunity to discuss it with the
 9 client, but the client is on notice that at any point in
 10 time we may need to have them down here within hours, so
 11 I would anticipate that if we need to do that, we'll
 12 certainly be ready for it.
 13 JUDGE CHAPPELL: As I said earlier, had I known
 14 the way this was going to progress, I would have had
 15 your witness here probably the first day of trial, and
 16 because we don't have a jury here, we just need to get
 17 everything we want in the record, and then we can make
 18 sense out of it in the briefing and posttrial work.
 19 That's how we'll make sense out of it, so it's not going
 20 to be to anybody's disadvantage if you start early and
 21 then we plug her witness in later. I just want
 22 everybody to know that.
 23 MR. EMORD: Thank you, Your Honor. I certainly
 24 understand that.
 25 JUDGE CHAPPELL: Okay. Thank you.

1 just a lot of -- like a clear section of the CD case or
 2 a DVD case, a lot of things that are clear but that's
 3 very brittle. Yeah.
 4 **Q. And what things would we be familiar with that**
 5 **are made out of polypropylene?**
 6 A. So polypropylene, the caps on the water bottles,
 7 the flexible cups, a lot of -- you know, that are not
 8 transparent. There are a lot of ropes and twine made
 9 out of polypropylene.
 10 **Q. Other than polyethylene, polypropylene,**
 11 **polystyrene, are there any other plastics that are**
 12 **considered conventional commodity plastics?**
 13 A. PVC.
 14 **Q. And what would we be familiar with that's made**
 15 **out of PVC?**
 16 A. So vinyl siding, vinyl seats, shower curtains,
 17 beach balls.
 18 **Q. And why are these the plastics that are utilized**
 19 **as commodity plastics?**
 20 A. Well, typically they're easy to produce from
 21 petroleum and they're low cost and they have properties
 22 that are useful for a lot of applications.
 23 **Q. What are those properties that are useful?**
 24 A. So they have -- they're able to be formed in
 25 different processes like injection molding and

1 Go ahead.
 2 BY MS. JOHNSON:
 3 **Q. Dr. McCarthy, right before we took the break,**
 4 **we were talking about testing parameters. Before we**
 5 **return to that, I want to cover some other things that**
 6 **we had talked about a little bit earlier about -- about**
 7 **the plastics. And I don't think we ever defined what a**
 8 **conventional plastic is.**
 9 **Can you explain to the court what a conventional**
 10 **plastic is.**
 11 A. Well, typically the conventional plastics are
 12 the ones that are more modern in that they're
 13 petroleum-based and, you know, polyethylene -- and make
 14 up the bulk of the plastics that we use today, as I
 15 mentioned, polyethylene, polystyrene, PVC,
 16 polypropylene, PET, as well as some engineering polymers
 17 like polycarbonate, PBT.
 18 **Q. And what kinds of things would we be familiar**
 19 **with that are made out of polyethylene?**
 20 A. So polyethylene, your typical trash bag, a milk
 21 container, things of that nature, a Frisbee, a
 22 Hula-Hoop.
 23 **Q. And what things would we be familiar with that**
 24 **are made out of polystyrene?**
 25 A. Polystyrene, your typical clear glasses, the --

1 extrusion. They have a lot of toughness. They have
 2 sufficient mechanical properties. They vary --
 3 you know, some of them have good permeability, things of
 4 that nature.
 5 **Q. I'm sorry. I didn't hear you. Could you repeat**
 6 **that.**
 7 A. Yeah. Permeability.
 8 **Q. Oh, permeability.**
 9 A. Yeah.
 10 **Q. And what is permeability?**
 11 A. So that's the prevention of, say, a gas or water
 12 to get through the material.
 13 **Q. We also -- we were talking about biodegradable**
 14 **plastics.**
 15 **And as I understood, the plastics that you were**
 16 **just discussing, the commodity plastics, PE,**
 17 **polypropylene, polystyrene, are generally considered**
 18 **nonbiodegradable.**
 19 A. That's right. Yeah.
 20 **Q. But there are some plastics out there that are**
 21 **biodegradable.**
 22 A. Sure. The largest amount are the ones that
 23 occur in nature. And it's interesting that the actual
 24 plastics industry was based on cellulose at one time,
 25 so cellophane, cellulose nitrate, cellulose acetate,

400

1 these things. But -- and so -- you know, so cellulose
 2 acetate that's used in, say, cigarette filters is
 3 actually a benefit to us that it's biodegradable.
 4 And so then there's the synthetic biodegradable
 5 polymers, such as PHAs, polylactic acid,
 6 polycaprolactone. Yeah.
 7 **Q. Can you explain for the court why we don't make**
 8 **our milk jugs and bottle caps out of these biodegradable**
 9 **plastics.**
 10 A. Well, there actually are a lot of applications
 11 that are being used using these biodegradable plastics,
 12 so there's a lot of composting bags that are produced, a
 13 lot of yogurt cups, a lot of forks, for example.
 14 Back in Lowell, during a recent folk festival,
 15 all of the food items, forks, spoons, cups, were made
 16 out of biodegradable plastic so that all of the material
 17 could be composted, and then it could be then used
 18 for -- people could put it in their gardens, so I think
 19 we're seeing a lot more use of truly biodegradable
 20 polymers. Yeah.
 21 **Q. Is there a difference in processing for**
 22 **polymerizing biodegradable plastics?**
 23 A. I mean, there are some differences. The main
 24 difference is price. There's an increase in price
 25 because they're not produced as on a large enough scale

401

1 as the other plastics are.
 2 **Q. Does it require different infrastructure to make**
 3 **a biodegradable plastic?**
 4 A. You mean to make it or to process it?
 5 **Q. To process it.**
 6 A. Oh, to process it.
 7 A lot of them can be processed on exactly the
 8 same equipment, you know, so most of the -- just a few
 9 of the settings might be -- might be changed, but a lot
 10 of it is processed on the same conventional equipment.
 11 **Q. And what about making it? Does it require**
 12 **different equipment or different infrastructure?**
 13 A. Yeah.
 14 So the -- so if you look at the polylactic acid
 15 material that is produced -- the lactic acid is
 16 produced by fermentation, so that's a different process
 17 than just a chemical plant. And then once the lactic
 18 acid is produced, it's then polymerized into polylactic
 19 acid.
 20 With respect to the PHAs, that's -- the PHAs
 21 are actually produced by bacteria, so they produce the
 22 bacteria -- the polymer within the cell of the bacteria,
 23 and so these are grown up into large vats of these
 24 cells, and then they're sliced open and the polymer is
 25 harvested.

402

1 So there are some differences. There's
 2 probably not another plastic that's produced like that.
 3 **Q. Are there differences in the mechanical**
 4 **characteristics between biodegradable plastics and**
 5 **conventional commodity plastics?**
 6 A. Well, there's differences in the mechanical
 7 properties between all of the plastics, you know, some
 8 of them just depending on what the glass transition
 9 temperature is, how much crystallinity there is and,
 10 you know, just what the melting -- whether it's
 11 crystalline or whether it's amorphous and what the
 12 melting point is.
 13 These all contribute to the differences in
 14 mechanical properties. But there are ways to adjust
 15 these properties through blending.
 16 **Q. So there -- you -- there are some -- some**
 17 **products that are made out of plastics that are**
 18 **biodegradable, but there aren't many.**
 19 A. There's -- I mean, there's a lot of products
 20 that are made out of it, but if you compare it to the
 21 total number of plastics products that are made in the
 22 world, it's a very small fraction.
 23 **Q. And why do the commodity -- excuse me --**
 24 **conventional plastics dominate, still dominate the**
 25 **market?**

403

1 A. I think the primary reason is price.
 2 **Q. Your expertise includes biodegradable polymers.**
 3 A. Yes.
 4 **Q. Why is there an interest in developing**
 5 **biodegradable polymers?**
 6 A. Well, it's -- I mean, there are applications
 7 where it makes a lot of sense to have a biodegradable
 8 polymer.
 9 So, for example, a composting bag where you --
 10 for leaf pickup, it would make sense to have a
 11 biodegradable polymer bag so that then that whole bag
 12 can be then composted with it.
 13 For things like plant pots where you might just
 14 be able to plant them in the ground and they would
 15 degrade.
 16 I mean, there's -- there's a whole use of
 17 biodegradable polymers in medical applications where
 18 you use them for sutures so that you don't have to go
 19 back in with a second surgery to remove the sutures.
 20 So there's a lot of applications where they make
 21 sense from a cost point of view.
 22 **Q. And what about plastics that are intended to be**
 23 **disposed of through traditional disposal methods? Is**
 24 **there interest in making those types -- those plastics**
 25 **biodegradable in those settings?**

404

1 A. Are you referring to, say, landfill?
 2 **Q. Yes.**
 3 A. Yeah. I'm not sure that there's a lot of
 4 interest in marketing that expense for use in
 5 landfills.
 6 **Q. And why is that?**
 7 A. Just because there's not a strong belief that
 8 there is a fast biodegradation that occurs in landfills
 9 as opposed to composting where you would get a benefit
 10 for something degrading in, say, six months.
 11 **Q. You had mentioned earlier about there are ways**
 12 **to affect the characteristics of plastics through**
 13 **blends.**
 14 **How -- can you explain a little bit more about**
 15 **how that works?**
 16 A. Well, one of the techniques that I'm mostly
 17 familiar with is the patent that I'm an inventor on
 18 relating to polylactic acid. And the -- one of the
 19 shortcomings of polylactic acid is that it becomes very
 20 brittle after just 24 hours after processing it. And
 21 that means it breaks very easily.
 22 And if we blend it with a second polymer that's
 23 much more ductile, like the material from -- the
 24 Bionolle material or the Ecoflex material, then what we
 25 get is a material -- with only 20 percent of that second

405

1 component, we're able to get a blend that is very, very
 2 ductile.
 3 So you can imagine that if you were trying to
 4 make a trash bag, it would become a benefit that if you
 5 were to put extra trash in it that it didn't break on
 6 you, that it actually stretched out to allow you to get
 7 more trash into it.
 8 **Q. And the blends that you're talking about, the**
 9 **PLA and the other component, are both components**
 10 **biodegradable?**
 11 A. Yes. That is the -- so the patent covers only
 12 blends that are biodegradable, so we knew, say, in
 13 advance that the PLA was a hundred percent
 14 biodegradable and that the Bionelle was a hundred
 15 percent biodegradable, so the patent does not -- does
 16 not do any testing to verify that they're
 17 biodegradable. They were known to be biodegradable at
 18 the very start.
 19 **Q. And do you have any experience or familiarity**
 20 **with blends of a nonbiodegradable plastic with a**
 21 **biodegradable plastic?**
 22 A. Yes. We had a project early on where we looked
 23 at blends of polyhydroxyalkanoates with polyethylene.
 24 **Q. And what was the purpose of that study?**
 25 A. We wanted to know whether the blending of the

406

1 nonbiodegradable would be detrimental to the
 2 biodegradation of the polyhydroxyalkanoate.
 3 **Q. And what was the ratio of the two components in**
 4 **those blends?**
 5 A. We looked at the whole range. I believe it was
 6 20, 40, 60, 80.
 7 **Q. And what did you conclude under -- as a result**
 8 **of your research on these --**
 9 A. That when we got a majority of the
 10 polyethylene, say the 60 and 80, that it did
 11 detrimentally affect the biodegradation of the
 12 polyhydroxyalkanoates.
 13 **Q. So you were not evaluating whether the**
 14 **polyethylene component was rendered biodegradable.**
 15 A. No. No.
 16 **Q. And why is that?**
 17 A. There's never been any scientific proof that
 18 polyethylene is biodegradable.
 19 **Q. And that's consistent with the opinions that**
 20 **you've given in this case.**
 21 A. That is correct, yeah.
 22 **Q. And your opinion about the blends of the ECM**
 23 **additive, adding 1 percent ECM biodegradable polymer**
 24 **into a 99 percent conventional plastic, what was your**
 25 **opinion about whether that renders the entire plastic**

407

1 **completely biodegradable?**
 2 A. That it would not render the polyethylene any
 3 more biodegradable than -- it would -- it just wouldn't
 4 change it.
 5 **Q. Now, when you're making plastic blends, are**
 6 **there things that you need to consider about the**
 7 **characteristics of the two components that would affect**
 8 **the -- if you're dealing with two biodegradable**
 9 **polymers, for instance, and you're --**
 10 A. Yes.
 11 **Q. -- blending them, are there things that you need**
 12 **to consider?**
 13 A. Yeah. With blends, there are really two very
 14 distinct classes of blends, one that is miscible where
 15 you form a one -- a true solution of the two polymers
 16 and the other one where it's immiscible where you
 17 actually have different phases of the two polymers, so
 18 it's similar to, you know, oil and water where they're
 19 immiscible versus alcohol and water where it's
 20 miscible.
 21 **Q. So if you combine two miscible blends, how does**
 22 **that affect the chemical properties or chemical nature**
 23 **of the blend?**
 24 A. So what you get is sort of an average between
 25 the two.

408

1 So, for example, the glass transition -- for a
 2 50/50 blend, if you had a glass transition temperature
 3 of one of 0 and one of 100, the blend would be a glass
 4 transition temperature of 50, where if they're
 5 immiscible, you'd have half the material be the
 6 Tg of 0 and half the material would have the Tg of 100.
 7 **Q. And Tg is?**
 8 A. The glass transition temperature. Yeah.
 9 **Q. Are there any other ways in which the**
 10 **miscibility of the two components would affect the**
 11 **characteristics of the other components as far as**
 12 **degradability or biodegradability?**
 13 A. So if you -- if you had a biodegradable
 14 component that was miscible with a nonbiodegradable
 15 component and it was miscible, you would have very
 16 severe detrimental effects even at low concentrations of
 17 the nonbiodegradable material.
 18 **Q. So -- and you mean detrimental effects to the**
 19 **ability of the degradable --**
 20 A. It would be detrimental with respect to the
 21 biodegradation in that the biodegradation of the
 22 biodegradable component would suffer because of the
 23 addition of the nonbiodegradable miscible component.
 24 **Q. So I'll just ask the question again so that the**
 25 **record is clear.**

409

1 **When you combine two polymers with different --**
 2 **that are not miscible and one is biodegradable and one**
 3 **is not biodegradable, how does that impact the**
 4 **biodegradability of the combined blend?**
 5 A. If they're not miscible?
 6 **Q. Excuse me. If they are miscible.**
 7 A. Okay. If they're miscible, yeah.
 8 If they're miscible, then the biodegradation of
 9 the biodegradable component would suffer by any addition
 10 of the nonbiodegradable material.
 11 **Q. And why -- can you explain why that is?**
 12 A. Because you form this true solution, so there
 13 will be interference in all places of this
 14 nonbiodegradable material.
 15 **Q. And what about if you had a blend between a**
 16 **nonbiodegradable polymer and a biodegradable polymer**
 17 **that were immiscible? Does that affect**
 18 **biodegradability?**
 19 A. It would affect biodegradability. There -- I
 20 mean, you could imagine a scenario where if you -- if
 21 the biodegradable component was a much lower viscosity,
 22 then it would then be concentrated on the outside, and
 23 so that would be more exposed to the microorganisms and
 24 you might see, you know, similar biodegradability of
 25 that component.

