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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
ECM BioFilms, Inc.,	)	**Docket No. 9358**
a corporation, also d/b/a	)	
Enviroplastics International	)	

COMPLAINT COUNSEL'S POST-TRIAL REPLY BRIEF

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

I. INTRODUCTION

Respondent's two hundred twenty page brief and more than three thousand findings of fact tellingly failed to cite to any credible evidence to contest the key facts in this case. Specifically, that ECM made false and unsubstantiated claims; these claims—about the product's sole attribute—are material to its customers and to end-use consumers; and ECM provided the means and instrumentalities to pass these deceptive claims to end-use consumers. Instead, Respondent's lengthy brief raises several specious arguments in an unsuccessful attempt to cloud the relevant issues in this case.

ECM offers four spurious arguments that Complaint Counsel's Post-Trial Brief did not squarely address.[1] First, ECM argues that Complaint Counsel was required to put forward testifying fact witnesses. But Complaint Counsel satisfied its burden of production through the introduction of sworn deposition testimony of numerous fact witnesses, live testimony from its experts, and tens of thousands of pages of ECM's business records.

Second, ECM attempts to evade liability by making two arguments to obscure its lack of competent and reliable scientific evidence for its express and implied claims, both of which are meritless. ECM first argues that Complaint Counsel failed to demonstrate it lacked

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[1] ECM's other arguments that:

- Consumer perception evidence is methodologically flawed (Resp. Post-Tr. Br. at 43-49) is addressed in Complaint Counsel's Amended Post-Trial Brief at 26-54.

- ECM's marketing claims are immaterial to customers and end-use consumers (Resp. Post-Tr. Br. at 77, 167) is addressed in Complaint Counsel's Amended Post-Trial Brief at 76-83.

- Its claims are protected by the First Amendment (Resp. Post-Tr. Br. at 195) are addressed at Complaint Counsel's Amended Post-Trial Brief at 97-100.

- The proposed remedy is unlawful (Resp. Post-Tr. Br. at 201) is addressed at Complaint Counsel's Amended Post-Trial Brief at 90-97.

substantiation for its claims because we did not explore *why* tests showed zero biodegradation (which ECM generically refers to as "negative results"). It is not Complaint Counsel's burden to explore the cause for negative results, but ECM's burden to show that it has substantiation for its express and implied claims.

ECM also asserts its testing substantiates a claim not alleged in this case, *i.e.*, that ECM Plastics will biodegrade faster than untreated conventional plastics because some test results purportedly show more biodegradation than untreated plastic or that attributable to load rate of the Additive.[2] Even assuming, for the sake of argument, that some valid tests of ECM-treated plastic show methane generation exceeding the untreated plastic or the Additive load rate, this fact alone substantiates neither the claims challenged by Complaint Counsel nor the claim that ECM now alleges it made.

Third, ECM personally attacks Complaint Counsel's experts. But the record shows that leading experts in the relevant fields of degradable polymers and solid waste management evaluated ECM's purported substantiation and rejected it solely because it is unreliable and does not support ECM's express and implied claims. ECM has offered no evidence that demonstrates otherwise.

Fourth, unable to mount factual or legal arguments, ECM makes various policy arguments, all of which are meritless. This case is squarely within the public interest, it is not ultra vires or an unfair trade regulation, and Complaint Counsel has not violated ECM's due process. ECM has had a fair opportunity to conduct discovery, fully brief and argue its positions, and present evidence at the hearing.

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[2] Although not an allegation in our Complaint, the evidence clearly shows that ECM has no substantiation even for a claim that ECM-treated plastics will biodegrade in a landfill in 30 to 100 years, as now estimated by Dr. Sahu, the only of ECM's experts willing to estimate any time period to complete biodegradation. (FOF ¶ 132; 188.)

II. ARGUMENT

A. Complaint Counsel Met its Burden of Production.

ECM argues that Complaint Counsel failed to meet its burden of production because it did not present live fact witnesses at trial. (Resp.'s Post-Tr. Br. at 36-37.) This argument is meritless. While Complaint Counsel indeed has the burden of production for its Complaint allegations,[3] the Commission's Rules make clear that Complaint Counsel was not obligated to call fact witnesses at trial. *See* Rule 3.43(d) ("A party is entitled to present its case or defense by sworn oral testimony and documentary evidence . . . ."). *Cf.* Rule 3.43(b) ("If otherwise meeting the standards for admissibility described in this paragraph, depositions . . . shall be admissible and shall not be excluded solely on the ground that they are or contain hearsay."). Complaint Counsel presented substantial deposition testimony from fact witnesses that the parties expressly stipulated to admit in evidence during trial.[4] Complaint Counsel also introduced abundant evidence establishing ECM's liability through live expert testimony and thousands of pages of ECM's business records and third-party documents.[5] Indeed, the record has abundant, uncontested evidence of the widespread representations that ECM made to its customers, and the claims that were passed to end-use consumers.[6] Thus, Complaint Counsel has vastly exceeded its burden of production.

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[3] *See* Rule 3.43 ("[T]he proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.").

[4] *See* JX-1-A (including all deposition transcripts in this matter).

[5] (*See generally* Compl. Counsel's Post-Tr. Proposed Findings of Fact and Conclusions of Law.)

[6] By contrast, ECM promised to demonstrate that its customers were sophisticated, and that the totality of ECM's communications with them created a "net impression" other than the

Notably, in an attempt to bolster its unfounded argument, ECM grossly mis-cites *FTC v. Tashman*, 318 F.3d 1273 (11th Cir 2003), by citing the dissenting opinion as the holding in the case. (*See* Resp.'s Post-Tr. Br. at 37.) The *actual* holding in *Tashman* concluded that ample evidence supported the Commission's allegations against the defendant. *Tashman*, 318 F.3d at 1278 ("[T]he record contains overwhelming evidence that misrepresentations were made and that reasonable consumers were likely to (and, in fact, did) rely on those statements.").

B. ECM's Claims, Including the Comparative Claim, Are Deceptive.

ECM raises two new arguments to evade liability for its deceptive claims. First, it argues that it is Complaint Counsel's burden to show that the Additive does not work at all, and because some tests show methane production at levels that exceed untreated plastic and the 1% load rate of the Additive, that alone substantiates ECM's marketing claims.

Second, ECM urges the Court to accept its assertion that it did not make the "implied rate claim," *i.e.*, the unqualified biodegradability claim. ECM concedes that it made the express nine-month-to-five-year rate claim, but ECM argues that it merely conveyed the claim that ECM Plastics are "intrinsically biodegradable."[7] (Resp. Post-Tr. Br. at 6-7.) ECM contends that it has substantiated this claim. (Resp. Post-Tr. Br. at 79.)

These arguments have no merit for three reasons. First, ECM is wrong that Complaint Counsel is required to explain negative results to establish ECM's lack of substantiation. Complaint Counsel proved ECM's express and implied claims that ECM Plastic will biodegrade completely in a landfill within five years are false. And Complaint Counsel has shown these

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express claims in their marketing materials. (*See* Initial Prehearing Conf. Tr., at 19, 23.) However, ECM produced no live testimony from its customers, or any other evidence, to support this theory.

[7] ECM defines "intrinsically biodegradable" as ECM Plastics that "will biodegrade in a reasonably short period of time compared with conventional plastic, provided the environmental conditions are suitable for biodegradation." (Resp. Post-Tr. Br. at 88.)

claims to be unsubstantiated—the relevant scientific community demands a high level