410

1 On the other hand, if the nonbiodegradable
 2 component had a lower viscosity and that concentrated on
 3 the outside, sort of encapsulating the biodegradable
 4 component, you might see zero biodegradability of your
 5 biodegradable polymer.
 6 JUDGE CHAPPELL: But wouldn't the manufacturer
 7 know that? If you're making a product and you've got I
 8 guess items going into the mix that are not homogeneous,
 9 it's not going to mix properly, are you going to let
 10 that product go out the door? Isn't that going to be
 11 obvious to the manufacturer?
 12 THE WITNESS: Well, some manufacturers actually
 13 want a coating on a material, so they purposely have a
 14 low molecular -- low-viscosity material that actually
 15 forms on the outside of the material.
 16 JUDGE CHAPPELL: So if you want it, it's a good
 17 thing.
 18 THE WITNESS: Yeah.
 19 JUDGE CHAPPELL: But either way, you're going to
 20 notice it.
 21 THE WITNESS: Yes. You would definitely -- it
 22 would be a good thing if you did it on purpose. Yeah.
 23 BY MS. JOHNSON:
 24 **Q. And generally, do you know whether a**
 25 **biodegradable polymer like polycaprolactone is miscible**

411

1 **with a nonbiodegradable polymer like polyethylene?**
 2 A. It is not miscible with polyethylene.
 3 **Q. So if they're not miscible and you blend these**
 4 **two polymers together, do you know what the viscosities**
 5 **are relative to each other?**
 6 A. Well, if you're doing a -- so the melting point
 7 of the polycaprolactone is 60 degrees centigrade,
 8 whereas the polyethylene is between 120 and 160, so if
 9 they are similar molecular weights, the polycaprolactone
 10 would have a lower viscosity.
 11 **Q. And what would -- and what would that mean as**
 12 **far as the blend of the two?**
 13 A. Well, I mean, like I said, you could design a
 14 film that had a high concentration of the
 15 polycaprolactone on the outside just by having a low
 16 viscosity of the polycaprolactone, and that might be
 17 advantageous to some biodegradation.
 18 **Q. But that would not alter the biodegradability of**
 19 **the underlying polyethylene.**
 20 A. No. It would have no effect.
 21 **Q. I want to go back to where we left off before**
 22 **the break when we were I think looking at your report at**
 23 **paragraph -- or excuse me -- at page -- this is**
 24 **Complaint Counsel's 891 at page 13. And we talked**
 25 **about -- you discuss paragraph 38.**

412

1 **Can you tell me what paragraph 38 is about.**
 2 A. Yeah.
 3 So this is conducting -- this is the testing
 4 that would have to be done to prove that the
 5 conventional plastics are converted somehow to
 6 biodegradable plastics with only 1 percent of the
 7 additives and specifically that the testing has to be,
 8 you know, independent, well-designed, well-conducted,
 9 well-controlled with respect to the plastic application,
 10 load rate, inoculum, test conditions, sample weight,
 11 over the appropriate duration of time.
 12 **Q. And why is it important to have a**
 13 **well-conducted, well-designed, well-analyzed study that**
 14 **accounts for all of those factors that you just**
 15 **identified?**
 16 A. Because when you're dealing with a
 17 biodegradable polymer and a nonbiodegradable polymer,
 18 you might be fooled into thinking that the blend itself
 19 is biodegradable when it really might just be the
 20 biodegradable polymer that's degrading.
 21 **Q. And could there be other reasons why a test**
 22 **might lead -- show some biodegradation but it not**
 23 **actually be the full blend that's biodegrading?**
 24 A. Well, yeah. There's the priming effect where
 25 you basically are getting degradation from the inoculum

413

1 that is then -- you're recording it as biodegradation of
 2 the nonbiodegradable polymer.
 3 **Q. Let's take a step back and explain what kind of**
 4 **testing is usually conducted to determine the**
 5 **biodegradability of plastics.**
 6 A. The most common would probably be the
 7 composting testing, where the testing is done for,
 8 you know, up to 180 days to prove that you have
 9 complete mineralization and disintegration of the
 10 material such that it would be suitable to put in a
 11 municipal compost environment.
 12 **Q. And as far as testing plastics that are**
 13 **intended to biodegrade in other types of conditions,**
 14 **what's the most common type of test that's used to**
 15 **evaluate those plastics?**
 16 A. So the second most common?
 17 **Q. Not necessarily specific test, just in general,**
 18 **what kinds of test --**
 19 A. Yeah.
 20 So there are test methods for soil exposure,
 21 and there are test methods for the marine environment,
 22 and then there are test methods for anaerobic
 23 environments.
 24 **Q. And how is biodegradability measured in these**
 25 **various tests?**

414

1 A. Most of the testing now is respiromic, so they
 2 test for carbon dioxide in the aerobic and carbon
 3 dioxide and methane in the anaerobic.
 4 You know, there was a testing initially back
 5 quite a few years that used weight loss, but that test
 6 has been abandoned because, you know, the weight loss
 7 provided some errors due to disintegration.
 8 **Q. So in -- you called it a respir- --**
 9 A. Respirometer.
 10 **Q. Is that the same thing as a gas evolution test?**
 11 A. Yep, yep.
 12 **Q. And can you explain how a gas evolution test is**
 13 **usually conducted?**
 14 A. Sure. Well, so you have your polymer that you
 15 would then place in your inoculum and then you would
 16 then test for, say, in either carbon dioxide or carbon
 17 dioxide and methane. And what you'd want to do is also
 18 have another vessel that just had a positive control,
 19 typically cellulose, and then you'd want to have another
 20 container that had a negative control, and typically the
 21 negative control is polyethylene.
 22 **Q. Is polyethylene an appropriate control when**
 23 **dealing with blends?**
 24 A. It is -- a majority of scientists believe that
 25 it is not biodegradable, so it is appropriate.

415

1 **Q. And one of the factors that you identified in**
 2 **your report -- one of them is the load rate. Can you**
 3 **explain what that factor is?**
 4 A. Yeah.
 5 So you -- you're going to always have a certain
 6 amount of gas that's evolved from the inoculum, and so
 7 what you want is to have a sufficient amount of polymer
 8 in there with respect to the amount of inoculum so that
 9 your reading is really the degradation of the polymer
 10 and not the degradation of the inoculum.
 11 **Q. I want to take a -- one step back and finish**
 12 **talking about a gas evolution test design.**
 13 **So for a gas evolution test, as I understand,**
 14 **you're measuring the by-products of biodegradation?**
 15 A. That is correct.
 16 **Q. And what are the by-products of anaerobic**
 17 **biodegradation?**
 18 A. It would be carbon dioxide and methane.
 19 **Q. So in this -- in a gas evolution test, one would**
 20 **be evaluating the production of carbon dioxide and**
 21 **methane to evaluate whether biodegradation is taking**
 22 **place.**
 23 A. That is correct.
 24 **Q. So can you just explain a little bit more some**
 25 **other parameters that go into setting up a gas evolution**

416

1 **test, the other factors that one would consider in**
 2 **designing a test to test the biodegradability of a**
 3 **blend.**
 4 A. So the most important would be temperature.
 5 You'd want to make sure that the temperature that you're
 6 running your experiment at is equivalent to your
 7 disposal temperature in order to make sure that it's
 8 simulating the same environment.
 9 **Q. Is there any other reason why temperature is**
 10 **important factor to consider in running a gas evolution**
 11 **test?**
 12 A. Yeah. Because as you increase temperature, you
 13 actually change the different microorganisms from, say,
 14 mesophilic temperatures to thermophilic temperatures.
 15 **Q. And why does that -- how does that play a role**
 16 **in measuring biodegradation?**
 17 A. Well, typically you get higher rates of
 18 degradation with the higher temperatures just because,
 19 you know, a reaction occurs at a much higher rate as you
 20 increase the temperature.
 21 But also you might get organisms that -- if
 22 you're testing, say, in a thermophilic environment, and
 23 you think that the thing is degrading because it's
 24 degrading great, if you then put it in a mesophilic
 25 environment, there may be no microorganisms that would

417

1 be able to degrade it.
 2 **Q. Can you tell us what temperature range is the**
 3 **mesophilic range?**
 4 A. It's around 50 to 55 degrees.
 5 **Q. And 55 degrees centigrade?**
 6 A. Centigrade, yeah. 50 to 55, yeah.
 7 **Q. And for the thermophilic range?**
 8 A. Is around 35 degrees centigrade.
 9 **Q. I want to make sure I understand.**
 10 **The thermophilic range is the hotter end?**
 11 A. Yeah.
 12 **Q. So what is the temperature range for the**
 13 **thermophilic?**
 14 A. 50 to 55 C.
 15 **Q. And what is the temperature range for the**
 16 **mesophilic?**
 17 A. Around 35 degrees centigrade.
 18 **Q. Is there any other fact that the change or**
 19 **different temperatures could have on the test, on the**
 20 **outcome of the test?**
 21 A. I mean, there could be some abiotic reactions
 22 that occur at the higher temperatures that might not
 23 occur at the lower temperatures.
 24 **Q. And what do you mean by "abiotic"?**
 25 A. So, for example, any type of oxidation that

418

1 might occur would be accelerated at the higher
 2 temperatures, any type of hydrolysis.
 3 So, for example, polylactic acid, the primary
 4 mechanism for its degradation is abiotic hydrolysis, so
 5 by going up in the temperature, increase the
 6 temperature, you increase that rate by a huge amount.
 7 **Q. We were talking earlier about the different**
 8 **properties of different plastics, so looking at your**
 9 **report, is it important to test the plastic that will be**
 10 **incorporating the additive in the test conditions?**
 11 A. Yes. I believe that -- if you have an additive
 12 that you're claiming is going to render a nondegradable
 13 plastic degradable, then one thing to maybe ensure that
 14 you're not getting a priming effect is to put just the
 15 additive alone into the inoculum and use that as your
 16 control so that now all -- you're subtracting out for
 17 that priming effect, and now all you're measuring is the
 18 biodegradation of the polyethylene, for example.
 19 **Q. So having the proper controls in a test are**
 20 **important.**
 21 A. Yes.
 22 **Q. And those include the positive control?**
 23 A. Right.
 24 **Q. What does the positive control do?**
 25 A. The positive control ensures that you have an

419

1 inoculum that's able to biodegrade cellulose to more
 2 than 70 percent. That's important, because if you
 3 didn't have that, then you wouldn't have a reference as
 4 to how active that -- those microorganisms were, so you
 5 might have more active microorganisms that could give
 6 you one result and less active that could give you the
 7 other result.
 8 **Q. And just -- I don't know if I had you explain**
 9 **this to the court, but the -- what is the inoculum?**
 10 A. The inoculum is basically the microorganisms
 11 that are made up from either an anaerobic digester or a
 12 compost that then is usually aged so that you try to
 13 eliminate a lot of the background noise from the gas
 14 evolution before you introduce your samples into it.
 15 **Q. And what is the background noise --**
 16 A. So --
 17 **Q. -- a result of?**
 18 A. So basically the inoculum will have then the
 19 microorganism plus some residual, you know, pieces of
 20 organic matter that they're degrading. And if you have
 21 fresh inoculum, then you're still degrading a lot of
 22 that fresh organic matter, and so it will give you a lot
 23 of gas evolution that you may interpret it to be the
 24 polymer.
 25 **Q. So typically the inoculum is aged. Can you**

420

1 **explain what that means.**
 2 A. So what you do, you just have the inoculum at a
 3 certain temperature for a specified period of time, and
 4 that's specified in the ASTM tests.
 5 JUDGE CHAPPELL: How would you differentiate
 6 inoculum from a catalyst?
 7 THE WITNESS: Inoculum from a?
 8 JUDGE CHAPPELL: Catalyst.
 9 THE WITNESS: Okay. So the -- a catalyst would
 10 be sort of a chemical that speeds up a chemical
 11 reaction, whereas the inoculum is basically the
 12 microorganism, sort of the -- you know, it would be like
 13 the -- if you were to make yogurt, you know, it would be
 14 like the stuff from the old yogurt that you put in the
 15 new yogurt to sort of get it started.
 16 So it's basically the transfer of the
 17 microorganisms to sort of start up the new degradation.
 18 JUDGE CHAPPELL: So at some point don't the two
 19 overlap? At some point they're the same thing?
 20 THE WITNESS: Well, the catalyst is basically
 21 the enzymes, so the enzymes aren't really living. It's
 22 really the cells that are living that keep producing the
 23 enzymes that are the catalyst to break down the
 24 polymers.
 25 So if you don't have the microorganism living,

421

1 then they can't produce the catalysts to break down the
 2 polymer. Yeah.
 3 BY MS. JOHNSON:
 4 **Q. So let's just make sure that the record is clear**
 5 **about what the inoculum is.**
 6 **First, where is the inoculum obtained usually**
 7 **for these kinds of tests?**
 8 A. So it would be obtained from the source that is
 9 going to be a typical disposal source, so again it would
 10 be composting for a composting test, soil for a soil
 11 test, marine for a marine test, and then anaerobic
 12 digester for an anaerobic digester test.
 13 **Q. And once the inoculum is collected from that**
 14 **source, what does it consist of?**
 15 A. So again it would consist of basically the -- so
 16 if you had, you know, a waste stream that was degraded,
 17 you would then have the degraded waste, some of the
 18 nondegraded waste and all of the microorganisms that are
 19 degrading that waste.
 20 **Q. And what's the purpose of the inoculum in the**
 21 **test?**
 22 A. So the purpose of it, to simulate the
 23 microorganism population that is typical in this
 24 disposal method.
 25 **Q. So the inoculum has a microbial community in**

422

1 **it?**
 2 A. Yes.
 3 **Q. And it's that microbial community that's**
 4 **responsible for the biodegradation that's seen in the**
 5 **test.**
 6 A. Exactly. That's why it's important to have a
 7 similar microorganism community as what you're trying to
 8 simulate with your test.
 9 **Q. So we've talked about the inoculum. We've**
 10 **talked about a positive control.**
 11 **What other factors do you have to look at in**
 12 **designing or putting together one of these gas evolution**
 13 **tests?**
 14 A. The negative control, which is typically
 15 polyethylene. And again you want the load rate to be
 16 such that you have enough polymer so that you get a good
 17 signal from the degradation of the polymer. Temperature
 18 is important. Moisture is also important.
 19 **Q. I want to ask, if you were evaluating the**
 20 **biodegradability of polyvinylchloride, would you want to**
 21 **use polyethylene as a negative control?**
 22 A. Sure. Because the negative control just tells
 23 you test to test, so in other words, you use cellulose
 24 and polyethylene in every -- you know, the same
 25 cellulose, the same polyethylene in every single test so

423

1 that then you have a consistent, you know, error bars,
 2 so to speak.
 3 **Q. Would you want to also have a negative control**
 4 **of a polyvinyl- -- untreated polyvinylchloride?**
 5 A. Well, I don't -- I wouldn't refer to that as a
 6 negative control. I'd refer to that as the comparison
 7 between the effect of the treatment.
 8 So if you were trying to compare how good the
 9 treatment was to the untreated, you'd want to have the
 10 polyvinylchloride that was exactly the same grade, that
 11 was produced on the same machine, that was the same
 12 thickness, that had the same amount of plasticizer, the
 13 same type of plasticizer, and they're exactly the same
 14 except for the additive.
 15 **Q. And what's the purpose of that?**
 16 A. That is so that you could compare how --
 17 you know, the difference in adding the additive, if
 18 there was any difference.
 19 **Q. And you mentioned before that another control**
 20 **that would be necessary for such a test would be a**
 21 **control that included the inoculum -- excuse me --**
 22 **included the treatment for the plastic, so the additive**
 23 **only in this case.**
 24 **Can you explain to the court why you would want**
 25 **to have an additive-only control.**

424

1 A. Yeah. Because, you know, there's been a lot of
 2 studies that show this priming effect where if you
 3 add -- you know, there was one test that was done with
 4 carbon-14 dating where they added it, they did it to
 5 glucose, and they were able to get 120 percent
 6 biodegradation of the glucose. But when they looked at
 7 the carbon-14 release, it was only 70 percent.
 8 So you can see that this -- there's a -- there's
 9 various materials that cause accelerated amount of the
 10 inoculum to degrade the undegraded material, so it gives
 11 them like energy to degrade the undegraded material,
 12 much higher than if it wasn't there.
 13 JUDGE CHAPPELL: I want to clarify what I was
 14 talking about earlier.
 15 When I hear "inoculum," I think of course of
 16 inoculation.
 17 THE WITNESS: Yeah.
 18 JUDGE CHAPPELL: And what I was trying to figure
 19 out in my own mind, the difference in an inoculum, at
 20 least as it's used in this case, and a catalyst, a
 21 catalyst would create the desired change yet would not
 22 change at all in itself.
 23 THE WITNESS: Right.
 24 JUDGE CHAPPELL: Whereas the inoculum does
 25 change.

425

1 THE WITNESS: Yeah.
 2 JUDGE CHAPPELL: Yet causes --
 3 THE WITNESS: It reproduces, so that's why I use
 4 the yogurt example.
 5 JUDGE CHAPPELL: Or sour dough bread.
 6 THE WITNESS: Excuse me?
 7 JUDGE CHAPPELL: Sour dough bread?
 8 Oh, you're from the East Coast.
 9 THE WITNESS: Yes. Exactly. Exactly. It does
 10 the same thing. Yes.
 11 JUDGE CHAPPELL: And in these tests, is the
 12 inoculum generally consumed completely?
 13 THE WITNESS: No. It should actually reproduce
 14 until the very end.
 15 JUDGE CHAPPELL: But it has to be aerobic.
 16 THE WITNESS: It can be aerobic or anaerobic.
 17 I mean, you'd want to choose the inoculum
 18 depending on what your disposal method is. If you
 19 wanted it to be composting, then it should be aerobic.
 20 If you want it to be landfill, it should be anaerobic.
 21 JUDGE CHAPPELL: And I know there is another
 22 landfill expert, but having unfortunately visited a
 23 number of landfills myself, there's a lot of variation.
 24 THE WITNESS: Yes.
 25 JUDGE CHAPPELL: So if you're going to replicate

426

1 a landfill, what, is there some general landfill
 2 inoculum? How do they arrive at that?
 3 THE WITNESS: Usually it's done by anaerobic
 4 digesters, so there are anaerobic digesters that
 5 produce methane as a fuel, so they take the garbage and
 6 they digest it anaerobically and harvest the methane in
 7 big reactive vessels. Unfortunately, there's not a lot
 8 that exist in this country, but it's very popular in
 9 Europe.
 10 JUDGE CHAPPELL: So if you're in this business,
 11 you can just order this digester for compost, landfill.
 12 There are companies that supply that.
 13 THE WITNESS: Yep.
 14 JUDGE CHAPPELL: All right. Thank you.
 15 THE WITNESS: Absolutely.
 16 BY MS. JOHNSON:
 17 **Q. Given some of the judge's questions, I just want**
 18 **to make sure this is clear.**
 19 **The inoculum consists of microbes, bacteria?**
 20 A. That's right.
 21 **Q. And other microorganisms?**
 22 A. I mean, it --
 23 **Q. Fungi?**
 24 A. So it's the microorganisms that you want to use
 25 to sort of degrade the material that you're testing, but

427

1 you can't just pull the microbes out one by one. You
 2 sort of have to collect them with the digested material
 3 and the nondigested material, yeah.
 4 **Q. So for compost --**
 5 A. Yeah.
 6 **Q. -- the inoculum that you would use in a**
 7 **composting test would be the compost itself?**
 8 A. Right.
 9 **Q. And that compost has microorganisms that are**
 10 **capable of aerobic biodegradation?**
 11 A. That's right.
 12 **Q. And it would also have some undigested organic**
 13 **matter.**
 14 A. There would be some undigested and some
 15 digested, yeah. That's the purpose of, you know,
 16 leaving it for a period of time so that you try to get
 17 the undigested degraded so you remove that from the
 18 background noise.
 19 **Q. And it's the bacteria that are in the inoculum**
 20 **that are responsible for biodegrading whatever the test**
 21 **substance is.**
 22 A. Right.
 23 So it's those bacteria that you want to get to
 24 grow so that they secrete the enzymes that will then
 25 degrade the polymer. Exactly.

428

1 **Q. So in that case, it's the enzymes that are being**
 2 **produced by the microbes that are responsible for the**
 3 **biodegradation that's --**
 4 A. Exactly. Exactly.
 5 **Q. It's not a catalyst that you're adding from --**
 6 A. No.
 7 **Q. -- some --**
 8 A. No.
 9 **Q. -- external source?**
 10 A. No.
 11 **Q. And if you are running a test to examine whether**
 12 **a plastic is capable of undergoing anaerobic**
 13 **biodegradation, you would not use aerobic compost; is**
 14 **that right?**
 15 A. That is correct, yeah.
 16 **Q. So what would you use if you were trying to**
 17 **evaluate the ability of a plastic to be biodegraded**
 18 **under anaerobic conditions?**
 19 A. Well, the ASTM specifies an anaerobic digester
 20 that is predominantly household waste.
 21 **Q. Let's explain for the court what the ASTM is.**
 22 A. Oh.
 23 So the ASTM is the American Society for Testing
 24 and Materials, and it's actually just a society of -- I
 25 mean, you pay dues to the society to join, but then

429

1 it's basically a volunteer organization where you get
 2 together, and it's, you know, basically leading people
 3 in the field, and you vote on what a standard should
 4 be.
 5 **Q. And when you say "standard," do you mean a**
 6 **testing standard?**
 7 A. So it could be a testing standard, a standard
 8 test method, or it could be a specification of,
 9 you know, what the test method has to require in order
 10 to classify something as something. The majority are
 11 standard test methods.
 12 **Q. So explain the difference between a test method**
 13 **on the one hand and a test specification on the other.**
 14 A. So, for example, you might have a specification
 15 that says, you know, this material is -- you know, is
 16 biodegradable in this environment as long as you get
 17 this amount of biodegradation in this amount of time
 18 using this test method and this test method and this
 19 test method.
 20 So it sort of outlined, you know, all the test
 21 methods and what the results have to be in order to
 22 claim that something is biodegradable in that
 23 environment, whereas a test method would just be the
 24 test.
 25 And so, for example, there's -- you know, if

430

1 you just did a test method, you couldn't claim that
 2 it's biodegradable because you did that test method
 3 because you might get only 10 percent biodegradation by
 4 doing that method, whereas the specification would say
 5 you have to get this amount using that test method in
 6 order to claim that it's biodegradable.
 7 **Q. And explain a little bit more about how -- who's**
 8 **involved in the process of developing these standard**
 9 **test methods and standard test specifications.**
 10 A. So it's typically people from industry and
 11 people from academia. And they're interested in having
 12 standards that can be used to compare different
 13 materials.
 14 So, for example, you might have a simple test
 15 method that is just for measuring the tensile strength
 16 of a material, right, so you want to know how strong
 17 the material is. And the reason you want to have one
 18 test method to measure how strong the material is,
 19 because you don't want someone doing this test method
 20 that says their material is, you know, a hundred pascals
 21 to break versus one that does a different test method
 22 and finds out it's a thousand, you know, and because
 23 then there's an unfair advantage in advertising or
 24 something.
 25 So you want everyone to do it exactly the same

431

1 way so that you can -- so that the customer then can
 2 compare, Oh, I want to buy this material because it's
 3 stronger than this material.
 4 **Q. And how are the industry and academia folks**
 5 **involved in the process of coming up with these test**
 6 **methods and specifications?**
 7 A. Sure.
 8 So it's voluntary. Someone takes the lead and
 9 designs whatever they want, a test method -- and it
 10 could be a group effort -- a test method or a
 11 specification. And then they propose it to the
 12 subcommittee, and it's sent out for ballot, and
 13 everybody on the subcommittee votes on what they think
 14 of that standard.
 15 And typically there are people that might want
 16 different changes, and so everybody has to input into
 17 those changes. And then those changes are voted on.
 18 So if someone wants a crazy change, for example,
 19 that no one else agrees with, then that change is not
 20 accepted. But if someone wants a reasonable change
 21 that everyone agrees with, then that change is
 22 accepted.
 23 **Q. And ultimately the end product is going to**
 24 **be -- does it have to pass -- be passed by a certain**
 25 **number of --**

432

1 A. Yes. It has to be passed by a majority. Yeah.
 2 And then it can always be changed the next
 3 year, you know, so it's sort of like a living method.
 4 Anyone can find out, hey, you know, we were wrong about
 5 this, we really should change it and make these
 6 improvements.
 7 And that's sort of why the weight loss test
 8 method was abandoned, because people just realized it
 9 was a bad test.
 10 **Q. Are you involved in the ASTM?**
 11 A. Yes.
 12 **Q. And what is your involvement with that**
 13 **organization?**
 14 A. I'm on the subcommittee for -- by -- polymer
 15 biodegradation.
 16 **Q. And how long have you been on that committee?**
 17 A. I would say twenty years maybe.
 18 **Q. And in the twenty years that you've been on that**
 19 **committee, have you been involved in developing some of**
 20 **the standards that we've been talking about?**
 21 A. Yes. Yes, I have.
 22 **Q. Have you written any standards?**
 23 A. I have not written any by myself. I've helped
 24 write them with other people.
 25 **Q. And what standards have you helped write?**

433

1 A. Mainly the one on composting and marine
 2 degradation.
 3 **Q. How else have you been involved in developing**
 4 **standards during your time on the ASTM subcommittee?**
 5 A. Voting on them and making recommendations and --
 6 yeah.
 7 **Q. Are there any standards that are currently**
 8 **under review that are relevant to the opinions in this**
 9 **case?**
 10 A. Yes, there is.
 11 **Q. And what standard would that be?**
 12 A. It's W -- can I look at -- I don't have it
 13 memorized.
 14 **Q. Can you -- so you're saying this information was**
 15 **put into your expert report?**
 16 A. Yes, it is.
 17 **Q. And could you direct us to where in your expert**
 18 **report it is.**
 19 A. Okay. It is on page 22, proposed ASTM standard
 20 test method. WK 41850.
 21 **Q. And have you -- are you familiar with the --**
 22 **this working standard?**
 23 A. Yes, I am.
 24 **Q. Has it been passed yet?**
 25 A. No, it has not.

434

1 **Q. Do you know who wrote the standard?**
 2 A. I don't know who wrote it. I know that
 3 Charles Lancelot I think has now taken over the lead for
 4 it.
 5 **Q. And this standard has been -- is going through**
 6 **this, the voting process right now?**
 7 A. Absolutely. Yep.
 8 **Q. And the way that you've described it in your**
 9 **report, is that the most current iteration of the**
 10 **standard as it stands?**
 11 A. You know, I just received an e-mail ballot from
 12 the ASTM yesterday that I haven't been able to read yet,
 13 so I'm not sure. But this is the most current that I
 14 have read.
 15 **Q. So let's talk about some of the other standards**
 16 **that you identified in your report that are currently in**
 17 **use for evaluating the biodegradability of plastics.**
 18 A. Sure.
 19 **Q. Can you tell us a little bit about the**
 20 **ASTM D5511 test.**
 21 A. Yeah. The 5511 is designed to be a screening
 22 test and it's designed to be a short-term test, up to
 23 30 days. It is 50 degrees, 51 degrees or so. And it --
 24 it's basically designed as an anaerobic short-term
 25 screening test.

435

1 **Q. And is the 5511 test similar to the kinds of**
 2 **tests that we've been -- and -- has the -- the kinds of**
 3 **parameters that we've been talking about, does it set**
 4 **forth the controls that are necessary for the test?**
 5 A. Yeah. I mean, it's basically designed for
 6 things that would show biodegradation within 30 days.
 7 **Q. And can you explain how -- what the setup is of**
 8 **the 5511 test?**
 9 A. It's basically a test tube -- I mean, a flask
 10 that then goes to a test tube under water where you
 11 collect the gas. I think there's a schematic in the
 12 standard.
 13 MS. JOHNSON: Just one moment, Your Honor. I
 14 apologize.
 15 (Pause in the proceedings.)
 16 I have Complaint Counsel's 83.
 17 Can I approach the witness, Your Honor?
 18 JUDGE CHAPPELL: Go ahead.
 19 MS. JOHNSON: May I?
 20 Thank you.
 21 BY MS. JOHNSON:
 22 **Q. I just handed you Complaint Counsel's 83.**
 23 **Can you -- what is this document?**
 24 A. So this is the D5511 that was approved in 2011.
 25 **Q. Is that the most recent version of the --**

436

1 A. I believe it is.
 2 **Q. Say --**
 3 A. I believe it is.
 4 MS. JOHNSON: I have Complaint Counsel's 84.
 5 May I approach the --
 6 JUDGE CHAPPELL: Go ahead.
 7 MS. JOHNSON: Thank you.
 8 BY MS. JOHNSON:
 9 **Q. Dr. McCarthy, what is Complaint Counsel's 84?**
 10 A. This is the most recent version of the 5511. I
 11 voted on it in 2012.
 12 **Q. And you said that somewhere in the standard it**
 13 **has a schematic?**
 14 A. Yeah. Page 2.
 15 **Q. And can you just explain for the court what this**
 16 **schematic describes.**
 17 A. So the flask to the left is where the inoculum
 18 would go with the test samples, and then it's inside an
 19 incubator that would control the temperature. And then
 20 the gas would then go through the tube into a cylinder
 21 that's placed in a water bath. And as the air bubbles
 22 down, it would then displace the water and be ready for
 23 collection. And then it could be collected out through
 24 port number 7.
 25 **Q. And what is done with the gas that's collected**

437

1 **and discharged through port number 7?**
 2 A. So you'd want to measure the amount of gas and
 3 then from that analyze how much of it is methane and how
 4 much of it is carbon dioxide.
 5 **Q. And what do those -- what are those measurements**
 6 **used for?**
 7 A. So what you use those for is to then convert the
 8 carbon that you collect back to the total amount of
 9 carbon that's in your test sample.
 10 **Q. And how does -- how do you do that? What's the**
 11 **process that's involved?**
 12 A. So it's outlined in -- on page 4. You can see
 13 equation 1 would basically be the conversion from the
 14 carbon in the polymer to methane and carbon dioxide.
 15 And then equations 2, equation 2 would be the
 16 amount of carbon -- yeah, that's the amount that goes --
 17 in the equation 2, yeah, that's the amount of percent
 18 degradation.
 19 **Q. And what other information do you need in order**
 20 **to calculate the percent degradation?**
 21 A. So what you have is the amount from your test
 22 minus the amount from the blank inoculum, so you see
 23 you're subtracting that carbon there. Yeah.
 24 **Q. And how do you know how much -- what the carbon**
 25 **content is of the test sample?**

438

1 A. By the weight. By the weight and the molecular
 2 formula.
 3 **Q. I'm sorry. Could you say that again.**
 4 A. So you know the weight and the molecular formula
 5 of it.
 6 **Q. So in order to calculate the carbon content of**
 7 **the -- of the test sample, you need to know the**
 8 **molecular formula.**
 9 A. Yes.
 10 **Q. What other calculations are required under the**
 11 **D5511 test method?**
 12 A. Well, there's a calculation for the -- basically
 13 the confidence limit, the 95 percent confidence limit,
 14 which is the, you know, the error that's -- that you
 15 get.
 16 **Q. And I believe that this was also discussed in**
 17 **your report about why it's important to look at the**
 18 **error in the test.**
 19 **Can you explain for the court why error is an**
 20 **important component of the test?**
 21 A. Right.
 22 So basically you have to run triplicates in
 23 order -- so that's three of the vessels per sample. And
 24 then you compare how close they are together.
 25 So if they're all very close together, you have

439

1 more confidence that you had a good, you know, test than
 2 if they're very far apart.
 3 So if you had something that was, say,
 4 15 percent biodegradation and it was plus or minus 2,
 5 that would be a better test than if you had 5 percent
 6 degradation and it was plus or minus 10.
 7 **Q. And why -- and why is that?**
 8 A. It means that it's more reproducible. You know,
 9 if you have a lot of scatter -- so if you're not able to
 10 reproduce the same number with the same test, then
 11 there's -- you're not as confident in that number. I
 12 mean, it's basically statistics.
 13 **Q. And what can you -- what does it mean to have**
 14 **5 plus or minus 10? What would that mean for the range**
 15 **of outcomes?**
 16 A. That would mean you probably wouldn't be able to
 17 say that there's degradation because, you know, you're
 18 not getting -- you're not getting a good reading, so you
 19 probably should do that over.
 20 **Q. We've talked about the plastic -- the controls**
 21 **for this kind of test. You've talked about the inoculum**
 22 **and how that plays a role in evaluating these kinds of**
 23 **tests.**
 24 **Are there anything -- are there other factors**
 25 **that are important to consider in evaluating and**

440

1 **designing a test, a gas evolution test of this kind?**
 2 A. Well, I mean, you know, the errors that we just
 3 discussed would determine the statistical significance
 4 of the results.
 5 **Q. And what information is -- I think you had**
 6 **mentioned before that it's a screening test. Can you**
 7 **explain what that means?**
 8 A. So it's done at a very high temperature, so
 9 50-plus degrees, and so it really wouldn't be applicable
 10 to, you know, landfills. But it would tell you whether
 11 something had an ability to biodegrade within 30 days.
 12 And you could compare, you know, plastic A to plastic B
 13 to plastic C.
 14 **Q. We were talking before about the various**
 15 **controls.**
 16 **In this test, does the -- are the kinds of**
 17 **controls that are required -- are they set out in the**
 18 **5511?**
 19 A. Excuse me?
 20 **Q. Are the controls that are required for the**
 21 **5511 -- are they indicated in the test method?**
 22 A. Yes. Yes, they are.
 23 **Q. And what controls does the test call for?**
 24 A. I can't -- I believe it's cellulose and -- let
 25 me just get here --

441

1 **Q. Does it call for --**
 2 A. Yeah. Cellulose and polyethylene. It's 11.1.2.
 3 **Q. Thank you.**
 4 A. Sorry about that. It's hard to read here.
 5 **Q. Does it -- so it calls for a cellulose control,**
 6 **and what -- and what -- in the types of controls we were**
 7 **talking about before, what would that be?**
 8 A. That's a positive control because that's the
 9 control that degrades the fastest.
 10 **Q. And then you mentioned polyethylene.**
 11 **What kind of control would that --**
 12 A. That's a negative control.
 13 **Q. And when we were talking before about how to**
 14 **design a test that would be competent and reliable**
 15 **scientific evidence for the claim of 1 percent of a**
 16 **biodegradable polymer added to 99 percent conventional**
 17 **polymer, what that -- what that would look like, you**
 18 **mentioned an additional -- an additional control.**
 19 **Is that control reflected in this test?**
 20 A. No, it is not.
 21 **Q. And why would this test not have that kind of**
 22 **control if it's an important aspect in understanding the**
 23 **biodegradability of a polymer?**
 24 A. Because this test is not designed for additives.
 25 It's designed for the entire polymer to be a hundred

442

1 percent composition of that one polymer type.
 2 **Q. So, for instance, one of the other**
 3 **biodegradable polymers that we were talking about**
 4 **earlier.**
 5 A. That's right. Yeah.
 6 **Q. You could use that test to evaluate?**
 7 A. Yeah. You can compare polylactic acid to
 8 polyhydroxyalkanoate to polycaprolactone, for example.
 9 **Q. Other than the 5511 test, what other tests do**
 10 **you discuss in your report that are the kinds of gas**
 11 **evolution tests that could be used to test biodegradable**
 12 **polymers?**
 13 A. The 5526.
 14 **Q. And how -- I have Complaint Counsel's CCX 87.**
 15 **Your Honor, may I approach the witness?**
 16 JUDGE CHAPPELL: Go ahead.
 17 BY MS. JOHNSON:
 18 **Q. Dr. McCarthy, what is Complaint Counsel's 87?**
 19 A. So this is the D5526 that was approved on 2012.
 20 **Q. And how -- just describe what this test method**
 21 **is.**
 22 A. So this is supposed to simulate slower-degrading
 23 materials at a temperature that's closer to landfill
 24 conditions, so 35 degrees centigrade. And it's suitable
 25 for longer-time degradation results.

443

1 **Q. Is it generally the same kind of test, a gas**
 2 **evolution test?**
 3 A. It's a gas evolution test. But you can see from
 4 the schematic on page 2 that it's a much more robust
 5 design that's suitable for going up to 300 days.
 6 **Q. So you're looking at the figure 1 on page 2?**
 7 A. Yep. Yeah.
 8 **Q. And comparing that to the figure 1 on page 2 of**
 9 **CCX 84.**
 10 A. That's right.
 11 **Q. And so these are different designs for the test.**
 12 A. Totally different designs. This one is designed
 13 for longer-term applications, so if you wanted to test
 14 longer than 30 days, you should go to the 5526.
 15 **Q. And why -- and why is that?**
 16 A. Just because of leakage. It's basically the
 17 leakage. The 5526 allows for all of the gas to be
 18 contained until it reaches a certain pressure, and then
 19 you release it into the sample bottle to analyze it.
 20 And you want to analyze it, you know, once a week or so.
 21 Yeah.
 22 **Q. And how is that different than the setup in the**
 23 **5511 test?**
 24 A. So the 5511 just goes into this water, and so
 25 you can see, there's not really a lot of -- I mean, it's

444

1 a lot cheaper test because the equipment is very cheap,
 2 but it's not built for, you know -- leakproof. It's not
 3 a leakproof design.
 4 **Q. And other than the design of the apparatus, are**
 5 **there other differences between the two tests?**
 6 A. Well, the temperature is more -- is closer to
 7 landfill temperatures.
 8 **Q. Are there any other differences between the two**
 9 **tests?**
 10 A. I think those are the principal ones.
 11 **Q. So it calls for the same inoculum?**
 12 A. Household -- pretreated household waste. Yeah.
 13 **Q. I think you mentioned this before, but is that**
 14 **inoculum generally available in the United States?**
 15 A. I don't know how many -- I don't think it's
 16 generally available. I don't know how many anaerobic
 17 digesters there are with -- for pretreated household
 18 waste there are in the U.S. I know they are very
 19 popular in Europe, and hopefully we can get there
 20 someday.
 21 **Q. Are there anaerobic digesters that treat other**
 22 **kinds of waste in the United States?**
 23 A. Sewage sludge.
 24 **Q. Anything else?**
 25 A. I don't think so.

445

1 **Q. Does it call -- does the 5526 call for the same**
 2 **negative control as the 5511?**
 3 A. I believe so. Let me see.
 4 (Pause in the proceedings.)
 5 I believe it does, but I can't really find it.
 6 **Q. Is the 5526 also designed to test a homogenous**
 7 **biodegradable polymer?**
 8 A. Yes.
 9 **Q. In your report, you also discussed a third**
 10 **standard that's -- that can be used to evaluate**
 11 **biodegradation in anaerobic conditions.**
 12 **What was the third test standard that you --**
 13 A. You mean the proposed one that we --
 14 **Q. Oh, I'm sorry.**
 15 A. -- covered?
 16 **Q. Not the proposed one. There was one other one**
 17 **that you mentioned.**
 18 A. Oh, the -- I think those are the primary ones,
 19 5511.
 20 **Q. Are you familiar with the -- with D5210?**
 21 A. Not as much as the --
 22 **Q. Is that a test that's not commonly run to use to**
 23 **evaluate biodegradation of --**
 24 A. I believe it's not common.
 25 JUDGE CHAPPELL: How much more time do you need?

446

1 MS. JOHNSON: Your Honor, I have a ways to go
 2 still.
 3 JUDGE CHAPPELL: Go ahead.
 4 BY MS. JOHNSON:
 5 **Q. Why is it that the 5526 test can be run for a**
 6 **much longer period than the 5511?**
 7 A. It's a -- basically a more robust design to
 8 prevent leaks.
 9 **Q. And how do you know that it's designed -- that**
 10 **it can run for time periods as long as 300 days?**
 11 A. Because it's been -- you can look on figure 2 on
 12 page 5. You can see the -- in the ASTM document that
 13 it's -- shows it being run --
 14 **Q. So this is Complaint Counsel 87's that you're --**
 15 A. Yep.
 16 **Q. And on page 5 of Complaint Counsel's 87 you're**
 17 **looking at the chart?**
 18 A. Yep.
 19 **Q. And what is -- and what does this depict?**
 20 A. So this is the biogas production that's been
 21 done with 5526 for 300 days.
 22 **Q. And when -- in what context is this being**
 23 **discussed, this curve? In what context is it**
 24 **appearing?**
 25 A. So it shows an example of it run to 300 days

447

1 that is been approved by the committee.
 2 **Q. So if it were run for a longer period of time**
 3 **than 300 days, would that be considered approved under**
 4 **the test?**
 5 A. If it -- you mean if it was then included in the
 6 standard?
 7 **Q. No.**
 8 **If a laboratory were to run a test for longer**
 9 **than 300 days, would that fall within what's been**
 10 **approved under the standard?**
 11 A. It would probably have to be then verified that
 12 that's possible to do. Yeah.
 13 **Q. And what's that verification process?**
 14 A. So what you'd want to do is have like three
 15 different tests run exactly the same material for
 16 exactly the same period of time and compare the results
 17 to make sure that you got the same results. And it's
 18 called a round-robin.
 19 **Q. It's called -- can you repeat?**
 20 A. A round-robin. That's what we call it. I don't
 21 know what it means.
 22 **Q. And is that one lab running three concurrent**
 23 **tests?**
 24 A. Yes. Each lab runs three tests and they compare
 25 the results. Yeah.

448

1 **Q. So it's --**
 2 A. And it doesn't have to be limited to three
 3 labs. It can be anybody that wants to participate in
 4 it.
 5 **Q. So multiple labs --**
 6 A. Multiple labs, yeah.
 7 **Q. -- are running the same test --**
 8 A. Three times.
 9 **Q. -- for the same duration on the same material.**
 10 A. Yes.
 11 **Q. And they use that to?**
 12 A. To verify that extra time.
 13 **Q. And what period of time has the 5511 been**
 14 **verified for?**
 15 A. 30 days.
 16 **Q. So that means different labs have conducted the**
 17 **same test on the same materials --**
 18 A. For 30 days.
 19 **Q. -- for 30 days.**
 20 A. Yeah.
 21 **Q. And we were talking earlier about the proposed**
 22 **new standard.**
 23 **How would that standard in its current form or**
 24 **the most current form that you're aware of be different**
 25 **than the standards that we've been discussing?**

449

1 A. It involves the use of an additive to a
 2 material. And it, you know -- it requires 60 percent
 3 biodegradation after the 180 days.
 4 **Q. So is it a gas evolution test?**
 5 A. It's a gas evolution test, yeah.
 6 **Q. And what does that entail? What kinds of things**
 7 **are being measured in the test?**
 8 A. So they're measuring the -- again, the carbon
 9 dioxide and methane and converting that to the percent
 10 biodegradation. And one of my comments, you know, was
 11 that the control should be the inoculum with the
 12 additive, again, to prevent the priming effect from
 13 giving you a false reading.
 14 **Q. And was that comment accepted by the committee**
 15 **that was considering the test?**
 16 A. I don't know yet.
 17 **Q. I have Complaint Counsel's 93.**
 18 **Your Honor, may I approach the witness?**
 19 JUDGE CHAPPELL: Okay.
 20 BY MS. JOHNSON:
 21 **Q. What is Complaint Counsel's 93?**
 22 A. So it's work number W -- work item number
 23 WK 41850, standard test method for determining the rates
 24 and rate constants for plastics biodegradation in an
 25 anaerobic laboratory environment under accelerated

450

1 conditions.
 2 **Q. And this is the standard that we were just**
 3 **discussing that's currently in consideration in the**
 4 **ASTM --**
 5 A. That's correct.
 6 **Q. -- committee?**
 7 A. Yep.
 8 **Q. And what -- in its current form, what are the**
 9 **parameters of the test?**
 10 **Well, first let me back up.**
 11 **You said this test is specifically designed to**
 12 **test what?**
 13 A. So it -- one of the things that is in the
 14 materials is that it allows for additives.
 15 **Q. So the comment --**
 16 JUDGE CHAPPELL: Hold on a second.
 17 If I'm understanding this right, we're talking
 18 about a proposed standard?
 19 MS. JOHNSON: Yes, Your Honor.
 20 JUDGE CHAPPELL: And how is that relevant?
 21 MS. JOHNSON: It reflects where we are in terms
 22 of developing test standards that are relevant to
 23 testing plastics with additives.
 24 JUDGE CHAPPELL: And how is that relevant?
 25 MS. JOHNSON: Because we're going to elicit the

451

1 opinion from our expert about what kinds of testing is
 2 necessary to substantiate claims that a 1 percent
 3 additive consisting of a biodegradable polymer blended
 4 into an additive -- excuse me -- a conventional plastic
 5 has not been substantiated by the kinds of testing that
 6 we've seen thus far.
 7 JUDGE CHAPPELL: And this opinion is supposed to
 8 compare or require some test that's not even a standard
 9 today?
 10 MS. JOHNSON: It's -- I'm not -- I'm not
 11 suggesting, Your Honor, and I'm not going to elicit
 12 testimony that -- that it's required to pass this
 13 particular test. Clearly, it's not and it's not even
 14 been in its final form yet. They're still voting on
 15 it.
 16 JUDGE CHAPPELL: And again, how is that
 17 relevant?
 18 MS. JOHNSON: I will move beyond it. We don't
 19 have to discuss it, Your Honor.
 20 BY MS. JOHNSON:
 21 **Q. So as I understand it, you've identified a**
 22 **number of factors that would need to be taken into**
 23 **account to design a test that would accommodate for all**
 24 **the potential variables that could affect the outcome of**
 25 **the test.**

452

1 A. Yeah.

2 **Q. Have you considered -- in connection with**

3 **forming your opinion in this case, have you reviewed**

4 **tests, test data from tests on ECM plastic?**

5 A. Yes, I have.

6 **Q. And what is your opinion regarding those tests?**

7 A. There are some tests that were conducted well

8 and some tests that were conducted poorly.

9 **Q. Do you have any other opinions about those tests**

10 **with respect to the claims that you were asked to opine**

11 **on?**

12 A. So the tests that are probably the most

13 problematic are the ones that are the 5511 that were

14 conducted at the very, very long periods of time and

15 indicate a lot of leakage.

16 **Q. So your opinion is that those tests conducted**

17 **for those periods of time are not reliable?**

18 A. Yes, that's correct.

19 **Q. In the tests that you've reviewed, did you see**

20 **any tests that could substantiate the kinds of claims**

21 **that ECM -- that we were asking you to evaluate that ECM**

22 **had made?**

23 A. No, I have not.

24 **Q. I think it's Complaint Counsel's 94. Is that**

25 **still up there? The appendix of tests? Or maybe it**

453

1 **wasn't 94.**

2 **What's the exhibit number on the bottom?**

3 A. 942.

4 942.

5 **Q. 942.**

6 **In Complaint Counsel's 942, does it reflect all**

7 **of the tests that you reviewed in coming to your**

8 **opinion?**

9 A. Yes, it does.

10 **Q. And what is your opinion with respect to whether**

11 **these tests substantiate the claims?**

12 A. That they do not substantiate the claims.

13 **Q. So can you just generally describe the kinds of**

14 **test data that you reviewed that encompassed these**

15 **various tests.**

16 A. So some of the tests were very qualitative, so,

17 for example, weight loss or chlorine ion content or SEM

18 measurements where there wasn't really a number of,

19 you know, biodegradation because they weren't the gas

20 evolution tests.

21 And then there were -- there was an aerobic

22 test, maybe a couple that were done by O.W.S. on it that

23 seemed very reliable.

24 And then there were tests that were done, a

25 number that were done on the 5511, and there were some

454

1 that were just done past the 30 days.

2 **Q. Were there other things that you considered in**

3 **evaluating whether those 5511 tests that were run for**

4 **more than 30 days, whether those tests were reliable,**

5 **other than just the length of the test?**

6 A. Well, so in terms of the leakage, so typically

7 you want -- you expect the gas that's being released to

8 be carbon dioxide and methane because those are the

9 degradation products of the polymer. And in some of the

10 tests that were done past 30 days, there was less than

11 10 percent of the total gas that was carbon dioxide and

12 methane.

13 **Q. And why --**

14 A. So you'd want at least 90 percent to be the

15 current -- yeah, go ahead.

16 **Q. So the results were atypical from what you would**

17 **see from a typical gas evolution test?**

18 A. Yeah. I mean, it's just because it's run too

19 long.

20 **Q. Was there anything else about the gas evolution**

21 **data that was atypical?**

22 A. There were some tests where the readings were

23 like exactly the same for three consecutive readings.

24 There were some tests where the samples weren't

25 really labeled as to how much ECM additive was in it.

455

1 There was some where there were not any error

2 bars or standard deviation or standard error given for

3 the samples.

4 Those are the ones I can think of right off the

5 top of my head.

6 **Q. And these are the things that we discussed**

7 **earlier that --**

8 A. Yes.

9 **Q. -- inform whether the test is well-controlled,**

10 **well --**

11 A. That's right.

12 **Q. Now, you said that some of the tests were just**

13 **qualitative.**

14 **Can you describe or explain to the court why a**

15 **qualitative test is not competent and reliable**

16 **scientific evidence to support the kinds of claims**

17 **here.**

18 A. So, for example, measuring a sample on an SEM

19 would be an example, so you -- if you measure -- anyone

20 that's done scanning electron microscopy on a plastic

21 polymer knows that you can cause degradation by doing

22 the microscopy. I mean, the sample beam can burn the

23 plastic. And you're trying to measure, you know, how

24 much plastic is degraded, so -- and you really don't

25 know whether it's degraded from microorganisms or

456

1 whether it's degraded from just the microscope or from
 2 just, you know, other means, so something like that
 3 would be qualitative.
 4 **Q. And so that's for the SEM tests.**
 5 **Were there other things in the tests that lead**
 6 **you to believe that they're not -- they're not**
 7 **reliable?**
 8 A. Well, there was one test that showed a chlorine
 9 ion concentration for PVC, for example, and they -- I
 10 think they made a claim that it showed biodegradation
 11 just from the chlorine ion concentration.
 12 **Q. And can you explain for the court why measuring**
 13 **chloride ions -- well, first of all, are you familiar**
 14 **with any literature in the area or has it ever been**
 15 **your experience that anyone has ever utilized a**
 16 **chloride ion test as a method for establishing**
 17 **biodegradability?**
 18 A. No.
 19 **Q. And can you explain for the court why it is that**
 20 **seeing a chloride ion does not affect the -- or does not**
 21 **necessarily indicate biodegradation.**
 22 A. Yeah.
 23 So the chlorine ion is on the side chain of the
 24 polymer, and so typically when you have the chlorine ion
 25 coming off of the PVC, it comes off of the hydrogen atom

457

1 next to it, and that forms a double bond.
 2 So you would result in -- with a double bond
 3 being there but no bond being broken, so you didn't get
 4 any of the backbone being broken just by the chlorine
 5 ion coming on it. And that double bond is not going to
 6 be any more attractive to a microorganism.
 7 **Q. So the appearance of chlorine ions is not**
 8 **indicative of some biological process.**
 9 A. Well, it's not indicative of biodegradation. It
 10 doesn't re- -- it doesn't result in a reduction in
 11 molecular weight, because the backbone is still intact.
 12 **Q. And I think we've talked about this before about**
 13 **why weight loss is not a good indicator of**
 14 **biodegradation.**
 15 **Were there some tests that you reviewed that**
 16 **relied on a weight loss --**
 17 A. Yes.
 18 **Q. -- as a way to determine biodegradation?**
 19 A. Yes. And those tests, as I mentioned, are
 20 problematic because all you need is disintegration
 21 to -- you know, just embrittlement, and then you miss a
 22 corner of the film and then you think that it's
 23 degraded, but really all you did was lose a corner to
 24 the test method.
 25 **Q. Now, you had -- I'm going to find a test here a**

458

1 **second.**
 2 **Your Honor, may I have a few moments to just**
 3 **find the exhibit I'm looking for?**
 4 JUDGE CHAPPELL: Yes.
 5 MS. JOHNSON: Thank you.
 6 (Pause in the proceedings.)
 7 MR. EMORD: Your Honor, while that's happening,
 8 I might give you an update on the witnesses. We have
 9 one fact witness on the way and should be here at around
 10 midnight tonight, and another fact witness is being
 11 hunted down but should be available in the either late
 12 afternoon tomorrow or certainly on Friday. And we're
 13 working to get more witnesses lined up.
 14 JUDGE CHAPPELL: What's your estimate of how
 15 long the direct exam will be of these witnesses? Is
 16 this like a short time or a few hours each?
 17 MR. EMORD: The direct exam of the witness
 18 who's arriving here tonight who will be first in line
 19 will probably last about an hour and a half to two
 20 hours. And the cross-examination -- it's Ken Sullivan,
 21 the CFO of ECM -- is hard for me to estimate, but I
 22 would suspect that given the cross will likely run on
 23 Dr. McCarthy through noontime tomorrow, Mr. Sullivan
 24 probably would be on in the afternoon. And it may be
 25 that we'll complete Mr. Sullivan on Thursday.

459

1 That would then leave the next fact witness that
 2 we have would be available Friday morning.
 3 JUDGE CHAPPELL: Okay. So you have these two in
 4 process.
 5 MR. EMORD: Yes.
 6 JUDGE CHAPPELL: Why don't we do this. That's
 7 enough for now.
 8 MR. EMORD: All right. Thank you, Your Honor.
 9 JUDGE CHAPPELL: Because this Dr. Frederick is
 10 supposed to be available Monday.
 11 MR. EMORD: Yes.
 12 JUDGE CHAPPELL: Correct?
 13 MS. JOHNSON: Yes, Your Honor.
 14 JUDGE CHAPPELL: So if need be, we'll take your
 15 two witnesses out of turn.
 16 MR. EMORD: All right.
 17 JUDGE CHAPPELL: Then we'll go back to the
 18 government, let them call their next witness then. Then
 19 they can rest their case, whenever, and then we'll go
 20 back to your case.
 21 MR. EMORD: Thank you, Your Honor.
 22 JUDGE CHAPPELL: Thank you.
 23 MS. JOHNSON: Your Honor, I just want to comment
 24 about that. Typically, under the scheduling order, we
 25 would get 48 hours --

460

1 JUDGE CHAPPELL: Forget that.
 2 MS. JOHNSON: Can we at least know who the
 3 witnesses are so that --
 4 JUDGE CHAPPELL: Yes, you can do that. But I'm
 5 not invoking a 48-hour notice provision because I
 6 requested this and they did it.
 7 MS. JOHNSON: Very well, Your Honor.
 8 JUDGE CHAPPELL: So there will be no negative
 9 consequence as a result of what they're doing.
 10 MS. JOHNSON: To either party, Your Honor.
 11 JUDGE CHAPPELL: But I'm sure -- I think he just
 12 told us one of the names.
 13 MS. JOHNSON: I'm sorry.
 14 MR. EMORD: Yes. Ken Sullivan. And then the
 15 second witness would be Bob Sinclair, the president and
 16 CEO of ECM, who will be on Friday, Friday morning.
 17 JUDGE CHAPPELL: And in the event your witness
 18 on Friday is not complete Friday, since -- your expert
 19 is coming Monday morning; correct?
 20 MS. JOHNSON: Yes, Your Honor.
 21 JUDGE CHAPPELL: Then you'll have the option to
 22 finish on Monday morning or stop where we are and
 23 continue after they rest their case.
 24 MR. EMORD: Thank you, Your Honor.
 25 JUDGE CHAPPELL: Go ahead.

461

1 MS. JOHNSON: One more clarification on that,
 2 Your Honor. If they finish with him on Monday, would we
 3 be expected to do the cross then or could we wait until
 4 we finish completing putting on the testimony of
 5 Dr. Frederick?
 6 JUDGE CHAPPELL: That's a good question.
 7 And you think Frederick is two days minimum.
 8 MS. JOHNSON: At least, Your Honor.
 9 JUDGE CHAPPELL: And he's your last witness;
 10 correct?
 11 MS. JOHNSON: Yes, he is, Your Honor.
 12 JUDGE CHAPPELL: Why don't you hold that
 13 question until we see where we are when the direct
 14 finishes and we have an idea of how much, you know, if
 15 we spill into Monday, how long it's going to take.
 16 MS. JOHNSON: Yes, Your Honor.
 17 JUDGE CHAPPELL: Because I intend to get
 18 Dr. Frederick going sometime Monday, hopefully by midday
 19 if not in the morning.
 20 MS. JOHNSON: Thank you, Your Honor.
 21 I have Complaint Counsel's 573 and 572.
 22 May I approach the witness, Your Honor?
 23 JUDGE CHAPPELL: Yes.
 24 BY MS. JOHNSON:
 25 **Q. Dr. McCarthy, did you review -- now, what are**

462

1 **those two documents?**
 2 A. These are two documents produced by
 3 Stevens Ecology on biodegradation testing of a loose
 4 fill product, and the second one is biodegradation
 5 testing of a plastic film product.
 6 JUDGE CHAPPELL: And just so we're clear on the
 7 record, I'm not penalizing any party for taking
 8 witnesses out of turn.
 9 And I don't know what the parties have agreed to
 10 with the 48-hour notice. If you've agreed to provide
 11 demonstrative or exhibits or whatever else, let's go
 12 ahead and do that so they're prepared.
 13 Is that a problem?
 14 MR. EMORD: That's fine.
 15 JUDGE CHAPPELL: Okay with you?
 16 MS. JOHNSON: Yes, Your Honor.
 17 JUDGE CHAPPELL: All right.
 18 BY MS. JOHNSON:
 19 **Q. Are these -- did you review these two tests in**
 20 **the course of preparing your opinions in this case?**
 21 A. Yes.
 22 **Q. And are these -- well, what kinds of tests are**
 23 **these?**
 24 A. These are anaerobic OECD 310, anaerobic
 25 ASTM 5511 mand anaerobic OECD 311.

463

1 JUDGE CHAPPELL: Let's go ahead and take our
 2 afternoon break now, unless you're telling me you've got
 3 five minutes left. Where are you?
 4 MS. JOHNSON: I do not, Your Honor. I have more
 5 than five minutes.
 6 JUDGE CHAPPELL: More than half an hour?
 7 MS. JOHNSON: I believe so.
 8 JUDGE CHAPPELL: All right. We're going to
 9 take our afternoon break. We're going to reconvene at
 10 4:30.
 11 We're in recess.
 12 (Recess)
 13 JUDGE CHAPPELL: Let's go back on the record.
 14 If you're wondering about the temperature in
 15 this room, we have two choices, we have cold and we have
 16 sauna, so I'm opting for cold, in case you're wondering.
 17 There's no middle ground.
 18 Go ahead.
 19 MR. EMORD: Your Honor, if I may, just on a
 20 procedural point.
 21 JUDGE CHAPPELL: Okay.
 22 MR. EMORD: I've forgotten. Forgive me. Is
 23 there a day next week when court would not be in
 24 session?
 25 JUDGE CHAPPELL: Yes. On the assumption that

464

1 Dr. Frederick may take three days, I think yesterday the
 2 way we left it, we would stick with the original planned
 3 day, which is next Thursday.
 4 MR. EMORD: Next Thursday?
 5 JUDGE CHAPPELL: No court next Thursday.
 6 MR. EMORD: All right. Thank you, Your Honor.
 7 BY MS. JOHNSON:
 8 **Q. Dr. McCarthy, I'd like to go back to looking at**
 9 **the two tests that we were looking at.**
 10 **Pardon. Before we go to that, let me just go**
 11 **back to -- to your expert report.**
 12 **In your report, did you identify the -- or**
 13 **discuss the various -- the tests that you reviewed in**
 14 **coming up with your opinion?**
 15 A. Yes.
 16 **Q. And you discuss some of the deficiencies that**
 17 **the tests had?**
 18 A. Yes.
 19 **Q. And where in your report can I find that**
 20 **information?**
 21 A. So the -- page 21 and 22.
 22 **Q. And that's where you discuss the various**
 23 **factors.**
 24 **Where do you discuss the analysis of those**
 25 **factors to the test?**

465

1 A. Excuse me?
 2 **Q. Do you -- excuse me. Let me just find page 21.**
 3 **On page 21, this is the -- where you discuss the**
 4 **ASTM, the 5511?**
 5 A. Yeah. And the ASTM 5526.
 6 MS. JOHNSON: Your Honor, if I may, there's some
 7 technical difficulties with the computer, so it may be a
 8 few minutes before we could pull up an image for you.
 9 Would you like me to keep going and give you -- find a
 10 hard copy for you or would you like to wait until we
 11 resolve this?
 12 JUDGE CHAPPELL: It's not that bad. We still
 13 have electricity. If I need to see something, I'll let
 14 you know, so go ahead.
 15 MS. JOHNSON: Okay.
 16 BY MS. JOHNSON:
 17 **Q. I just wanted to direct your attention to**
 18 **page 30 of your report where you -- in paragraph --**
 19 **or -- excuse me -- subsection 3 Romanette (i)?**
 20 A. Yes.
 21 **Q. What's the -- what does -- what section -- or**
 22 **excuse me.**
 23 **What are you discussing in this section of your**
 24 **test -- of your report? Pardon me.**
 25 A. Okay. So this is the testing that I reviewed

466

1 that were related to ECM plastic additive that I have
 2 concluded that the results are unreliable.
 3 **Q. And in that discussion you present the**
 4 **information in the same way that we've been discussing**
 5 **it all throughout today.**
 6 A. Exactly. Yep.
 7 **Q. So can you just explain what you did here.**
 8 A. So in other words, I went through all of the
 9 sections that I -- my opinion was required of the
 10 plastic application, so the polypropylene, polyethylene,
 11 PET, polystyrene, both linear, low-density polyethylene,
 12 ethylene vinyl acetate foam and high-impact polystyrene.
 13 **Q. So this is your analysis of the various tests**
 14 **that you reviewed in determining -- in coming up with**
 15 **your opinion in this case?**
 16 A. That is correct, yeah.
 17 **Q. And this paragraph 77 is an evaluation of all of**
 18 **the tests with respect to this particular --**
 19 A. The particular materials. Yeah.
 20 And then 78 is the different load rates of the
 21 different tests: the ChemRisk assessment, the FTC, the
 22 Advanced Materials Center, the O.W.S. final report, the
 23 O.W.S. second final report, and the high solids
 24 anaerobic digestion tested the ECM testing alone.
 25 **Q. Earlier in your testimony you stated that not**

467

1 **every test was performed -- not every test that you**
 2 **reviewed was unreliable.**
 3 **Is the CCX 572 and 573 -- are those two of the**
 4 **tests that you were referring to?**
 5 A. Yes. That's correct.
 6 **Q. And what about these tests make them more**
 7 **reliable?**
 8 A. They used the proper standards, they were
 9 exposed to the proper period of time, and they did the
 10 proper standard deviation.
 11 **Q. So they reported all of the information that you**
 12 **would expect to see in order to evaluate whether the**
 13 **test --**
 14 A. That is correct, yeah.
 15 **Q. Dr. McCarthy, to make it easier for the**
 16 **court reporter, let me finish asking the question in its**
 17 **entirety, and then you can go ahead and answer.**
 18 **Otherwise, I tend to trail off and not finish.**
 19 A. Okay.
 20 JUDGE CHAPPELL: Do you want her to read your
 21 last question?
 22 MS. JOHNSON: Yes, Your Honor. That would be
 23 very helpful.
 24 JUDGE CHAPPELL: She's going to read it, and
 25 then it ends abruptly, and you'll need to finish it.

468

1 And then he'll need to answer it.
 2 (The record was read as follows:)
 3 "QUESTION: So they reported all of the
 4 information that you would expect to see in order to
 5 evaluate whether the test -- "
 6 BY MS. JOHNSON:
 7 **Q. So they reported all the information that you**
 8 **would expect to see in being able to evaluate the**
 9 **reliability of the test.**
 10 A. Yes. That is correct.
 11 **Q. And that information, as we discussed before,**
 12 **includes what?**
 13 A. Includes what I put down, you know, the loading
 14 rate, the inoculum, the length of time, the temperature,
 15 the moisture, volatile solids.
 16 JUDGE CHAPPELL: Hold on a second. Lawman is
 17 going to adjust his microphone.
 18 (Pause in the proceedings.)
 19 Thank you.
 20 THE WITNESS: This is better.
 21 In addition, they used the correct positive
 22 controls and negative controls.
 23 BY MS. JOHNSON:
 24 **Q. And do you recall what the conclusion or results**
 25 **of these tests were?**

469

1 A. Yes.
 2 **Q. And what were the results of these tests?**
 3 A. So for the loose fill test, they concluded that
 4 under the aerobic composting conditions there was
 5 microscopic evidence of minor deterioration and attack,
 6 only minor mineralization of the product or the carbon
 7 dioxide gas was measured, and its significance was
 8 questionable.
 9 Under anaerobic high solids, high temperature
 10 conditions, ASTM D5511, no deterioration of the product
 11 or gas production was seen.
 12 Under anaerobic low solids, moderate temperature
 13 conditions, OECD 311, no deterioration of the product or
 14 gas production was seen.
 15 And the conclusion is that the product is at
 16 least partially subject to attack by microorganisms
 17 under aerobic conditions and is inert under anaerobic
 18 conditions.
 19 **Q. And what does "inert under anaerobic conditions"**
 20 **mean?**
 21 A. Does not degrade.
 22 **Q. Does not degrade? Does it mean that it does not**
 23 **biodegrade as well?**
 24 A. Does not biodegrade. That's correct.
 25 **Q. And for Complaint Counsel's 573, do you recall**

470

1 **what the conclusion of the lab that conducted the test**
 2 **was with respect to observed biodegradation?**
 3 A. Yes. The aerobic biodegradation, OECD 310, was
 4 approximately 1.5 to 2 percent mineralized during 60-day
 5 incubation.
 6 In the anaerobic biodegradable assay, OECD 311,
 7 approximately 3 percent of the film was mineralized.
 8 And in a second, less similar -- less sensitive
 9 anaerobic biodegradable assay, ASTM 5511, no detectable
 10 mineralization was observed.
 11 The conclusion is that only minor degradation of
 12 the sample occurred and does not meet the OECD or ASTM
 13 definitions of "biodegradable."
 14 **Q. And what is your understanding of what that --**
 15 **what the -- what information the lab is conveying about**
 16 **the biodegradability of the test product?**
 17 A. That it does not -- it shows that it is not
 18 biodegradable.
 19 **Q. And --**
 20 JUDGE CHAPPELL: One thing I want to say for the
 21 record, with the benefit of realtime, I want to make
 22 sure this is clear. With the changing of witness
 23 schedules, in the event the two respondent witnesses are
 24 finished Friday, early, we'll call it a week and take
 25 off.

471

1 Fair enough?
 2 MR. EMORD: Fair enough.
 3 MS. JOHNSON: Yes, Your Honor.
 4 JUDGE CHAPPELL: All right. Go ahead.
 5 MS. JOHNSON: Just one clarification. Do you
 6 mean just for giving their direct or are you
 7 anticipating that we would be doing their cross on --
 8 JUDGE CHAPPELL: Yes. Finished. If for some
 9 reason somehow we're finished with those two witnesses
 10 early Friday, we'll call it a day.
 11 BY MS. JOHNSON:
 12 **Q. Now, there's one aspect of the factors that**
 13 **we -- that you identified in your report that we have**
 14 **not discussed, and that's the duration of the --**
 15 JUDGE CHAPPELL: Wait a second. Now I
 16 understand your question.
 17 You need to be prepared to do your cross.
 18 MS. JOHNSON: Yes, Your Honor.
 19 JUDGE CHAPPELL: The only way you may get a
 20 waiver is if he doesn't finish his direct on Friday.
 21 Then we'll discuss when you can do your cross, if he's
 22 not finished Friday.
 23 MS. JOHNSON: If he's not finished with his
 24 direct by the conclusion of the business day on
 25 Friday --

472

1 JUDGE CHAPPELL: Yes.
 2 MS. JOHNSON: -- then -- but if he is done with
 3 his direct before the conclusion of the business day on
 4 Friday, we are expected to be prepared to do his cross
 5 at that time.
 6 JUDGE CHAPPELL: That's right.
 7 BY MS. JOHNSON:
 8 **Q. There is one other factor, Dr. McCarthy, that we**
 9 **haven't really talked about, and I -- and I want to get**
 10 **to that factor, and that has to do with the duration of**
 11 **the test.**
 12 **Can you explain why the test needs to run -- or**
 13 **how long a test needs to run, a biodegradation test**
 14 **would need to run.**
 15 A. So each test is designed to have a period of
 16 time where it's accurate, again, based on things like
 17 leakage and things of that nature and how -- and so --
 18 so there are -- for example, the 5511 is designed for
 19 30 days, and the 5526 is designed for 300 days for that
 20 very reason, that, you know -- but you would want -- in
 21 order to have -- you know, most of the ASTMs, in order
 22 to have a successful test, you would want to have the
 23 biodegradation of the positive control reach
 24 70 percent.
 25 **Q. And if the test is properly controlled, so the**

473

1 **70 percent for the cellulose is reached, what**
 2 **information can be gleaned from the test results?**
 3 A. That it had sufficient microbial activity to
 4 yield a successful biodegradability test.
 5 **Q. And we talked earlier before about this**
 6 **5511 test and similar gas evolution tests being**
 7 **screening tests.**
 8 **Are there other kinds of tests that are used to**
 9 **evaluate the biodegradability of polymers?**
 10 A. There's a 5526, and then there's the use of
 11 carbon-14, such as what Ann-Christine Albertsson did.
 12 **Q. And how is a carbon-14 test run? How would you**
 13 **run a carbon-14 test?**
 14 A. So first you'd have to make the monomer -- or
 15 you would have someone make the monomer using the
 16 carbon-14 labeling on the monomer. And then you would
 17 polymerize it. And then you would introduce it into the
 18 reactor, the incubator. And then when the carbon-14 gas
 19 is given off, it's radioactive, so you'd measure it with
 20 a radioactive measurement, and you detect then the
 21 amount of the carbon-14 carbon dioxide that would be
 22 produced.
 23 And the beauty of that is you know exactly that
 24 it comes from, say, the polyethylene, which is what
 25 Ann-Christine Albertsson did, so there's no question.

474

1 It's not from the inoculum. It's not from the additive.
 2 It has to be from the polyethylene.
 3 JUDGE CHAPPELL: And what would that cost?
 4 THE WITNESS: That -- it would cost between
 5 \$50,000 and \$100,000.
 6 BY MS. JOHNSON:
 7 **Q. That kind of test is still a type of gas**
 8 **evolution test; correct?**
 9 A. Yes. But the thing is it's labeled specifically
 10 for one particular polymer, you know, for the -- I mean,
 11 that's exactly why the Eastman material -- the Eastman
 12 people did it, because no one believed that the benzene
 13 ring was able to be degraded by a microorganism. They
 14 just thought maybe the benzene ring was just fragmented
 15 and that it wasn't really mineralized. But by labeling
 16 just the benzene ring on the terephthalate, they were
 17 able to show that it was completely converted to carbon
 18 dioxide, and so that's -- that was how they got
 19 approval.
 20 **Q. Other than carbon-14 testing, are there other**
 21 **ways that one can demonstrate that it wasn't just the**
 22 **additive or the inoculum that is biodegrading?**
 23 A. You mean that it was --
 24 **Q. Is there another way to verify or to establish**
 25 **that the plastic -- the back -- the plastic backbone,**

475

1 **the nondegradable plastic, is biodegrading as opposed to**
 2 **other potential factors?**
 3 A. Not 100 percent. I mean, that -- this
 4 carbon-14 tells you a hundred percent that it is the
 5 nondegradable plastic, unless you get, say, a hundred
 6 percent carbon -- carbon dioxide and methane
 7 conversion.
 8 **Q. So if you run the test long enough to**
 9 **completely convert it, then all of the theoretical**
 10 **carbon in the test sample, that's another way.**
 11 A. Yeah.
 12 **Q. Do you have to reach six -- do you have to reach**
 13 **a hundred percent in order to establish that it's**
 14 **biodegradable?**
 15 A. Well, I mean, that would give you a hundred
 16 percent conclusion that it was the -- not the inoculum
 17 and not the additive. But, you know, it depends -- see,
 18 if the cellulose -- say the cellulose reached
 19 90 percent. Then you would only be required to reach
 20 90 percent.
 21 **Q. And can you explain why that is?**
 22 A. That's because the -- you're always comparing to
 23 the positive control as to the amount of degradation,
 24 and the assumption is that the cellulose degrades as far
 25 as it can go, and so it would not be fair to require a

476

1 polymer to degrade higher than that.
 2 **Q. Let's talk about the extent of biodegradation.**
 3 **Is it expected that cellulose would be -- would**
 4 **reach a hundred percent biodegradation?**
 5 A. Okay. So a hundred percent biodegradation
 6 means that it's a combination of carbon dioxide,
 7 methane and biomass, and so it would not be expected
 8 that you would get a hundred percent of carbon dioxide
 9 and methane. There could be some conversion of that
 10 carbon to biomass that would not be released until those
 11 microorganisms were -- died and were ingested.
 12 **Q. So if we're just talking about conversion of**
 13 **the cellulose and not the result -- not the biomass,**
 14 **would you -- you -- would you expect to achieve a**
 15 **hundred percent biodegradation through gas evolution?**
 16 A. Of the cellulose?
 17 **Q. Of just the cellulose.**
 18 A. I've seen results that have shown a hundred
 19 percent degradation. I've seen results that show over a
 20 hundred percent degradation due to the priming effect,
 21 and so -- but it's not required that you get a hundred
 22 percent.
 23 **Q. What would it mean if you did obtain a hundred**
 24 **percent gas conversion of the theoretical carbon amount**
 25 **in cellulose? That all of the carbon in the cellulose**

477

1 **has been converted to gas?**
 2 A. Either all of the carbon in the cellulose has
 3 been converted into gas or you had some priming effect
 4 that made up for the extra carbon dioxide and methane.
 5 **Q. Could you explain for the court what**
 6 **recalcitrance is.**
 7 A. Okay. So there's some documents from some of
 8 the people working for ECM that try to extrapolate on a
 9 straight line that if they have a certain degradation
 10 rate that it would go on a straight line to a hundred
 11 percent. The problem is that there are parts of the
 12 polymer that are more difficult to degrade than other
 13 parts.
 14 So, for example, the polymer has a crystalline
 15 region and an amorphous region, and so you could have a
 16 degradation rate of just the amorphous region that was
 17 very, very fast. And if you kept -- if you extrapolated
 18 that, then you would expect a very high biodegradation
 19 rate. But what would happen, once that disappeared and
 20 you get into the crystalline region, it would slow down
 21 and possibly even stop.
 22 And so that's the problem with the extrapolation
 23 in this. Yeah.
 24 **Q. Is extrapolation recognized or used in**
 25 **biodegradation studies?**

478

1 A. It is prohibited under the ASTM standards.
 2 **Q. Are there any circumstances where extrapolation**
 3 **would be appropriate?**
 4 A. With respect to time?
 5 **Q. Yes.**
 6 A. I don't know of any.
 7 **Q. If you reached a certain percentage, could you**
 8 **extrapolate from there?**
 9 A. I mean, there is a proposal that the 60 percent,
 10 if it's a linear line that you could extrapolate, but
 11 that's still under review and it's not anything that's
 12 been proven.
 13 **Q. And that's a proposal based on?**
 14 A. That's the proposal that we can't talk about.
 15 **Q. This is the working ASTM standard that we've**
 16 **been --**
 17 A. Yeah. Yeah.
 18 **Q. -- that we discussed earlier?**
 19 A. Yeah.
 20 **Q. Is that 60 percent -- is that number reflected**
 21 **in other standards?**
 22 A. I don't think so.
 23 **Q. Are there other standards that have a**
 24 **requirement to reach a certain percentage of**
 25 **biodegradation in order to say that the plastic will**

479

1 **completely biodegrade?**
 2 A. Yeah. In the composting test it's 90 percent.
 3 **Q. And how -- are you familiar with how the**
 4 **90 percent was determined for that test?**
 5 A. Again, it was a committee that agreed that that
 6 was the proper limit.
 7 **Q. And how long -- and what standard is that? If**
 8 **you recall.**
 9 A. I don't know the exact. It's the -- I could get
 10 that for you. I think it's referred to in the 6400.
 11 **Q. And do you know how long the 6400 standard has**
 12 **been used as a standard for composting?**
 13 A. Quite a few years. I'm not sure exactly the
 14 amount of years, but quite a few.
 15 **Q. So presently, the current standard for**
 16 **conversion of carbon before you can extrapolate to**
 17 **complete biodegradation is 90 percent.**
 18 A. For that test, yeah.
 19 **Q. So your opinion in this case with respect to**
 20 **whether adding 1 percent of the ECM additive to**
 21 **99 percent conventional polymer renders the plastic**
 22 **biodegradable, can you just state for the court what**
 23 **your opinion is in this case?**
 24 A. It's my opinion that that is false.
 25 **Q. And your opinion -- and what is your opinion**

1 with respect to whether a plastic treated with 1 percent
 2 ECM additive will completely biodegrade in a landfill
 3 within five years?
 4 A. It's my opinion that that is false.
 5 **Q. Do you have any other opinions?**
 6 A. It's my opinion that there is not scientific
 7 evidence supporting either of those claims.
 8 MS. JOHNSON: I'm done with this. I pass the
 9 witness.
 10 JUDGE CHAPPELL: Will there be cross?
 11 MR. EMORD: Yes, Your Honor.
 12 JUDGE CHAPPELL: Let it commence.
 13 - - - - -
 14 CROSS-EXAMINATION
 15 BY MR. EMORD:
 16 **Q. Good afternoon, Dr. McCarthy.**
 17 A. Good afternoon.
 18 **Q. Do you recall being deposed in this proceeding**
 19 **in June of 2014?**
 20 A. Yes.
 21 **Q. And today you testified that you have a Ph.D. in**
 22 **polymer engineering; is that correct?**
 23 A. It's a -- the actual title is macromolecular
 24 science, but it's in the engineering school, and the
 25 "macromolecular" means polymers, so...

1 **Q. The question was, though, do you know about all**
 2 **of the biochemical interactions?**
 3 A. I don't know about all of them.
 4 **Q. Okay. And you're not an expert in microbial**
 5 **life forms.**
 6 A. That is correct, I'm not an expert.
 7 **Q. You're not a microbiologist.**
 8 A. No, I'm not.
 9 **Q. And if I wanted to know, for example, the names**
 10 **of each kind of microbial life form that exists in a**
 11 **landfill and each of the by-products and enzymes those**
 12 **life forms produce, you wouldn't be the one to be able**
 13 **to tell me that now, would you?**
 14 A. I don't know if anyone could tell you that.
 15 **Q. Well, but you would not be able to tell me that;**
 16 **right?**
 17 **Correct?**
 18 A. No. That's correct.
 19 **Q. And you're not an expert in the kinds of**
 20 **microorganisms that dwell in a landfill.**
 21 A. No, I'm not.
 22 **Q. You're not an expert in the colonization of**
 23 **microorganisms that form in landfills.**
 24 A. No, I'm not.
 25 **Q. Now, at your deposition, you described your**

1 **Q. But the actual title of your Ph.D. is**
 2 **macromolecular science?**
 3 A. That's correct.
 4 **Q. Not polymer engineering.**
 5 A. Well, it's basically the same thing.
 6 **Q. Is it?**
 7 A. It's in the engineering school and it's called
 8 macromolecules, and what I -- what I learned there is
 9 essentially polymer engineering.
 10 **Q. Now, you don't have a graduate-level degree in**
 11 **organic polymer chemistry, do you?**
 12 A. A degree in that? No, I don't.
 13 **Q. All right. And you don't have a graduate-level**
 14 **degree in chemistry.**
 15 A. No.
 16 **Q. Are you a biochemist?**
 17 A. No.
 18 **Q. In other words, if I wanted to know about all of**
 19 **the biochemical interactions that take place between**
 20 **different species of microorganisms and fungi on the one**
 21 **hand and plastic on the other, I should ask someone else**
 22 **that.**
 23 A. Well, I know a lot about the plastics and the
 24 interactions with plastics. I'm not sure that
 25 biochemists would know that.

1 expert report in this proceeding as "a collaborative
 2 effort between myself and complaint counsel"; is that
 3 right?
 4 A. It was -- it was -- there was both of us work --
 5 yeah.
 6 **Q. Well, I'm asking you specifically -- you can say**
 7 **you don't remember. We'll then get the transcript and**
 8 **help you then.**
 9 **Do you remember at your deposition when you were**
 10 **asked about your expert report in this proceeding and**
 11 **you described it as "a collaborative effort between**
 12 **myself and complaint counsel"? Do you remember that?**
 13 A. Probably. Yeah.
 14 **Q. Now, in particular, let's take a look at your**
 15 **expert report.**
 16 **Your Honor, may I approach the witness?**
 17 JUDGE CHAPPELL: Yes.
 18 BY MR. EMORD:
 19 **Q. Now, if you'll take a look at page 5 of your**
 20 **expert report and in particular footnote 1 on page 5.**
 21 **Do we have that on the screen?**
 22 **Do you see that, Dr. McCarthy?**
 23 **Footnote 1 page 5?**
 24 **Do you see it?**
 25 **I'm sorry. You have to audibly answer.**

EXHIBIT D

2964

1 to consult with co-counsel?
 2 JUDGE CHAPPELL: Go ahead.
 3 MR. AWERBUCH: Thank you.
 4 (Pause in the proceedings.)
 5 Thank you, Your Honor.
 6 BY MR. AWERBUCH:
 7 **Q. Dr. Michel, complaint counsel informed you that**
 8 **you had to disclose all documents you relied upon in**
 9 **forming your rebuttal report; correct?**
 10 A. Yes.
 11 **Q. And you did in fact provide those documents?**
 12 A. Yes.
 13 **Q. And you provided them electronically; right?**
 14 A. Yes.
 15 **Q. And there were three subfolders; is that right?**
 16 A. I don't recall, but possibly, yeah.
 17 **Q. Well, from what you remember, was one labeled**
 18 **ASTM, one subfolder labeled Literature and the other**
 19 **subfolder labeled Reports?**
 20 A. That sounds right.
 21 **Q. And in the folder labeled Reports, you supplied**
 22 **all of the reports you relied upon in this case to form**
 23 **your opinion; right?**
 24 A. I believe so.
 25 **Q. And that folder included exactly four documents;**

2965

1 **is that correct?**
 2 A. I don't recall exactly, but I expect so,
 3 something like that.
 4 **Q. And these four documents were the 2008 Environ**
 5 **bioPVC report, an interim report for the anaerobic**
 6 **biodegradation of bioPVC from 2007, and then two**
 7 **invoices from Northeast Biodegradation Laboratories, LLC**
 8 **to PPC Industries, Inc.; is that correct?**
 9 A. Yes. That sounds correct.
 10 **Q. And that bioPVC test that you reviewed, that was**
 11 **not a gas evolution test, was it?**
 12 A. I don't believe so.
 13 **Q. And the two invoices you reviewed were**
 14 **literally just invoices with no testing data**
 15 **whatsoever; correct?**
 16 A. I -- yeah, I don't recall exactly, but I expect
 17 so, yeah. I expect they were just invoices because
 18 that --
 19 **Q. And besides the Environ bioPVC report and the**
 20 **fact of the financial amount of how much PPC paid to**
 21 **Northeast Biodegradation Laboratories, your rebuttal**
 22 **report doesn't reference any other tests done on the**
 23 **ECM product besides the test that you yourself**
 24 **conducted; right?**
 25 A. I'm sorry.

2966

1 **Q. In your rebuttal report, the only tests besides**
 2 **the one you conducted that you specifically mention are**
 3 **the Environ bioPVC report and the two invoices from**
 4 **PPC Industries to Northeast Labs; correct?**
 5 A. I believe so.
 6 **Q. And with respect to test data, your rebuttal**
 7 **report didn't contain any reference to any other tests**
 8 **besides your test and the Environ bioPVC test; correct?**
 9 A. The rebuttal data that I submitted? You mean in
 10 that folder, that particular folder, or...
 11 **Q. In the folder that you supplied labeled Reports,**
 12 **but I'm only asking you about your rebuttal report right**
 13 **now.**
 14 **In your rebuttal report, other than data from**
 15 **the Environ bioPVC report and from your own article,**
 16 **your rebuttal report contains absolutely no data from**
 17 **any other tests regarding the ECM additive; correct?**
 18 A. Correct.
 19 **Q. And your rebuttal report doesn't contain any**
 20 **statistical analysis of other tests at issue in this**
 21 **case; right?**
 22 A. No. I don't believe it does.
 23 **Q. In fact, with respect to your rebuttal report,**
 24 **other than the Environ study, which was not a gas**
 25 **evolution test, the only test you relied upon in forming**

2967

1 **your opinion was the testing you performed for**
 2 **Myers Industries; correct?**
 3 A. Yes.
 4 JUDGE CHAPPELL: How much more time do you
 5 need?
 6 MR. AWERBUCH: Five or ten minutes.
 7 JUDGE CHAPPELL: Will there be any redirect?
 8 MS. JOHNSON: Yes, Your Honor.
 9 JUDGE CHAPPELL: We're going to go ahead and
 10 take a lunch break then. We will reconvene at 2:05.
 11 We're in recess.
 12 (Whereupon, at 1:06 p.m., a lunch recess was
 13 taken.)
 14
 15
 16
 17
 18
 19
 20
 21
 22
 23
 24
 25

EXHIBIT E

INITIAL PREHEARING CONFERENCE

ECM BioFilms, Inc.

11/21/2013

5

1 the -- before this case even began. We did have our
 2 mandatory meeting prior to this scheduling conference.
 3 We've talked about it. The parties are not in agreement
 4 over settlement.
 5 JUDGE CHAPPELL: Not in agreement over what
 6 "a short period of time" means?
 7 MS. JOHNSON: We didn't discuss it to that level
 8 of detail, Your Honor.
 9 JUDGE CHAPPELL: You didn't get that far. Okay.
 10 Thank you.
 11 Anything to add to that?
 12 MR. EMORD: I just would concur.
 13 JUDGE CHAPPELL: Okay. At this time I'll allow
 14 each side to make a presentation or overview of their
 15 case, limited to 15 minutes.
 16 Because this hearing is open to the public, to
 17 the extent there is any confidential information
 18 involved, I don't want you to reveal it at this
 19 hearing.
 20 I'll start with the government. Go ahead,
 21 whenever you're ready.
 22 MS. JOHNSON: Thank you, Your Honor.
 23 Your Honor, this is a simple and
 24 straightforward case. ECM makes express and implied
 25 claims about its additives that are untrue and

6

1 unsubstantiated.
 2 ECM's violations of the FTC Act are clear, and
 3 the remedies that we seek in this case are warranted.
 4 Your Honor, ECM would like you to think that
 5 this case is about the First Amendment, but as the
 6 Supreme Court stated in Central Hudson, there is no
 7 First Amendment protection for deceptive commercial
 8 speech.
 9 So what are ECM's claims and why are they
 10 deceptive?
 11 By and large, ECM's claims are express. ECM
 12 made two slightly different express claims over time.
 13 The first one was prior to October 2012. ECM
 14 claimed that plastics treated with the ECM additive will
 15 completely biodegrade in nearly all landfills in a
 16 period of time of nine months to five years.
 17 After the release of the FTC's revised
 18 Green Guides, ECM modified its claim to state that
 19 plastics treated with the ECM additive would completely
 20 biodegrade in most landfills in some period of time
 21 greater than a year.
 22 Both of these claims are false and
 23 unsubstantiated.
 24 Further, with its logos and certificates, ECM
 25 passed along express and implied claims through its

7

1 customers and its distributors to end-use consumers that
 2 were also false and unsubstantiated.
 3 JUDGE CHAPPELL: Did you say that the new claim
 4 said some period of time greater than one year?
 5 MS. JOHNSON: Yes, Your Honor.
 6 JUDGE CHAPPELL: And you said that's false?
 7 MS. JOHNSON: Yes, Your Honor.
 8 The -- it's false because they continued to make
 9 express claims throughout their entire Web site that
 10 still said the nine-month-to-five-year claim, and it's
 11 false because things don't require -- I mean, if you're
 12 talking, you know, things -- all things at all time will
 13 eventually biodegrade, that's correct, so --
 14 JUDGE CHAPPELL: So greater than one year can be
 15 a long time.
 16 MS. JOHNSON: It could be, but it would be a
 17 meaningless claim if it didn't mean anything -- didn't
 18 mean about a year.
 19 JUDGE CHAPPELL: I also saw a phrase throughout
 20 the complaint "a short period of time."
 21 How do you define "a short period of time"?
 22 MS. JOHNSON: Well, we don't need to define
 23 "a short period of time here," Your Honor, because ECM
 24 made express claims of nine months to five years, so
 25 just focused on the claims, the express claims that ECM

8

1 made --
 2 JUDGE CHAPPELL: Well, you need to answer my
 3 question.
 4 MS. JOHNSON: Oh, sure.
 5 JUDGE CHAPPELL: What do you think "a short
 6 period of time" means?
 7 MS. JOHNSON: Me personally or the government?
 8 Your Honor, the short, you know --
 9 JUDGE CHAPPELL: No. You're speaking for
 10 complaint counsel.
 11 MS. JOHNSON: Yes, yes. Yes, Your Honor.
 12 So if you're talking about the language "in a
 13 reasonable period of time," that language in the --
 14 there's some guidance in the Green Guides that says
 15 consumers would understand that to mean a period of
 16 time of one year -- of about one year for an unqualified
 17 claim.
 18 So if ECM's claims were that its product is --
 19 you know, once added to a plastic makes the plastic
 20 biodegradable, then -- and that claim gets passed down
 21 to consumers, consumers can reasonably interpret that to
 22 mean in one year in a landfill.
 23 JUDGE CHAPPELL: Okay. If I understood you
 24 earlier, it's your position that whatever period of time
 25 is necessary is not an issue in the case, since you said

EXHIBIT F

1 creates a priming effect. It also allows the bacteria
2 to break down more of the organic material that's in the
3 inoculum, also increasing the amount of methane
4 generated in these tests.

5 This is something that is recognized in the
6 literature. Dr. Barlaz testified that he had seen this
7 discussed in the anaerobic context.

8 The priming effect is real. It's referred to in
9 fact in a number of the tests that are in evidence. If
10 you read the conclusions, they talk about this, that
11 some of the results could be the result of the priming
12 effect.

13 Without controlling for the priming effect,
14 without showing that the plastic could -- will continue
15 to biodegrade and not become recalcitrant by conducting
16 a test past 60 percent, by not running tests that have
17 a negative control involving the same plastic product,
18 not just polyethylene in general but the same -- the
19 same cut of low linear density polyethylene or the same
20 polystyrene or the same PVC, without running tests with
21 those negative controls, without having information
22 about what the carbon content is for the sample, by
23 running tests with large amounts of inoculum and very
24 small sample sizes, all of these things affect the
25 integrity and validity of the results that come out of

1 appeared on a couple of -- a couple of Web sites.

2 So as I said, the law is clear that ECM is
3 liable for providing the means and instrumentalities to
4 disseminate deceptive claims to end-use consumers.

5 So the last thing I wanted to address is the
6 remedy here.

7 The order that we've asked the court to
8 enter --

9 JUDGE CHAPPELL: The proposed remedy?

10 MS. JOHNSON: Excuse me, Your Honor?

11 JUDGE CHAPPELL: The proposed remedy?

12 MS. JOHNSON: The proposed remedy, yes.

13 The notice order that was submitted with the
14 complaint and issued by the commission is -- and I
15 should just step back and say that the commission --
16 excuse me -- there is broad authority for entering
17 appropriate injunctive relief, and it's only
18 circumscribed by it being necessary to stop ongoing
19 deception and that it be clear and -- sufficiently clear
20 and precise to be understood.

21 JUDGE CHAPPELL: Let me ask you a big-picture
22 question, purely hypothetical.

23 Is it your position, if respondent were found
24 liable on merely the express claims, not any implied
25 claims, that the same remedy would be in store, would be

1 these tests. And our experts have reviewed them and
2 have rejected them as competent and reliable scientific
3 evidence to support the claims that ECM has -- is making
4 about complete biodegradation in a landfill in a
5 specific period of time.

6 And again, the last part of the analysis is, are
7 these claims material. And I've already walked through
8 the analysis. Biodegradability is the sole attribute
9 that this product confers to plastic.

10 And I've walked through the different lines of
11 evidence that consumers -- that consumers care about
12 biodegradable plastics and that consumers who care
13 about the environment care about biodegradable
14 plastics, and there's no question that these claims are
15 material.

16 The last part of our complaint alleges that ECM
17 provided the means and instrumentalities to pass along
18 deceptive claims.

19 We just walked through why the claims are
20 deceptive. And there's no denying the record is
21 replete with examples of ECM providing its logo,
22 providing advice to its customers on how to market,
23 providing them fliers to provide to downstream
24 consumers -- for their customers and consumers,
25 providing the Certificate of Biodegradability which

1 required?

2 MS. JOHNSON: Yes, Your Honor.

3 ECM for years has known that its testing
4 doesn't substantiate their claims. ECM doesn't even
5 own the technology that it -- that ECM additive
6 technology. There would be nothing prohibiting it from
7 making different claims going forward about a different
8 biodegradable technology.

9 I think the fencing-in relief is perfectly
10 appropriate whether there's liability on just the
11 express claims versus both the express and implied
12 claims.

13 So the first part of the injunction asks to
14 prohibit unqualified claims unless they're substantiated
15 by competent and reliable scientific evidence that the
16 plastic will completely biodegrade after customary
17 disposal within a year.

18 And this is supported by the consumer perception
19 evidence that we have in our record -- excuse me -- that
20 we've introduced into the record. That would still
21 allow the --

22 JUDGE CHAPPELL: And there's your drawing the
23 line at one year; is that correct?

24 MS. JOHNSON: Yes, Your Honor.

25 And that would still allow --

EXHIBIT G

37

1 that conclusion.
 2 COMMISSIONER OHLHAUSEN: -- you know, not what
 3 the scientist thinks of the claim but what the average
 4 consumer thinks.
 5 MR. EMORD: And the average consumer's thinking
 6 on that, based on the Stewart survey, mirrors the
 7 scientific definition, which is quite extraordinary.
 8 Consumers understand it to relate to the breakdown,
 9 biological breakdown of products, not rate.
 10 COMMISSIONER OHLHAUSEN: But it seems that it
 11 relates to -- they understand that it may be different
 12 for different products.
 13 MR. EMORD: Yes.
 14 COMMISSIONER OHLHAUSEN: But the fact that we
 15 are considering this in the instance of a plastic
 16 product, what is the evidence on what --
 17 MR. EMORD: There is no evidence that consumers
 18 have any particular awareness and indeed nothing in
 19 science of the scientific awareness that there would be
 20 any specific rate of biodegradation that you could
 21 ascribe to any particular plastic product, so it --
 22 CHAIRWOMAN RAMIREZ: Counsel, if I may focus on
 23 the question that was asked to consumers in the Stewart
 24 survey about plastic products, and that's the specific
 25 claim, question 5B. And as I read the results there, a

38

1 significant minority did take this claim to mean that
 2 the product would biodegrade within one year, so tell me
 3 why that is not an answer to the question that we've
 4 been asking.
 5 MR. EMORD: Well, I think that again you have to
 6 look at the totality of the information, and so --
 7 CHAIRWOMAN RAMIREZ: What should I look at that
 8 would tell me that a significant minority does not
 9 interpret this specific claim to mean that something
 10 will -- that plastic products will biodegrade within a
 11 year, so what -- don't refer to totality. Give me
 12 specifics.
 13 MR. EMORD: Okay.
 14 So we have a specific question that yielded a
 15 response, 4A: Do you think there are differences in the
 16 amount of time it takes for different types of products
 17 to biodegrade, decompose --
 18 CHAIRWOMAN RAMIREZ: So I should just ignore
 19 the -- are you telling me I should ignore the responses
 20 to 5B, which is taking the --
 21 MR. EMORD: No. I say look at it with regard to
 22 all of the questions asked --
 23 CHAIRWOMAN RAMIREZ: All of the questions in the
 24 survey.
 25 MR. EMORD: -- because really that's only the

39

1 fair way to judge what consumers understand.
 2 And as a response --
 3 CHAIRWOMAN RAMIREZ: Okay.
 4 MR. EMORD: -- if you were to take a part of the
 5 survey --
 6 CHAIRWOMAN RAMIREZ: Thank you.
 7 MR. EMORD: I'm sorry.
 8 CHAIRWOMAN RAMIREZ: So unless you want -- do
 9 you want to address any other topics? Your time is up,
 10 so...
 11 MR. EMORD: Well, I do, but I reserve ten
 12 minutes for rebuttal.
 13 CHAIRWOMAN RAMIREZ: Ten minutes? Well --
 14 all right.
 15 MR. EMORD: All right. Thank you very much.
 16 CHAIRWOMAN RAMIREZ: Thank you.
 17 Ms. Johnson?
 18 MS. JOHNSON: Thank you, Commissioners.
 19 Commissioners, this is a classic,
 20 straightforward case of deceptive advertising.
 21 ECM made express and implied claims. Those
 22 claims were false and unsubstantiated. Those claims
 23 were material.
 24 Now, ECM doesn't dispute the fact that it
 25 disseminated the express claim, the claim that plastics

40

1 treated with the ECM additive will completely break
 2 down in a landfill within five years and that --
 3 excuse me -- nine months to five years.
 4 And ECM concedes that these claims are false.
 5 Nothing will biodegrade in a landfill within five
 6 years.
 7 And one ECM expert offered the unsupported
 8 opinion that an ECM plastic will completely break down
 9 in somewhere between thirty to a hundred years.
 10 What ECM disputes in its appeal is the question
 11 of materiality, the materiality of the express claim.
 12 And there's abundant evidence in the record
 13 demonstrating that the express claim is material.
 14 But before I address that evidence, I wanted to
 15 talk about the issues that complaint counsel raised in
 16 its appeal.
 17 We challenged three things: the findings with
 18 respect to the implied claims, the findings with respect
 19 to the type and level of substantiation, and the
 20 findings with respect to the remedy.
 21 And I want to start by talking about the
 22 implied claims and specifically ECM's unqualified
 23 claim.
 24 Like its express claim, ECM doesn't dispute
 25 that it disseminated the unqualified claim. And it

57

1 least 35 percent of consumers understand biodegradation
 2 or the term "biodegradable" as a claim to mean complete
 3 decomposition in a landfill in less than one year.
 4 COMMISSIONER BRILL: Can I turn to the remedy
 5 issue? I don't know where we are on time, but I did
 6 want to ask you some questions about the remedy.
 7 Is that okay (directed to Chairwoman Ramirez)?
 8 Okay.
 9 So let's just assume for the moment
 10 hypothetically that a majority of the commission were
 11 to find that there was an unqualified biodegradable
 12 claim that was made that was unsubstantiated and just
 13 hypothetically we were to find liability.
 14 As I read your order, your proposed order in
 15 your opening brief, you seemed to ask for us to
 16 prohibit ECM from advertising that any product is
 17 biodegradable unless it, ECM, can substantiate that the
 18 products will completely decompose into elements found
 19 in nature within one year, yet you are arguing in the
 20 context of this de novo hearing that the failure that
 21 ECM -- the failure that we should find in terms of the
 22 substantiation is that ECM failed to substantiate the
 23 consumers' understanding that the products would
 24 biodegrade within five years or five years or earlier.
 25 So what I'm getting at is, there seems to be a

58

1 mismatch between what you're requesting in the order
 2 and what you're asking us to find in terms of
 3 liability. And I want to understand why that is and
 4 what would be the significance if we were, assuming
 5 again all the hypotheticals I said are true, we were to
 6 find liability here and we were to issue an order on
 7 this issue of the unqualified claim, if we were to
 8 issue this order that focused on the need to
 9 substantiate that the product will completely decompose
 10 into elements found in nature within five years rather
 11 than one year.
 12 MS. JOHNSON: The reason why the order is
 13 framed around one year is because the evidence
 14 demonstrates that there are significant minorities of
 15 consumers who understand the claim to mean exactly
 16 that. And the order is necessary to prevent both the
 17 ongoing deception that ECM is engaging in currently in
 18 using its claims and any future deception.
 19 Consumers --
 20 COMMISSIONER BRILL: Is there any difference
 21 really, though, given these products at hand, given --
 22 ECM is basically a one-product company; right? I mean,
 23 this is all that they produce, are these pellets to
 24 allegedly make plastic biodegradable.
 25 Is there any difference between one year and

59

1 five years given this product? In terms of whether --
 2 you know, the science that would substantiate either of
 3 those claims?
 4 MS. JOHNSON: No, there is no difference. For
 5 all practical purposes, nothing is going to biodegrade
 6 in a landfill within five years, let alone one year.
 7 COMMISSIONER BRILL: Not even banana peels.
 8 COMMISSIONER McSWEENEY: Let me follow up on this
 9 question.
 10 Are you aware of any laboratory tests that could
 11 adequately substantiate a claim that a product would
 12 decompose in a landfill, any laboratory tests that would
 13 adequately substantiate the claim?
 14 MS. JOHNSON: Could you repeat the question.
 15 I'm sorry.
 16 COMMISSIONER McSWEENEY: Are you aware of any
 17 laboratory tests that could adequately substantiate a
 18 claim that a product would decompose in a landfill?
 19 MS. JOHNSON: There are certainly tests that
 20 Dr. McCarthy identified that could substantiate claims.
 21 He identified a minimum threshold gas evolution
 22 test. That's a gas evolution test like ASTM D5511 but
 23 one that is designed to run for much longer periods of
 24 time and would have to reach a certain minimal
 25 threshold -- a certain minimum threshold of

60

1 biodegradation in a certain time frame. That's one test
 2 that ECM could use to substantiate its claim and,
 3 you know, substantiate any biodegradability claim.
 4 And the other is a radiolabeling test, a test in
 5 which you radiolabel the carbon in the long chains of
 6 polymers and use a scintillation device in order to
 7 count how much of the radiolabeled carbon comes out
 8 during the gas evolution test.
 9 Either one of those tests would demonstrate that
 10 the conventional plastic component of the plastic was
 11 biodegrading and being liberated through a
 12 biodegradation process and could be used, if carried out
 13 long enough, to determine that this process would in
 14 fact continue to completion.
 15 COMMISSIONER OHLHAUSEN: Counsel, I have a
 16 question.
 17 So you tried the case on the idea that the
 18 implied claim that consumers took from the unqualified
 19 biodegradable claim was that it would degrade within a
 20 year. And as Commissioner Brill has pointed out, that's
 21 how you also have it in the proposed order. But my
 22 understanding was, on appeal, you are arguing that it
 23 was actually an implied rate of one to five years.
 24 So what -- where is the source of my confusion?
 25 MS. JOHNSON: We've always held the position

61

1 that ECM's unqualified biodegradable claim conveyed
 2 complete decomposition in a landfill within one year
 3 and that a significant minority consumers would be
 4 deceived by any unqualified biodegradable claim.
 5 COMMISSIONER OHLHAUSEN: And I actually have a
 6 question about that, too.
 7 So looking at the Frederick GCS survey, his
 8 question -- he had a question on just a blank, unlabeled
 9 plastic bag and asked consumers what's the best estimate
 10 of time it would take for this plastic bag to
 11 biodegrade. Fourteen percent of the coded responses
 12 said it would biodegrade in one year and 26 percent said
 13 that it would biodegrade in five years or less.
 14 So what are we to make of that, if we're
 15 looking at a substantial minority, if you've got
 16 26 percent of these consumers saying plastic degrades
 17 in five years even if there is a biodegradable claim on
 18 the plastic? How does that play into what a significant
 19 minority is, considering for some of these one-year
 20 claims I think they're, you know, already down into the
 21 low end of the estimate?
 22 MS. JOHNSON: When Professor Frederick presented
 23 the same question to the respondents in his surveys with
 24 the "biodegradable" label on the plastic product, it
 25 substantially increased the numbers of people -- of

62

1 consumers who understood it to mean biodegradable in a
 2 landfill within one year and further increased the
 3 numbers who thought it to be --
 4 COMMISSIONER OHLHAUSEN: And then what is the
 5 difference there?
 6 MS. JOHNSON: I don't know the exact numbers,
 7 Commissioner. I apologize. But I can get them for you.
 8 But they're certainly in Dr. Frederick's appendix in
 9 which he shows the correlation between the two, the two
 10 different questions.
 11 So it's clear that when a plastic product bears
 12 a "biodegradable" logo, it does affect how consumers
 13 interpret the claim and it does increase the time that
 14 they estimate to complete biodegradation.
 15 CHAIRWOMAN RAMIREZ: So just so that I'm clear
 16 about this one versus five years, because there was
 17 certainly confusion in the briefing on that issue and
 18 the position that complaint counsel is taking, you are
 19 asking that the commission interpret, based on the
 20 evidence, the word "biodegradable" to impose a one-year
 21 limitation, is that right, or is it five years, so which
 22 of the two is it?
 23 MS. JOHNSON: There is certainly enough evidence
 24 in the record --
 25 CHAIRWOMAN RAMIREZ: So what is your position?

63

1 MS. JOHNSON: The position is one year.
 2 CHAIRWOMAN RAMIREZ: Okay.
 3 MS. JOHNSON: But even greater majorities -- a
 4 majority of consumers would be deceived by even a
 5 five-year claim. Or five-year time frame.
 6 So I was talking -- I was about to talk about
 7 the consumer perception evidence in the case,
 8 specifically APCO and Synovate, and how it's
 9 methodologically sound that Professor Frederick reviewed
 10 the two studies and concluded that they were reasonably
 11 reliable and valid. And Dr. Stewart concurred, said
 12 that they were both well-executed and well-designed on a
 13 number of dimensions.
 14 And really the only flaw that any of the experts
 15 identified with respect to the GCS -- excuse me -- with
 16 respect to the APCO and Synovate studies were the
 17 potential bias and the potential biases introduced in
 18 the two in two of the questions. APCO was skewed
 19 towards shorter time frames. Synovate was skewed
 20 towards longer time frames.
 21 And what Professor Frederick explained is that
 22 given these potential potentially opposing biases
 23 pulling the responses in opposite directions, it was
 24 remarkable and powerful evidence, that the fact that
 25 65 percent of the responses to APCO were five years or

64

1 less and 70 percent to Synovate were five years or less
 2 was powerful evidence that -- in the accuracy of those
 3 particular studies.
 4 And he was -- and based on his conclusion that
 5 they were reasonably reliable and valid, he was able to
 6 draw another conclusion that at least a significant
 7 number of consumers understand the claim to mean less
 8 than one year.
 9 But, of course, Professor Frederick did not
 10 rely on that evidence alone. He conducted -- he
 11 designed and executed a number of surveys using
 12 Google Consumer Surveys and asked a variety of
 13 questions in order to test the robustness of his
 14 conclusions with respect to APCO and Synovate.
 15 And when looking at the GCS surveys and
 16 particularly in comparing them to how Dr. Stewart
 17 conducted his surveys, it's clear that GCS is not only
 18 methodologically sound but more reliable in many ways,
 19 particularly to the issues probative in this case, than
 20 Dr. Stewart's study.
 21 COMMISSIONER OHLHAUSEN: Counsel, let me ask you
 22 another question.
 23 I actually found in my notes the difference in
 24 when the plastic bag was labeled with a "biodegradable"
 25 symbol or a claim. It shifted public -- it shifted the

EXHIBIT H

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Edith Ramirez, Chairwoman**
 Julie Brill
 Maureen K. Ohlhausen
 Terrell McSweeney

In the Matter of)	
)	
)	Docket No. 9358
ECM BioFilms, Inc.,)	
a corporation, also d/b/a)	
Enviroplastics International,)	CONFIDENTIAL DOCUMENT
)	
Respondent.)	
<hr style="border: 0.5px solid black;"/>		

**DECLARATION OF ROBERT SINCLAIR IN SUPPORT OF RESPONDENT’S
APPLICATION FOR STAY PENDING JUDICIAL REVIEW**

I, Robert Sinclair, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am over the age of eighteen years and I make this declaration on personal knowledge of its contents and in further support of Respondent’s Application for Stay Pending Judicial Review.

2. I am the President and CEO of ECM BioFilms, Inc. As a result of my job responsibilities, I have extensive experience with the operations of ECM BioFilms, Inc.

3. I have reviewed the Commission’s October 11, 2015 Order and Opinion (the “Order”). Based on my knowledge of ECM’s operations, and as the President of ECM, I have determined that the Commission’s Final Order will {

4. ECM sells one product, a biodegradable additive that, when added to plastics during the manufacturing process, renders the plastic biodegradable in substantially shorter periods of time than traditional or untreated plastics.

5. ECM's customers

6. The Final Order substantially limits ECM's ability to disseminate scientific information to consumers, including the many accelerated gas evolution biodegradability tests that have shown ECM plastic to be intrinsically biodegradable.

7. Those limitations on ECM's scientific speech prevent ECM from

8. The Final Order

9. ECM does not intend to use a Commission or Judicial Stay to continue or perpetuate its prior advertising claims. ECM intends to revise its advertising materials consistent with the scientific evidence produced before and at trial.

10. Since the FTC Green Guides were released in 2012, ECM has changed the claims it makes about its products. ECM previously claimed that plastic products infused with the ECM Additive will biodegrade within nine months and five years. However, ECM stopped making

that claim years ago, and has no intention of making that claim again, given that ECM now has more knowledge about its additive and the mechanism of action. ECM subsequently made the claim that plastic products amended with the ECM Additive would biodegrade in some period greater than a year. ECM believed that claim to be in compliance with the Green Guides. But it will now refrain from making that claim in the future.

11. ECM has

12. ECM sells its additive in a competitive market. There are at least {

}

13. ECM's projected 2015 revenues from gross sales is

}


14. ECM employs 6 individuals. In 2011, before the FTC changed the standards and then initiated this matter, ECM employed 7 individuals. The {

15. Put simply, {

16. Without a Stay of the Final Order, {

17. Without a Stay of the Final Order, { }

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed this 30th day of October, 2015.



Robert Sinclair

EXHIBIT I

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Edith Ramirez, Chairwoman**
 Julie Brill
 Maureen K. Ohlhausen
 Terrell McSweeney

In the Matter of)	
)	
ECM BioFilms, Inc.,)	Docket No. 9358
a corporation, also d/b/a)	
Enviroplastics International,)	CONFIDENTIAL DOCUMENT
)	
Respondent.)	
)	

**DECLARATION OF KENNETH C. SULLIVAN IN SUPPORT OF RESPONDENT’S
APPLICATION FOR STAY PENDING JUDICIAL REVIEW**

I, Kenneth C. Sullivan, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am over the age of eighteen years and I make this declaration on personal knowledge of its contents and in further support of Respondent’s Application for Stay Pending Judicial Review.

2. I am the Vice President and Chief Financial Officer of ECM BioFilms, Inc. As a result of my job responsibilities, I have extensive knowledge of the finances of ECM BioFilms, Inc.

3. I have reviewed the Commission’s October 11, 2015 Order and Opinion. Based on my knowledge and position with ECM, I have determined that the Order will {

}

4. The FTC litigation against ECM has :


5. In 2011, ECM had {

6. To {

:
:
:
:
:
:
:

7. ECM is a small company that had 7 employees in 2011 and has since reduced staff to its current level of 6 employees. ECM {

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed this 30th day of October, 2015.



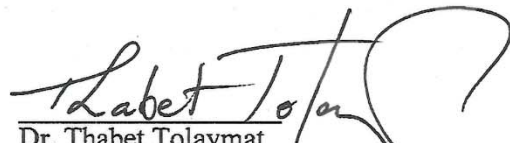
Kenneth C. Sullivan

EXHIBIT J

EXPERT REPORT OF DR. THABET TOLAYMAT
SUMMARY & CONCLUSIONS

I am environmental engineer with the United States Environmental Protection Agency (“EPA”). As an EPA engineer in solid waste management, I have substantial responsibility for, and experience with, United States (“U.S.”) landfills. In my expert opinion:

- Plastic products manufactured with ECM’s additive (“ECM Plastics”) will not completely biodegrade in five years or less under ordinary U.S. landfill disposal conditions. The most common waste disposal method in the United States is by landfill, and most landfills do not have conditions that would allow for complete biodegradation in that timeframe (or anywhere near that timeframe).
- ECM testing data are not competent and reliable scientific evidence that ECM Plastics will biodegrade in five years or less in most landfills because none of the tests ECM offers to substantiate its claims simulate the conditions (*e.g.*, oxygen, moisture level, temperature) found in typical U.S. landfills. Additionally, the tests are based on inaccurate assumptions and faulty calculations and have severe methodological shortfalls.
- The materials I analyzed to prepare this report are listed on Exhibit A hereto, and they include the materials upon which ECM relies to substantiate its claims. I am not aware of any competent and reliable scientific evidence that ECM Plastics will biodegrade in typical landfills any more rapidly than plastics made without the ECM additive.


Dr. Thabet Tolaymat
U.S. Environmental Protection Agency

DATED: 6-4-2014

pounds) will remain after 6 years. Comparatively, it would take almost 35 years for the same 50 pounds of mass to decompose in a Subtitle D landfill in an arid climate.

Table 1. Decay Rates and Half Life of Different Types of Landfills

Landfill Type	Precipitation (inch)	Decay Rate (yr ⁻¹)	Half Life (yrs)
Arid	<20	0.02	34.6
Moderate	20 to 40	0.038	18.2
Wet	> 40	0.057	12.2
Bioreactor	None	0.12	5.8

Waste, of course, is heterogeneous; different types of MSW will have different decay rates.

Table 2 below shows the IPCC’s decay values for various types of waste and climate.

Table 2. Ranges of Decay Rate (k) Values by Waste and Climate Type

Waste Type	Example of Waste Type	Decay Rate (k Values (yr ⁻¹))		Half-life (yrs)	
		Dry Climates	Wet Climates	Dry Climates	Wet Climates
Slowly degrading wastes	Paper, textiles, wood or straw	0.01 to 0.05	0.02 to 0.07	70 to 14	35 to 10
Moderately degrading wastes	Other [non-food] organic putrescible/garden and park waste	0.04 to 0.06	0.06 to 0.1	17 to 12	12 to 7
Rapidly degrading wastes	Food waste and sewage sludge	0.05 to 0.08	0.1 to 0.2	14 to 9	7 to 3.5
Bulk wastes	Combination of above materials	0.04 to 0.06	0.08 to 0.1	17 to 12	9 to 7

These more granular decay rates show that even in wet climates MSW that is readily biodegradable (*e.g.*, food waste) will take anywhere from 7-14 years to fully biodegrade.⁹ And the time for slowly degrading wastes takes up to 70 years in the same wet climate.

36. In short, whether considered by the entire landfill site, as in Table 1, or by the particular biodegradable component of the solid waste mass, as in Table 2, one would not expect complete biodegradation of even the most readily biodegradable component of MSW in the most favorable conditions in less than 7 years.

⁹ A rough estimate of the time to complete decomposition for fully degradable organics is double the half-life.

EXHIBIT K

765

1 which is going to have 500 kilograms of our stuff, which
 2 would be about 1100 pounds.
 3 JUDGE CHAPPELL: But where do they buy that? Do
 4 you have a storefront or is it online?
 5 THE WITNESS: No. They have to buy it directly
 6 from us, and you know, there's --
 7 JUDGE CHAPPELL: But I mean, where is "us"? How
 8 does a company buy your product?
 9 THE WITNESS: Well, eventually they're going to
 10 place an order, and we're going to fulfill that order
 11 and ship them the material from our manufacturing site,
 12 which is in Carpentersville, Illinois currently.
 13 JUDGE CHAPPELL: But how do they place the
 14 order?
 15 THE WITNESS: They would send it to Tom Nealis
 16 or they would send it to me or they would send it to
 17 customer service.
 18 And we have a procedure of putting that order
 19 in, of double-checking, you know, that we want to sell
 20 that company, that -- because these companies, first
 21 off, they have to be cleared. They have to sign a
 22 letter assuring us that they understand the correct
 23 loading rate is over 1 percent by weight, and then we
 24 certify them and their products thereafter.
 25 And so all that process -- and of course, you

766

1 have to go through credit checks and other things like
 2 that.
 3 JUDGE CHAPPELL: But can the product be
 4 purchased over the Internet?
 5 THE WITNESS: No.
 6 JUDGE CHAPPELL: And do you have a storefront or
 7 bricks-and-mortar office where customers can physically
 8 walk in and place an order?
 9 THE WITNESS: No. No, nothing of that sort.
 10 JUDGE CHAPPELL: Does ECM sell anything other
 11 than the pellets?
 12 THE WITNESS: No.
 13 JUDGE CHAPPELL: Go ahead.
 14 BY MR. EMORD:
 15 **Q. Do people place orders by phone?**
 16 A. They can. They can call in.
 17 **Q. Or do they send you a fax or --**
 18 A. Yeah. Generally they're going to follow up with
 19 a fax or an e-mail.
 20 But again, the correspondence can be in various
 21 forms, but it still has to go through all that process
 22 of being -- I actually -- I won't say for every single
 23 one because I'm out of town sometimes and then I'll have
 24 my CFO do it, but we go through a process where we
 25 approve every order, because it's not just a simple

767

1 thing that you would fill out an order from whoever
 2 would place it. This company has to have gone through
 3 all this process for us to fill out an order for them,
 4 however it comes in.
 5 **Q. How long does it take from the initial contact**
 6 **with a prospective customer until a company becomes an**
 7 **actual customer?**
 8 A. Well, in -- I would say the average is
 9 probably -- it's got to be six months to a year, and in
 10 some cases it's been several years.
 11 **Q. What do you tell customers that the ECM additive**
 12 **will do?**
 13 A. It makes their plastic product that they use it
 14 in biodegradable.
 15 But the key as well is that it is not going to
 16 affect them in a negative sense with their products in
 17 every other way.
 18 In other words, their product, if it is
 19 recyclable the way they manufacture it normally, with
 20 our additive is not going to affect that recyclability.
 21 Also, it's very important that it's discerned
 22 from other types of technologies out there because shelf
 23 life and usable life is very important to the customers
 24 obviously.
 25 In other words, if you make a product for some

768

1 function, let's say a bag for use in whatever, and yet
 2 in a storehouse someplace it falls apart or it
 3 deteriorates before it goes out and does that function,
 4 well, that's a horrendous waste and expense for
 5 companies, and so we have to be able to assure them and
 6 can that their plastic product is going to last on the
 7 shelf in a warehouse as long as it normally would
 8 without our additive.
 9 And so all these things -- and of course, cost
 10 is very important. All these things are the factors in
 11 what I would tell them, you know, of why this is their
 12 best option, is to take the end-of-life scenario for
 13 whichever one of these products it is and make it better
 14 than it was beforehand.
 15 **Q. Have you ever made a claim that the ECM additive**
 16 **would cause plastics to biodegrade within nine months to**
 17 **five years?**
 18 A. We certainly have, you know, used those words
 19 out there, but that was never a definitive claim.
 20 People do not buy it based on that type of claim. It
 21 simply is something that was used more in later years as
 22 we started out to differentiate our material from stuff
 23 that was also out there in the marketplace that would go
 24 poof, it's gone and be done and gone in six months or
 25 less in a specific place.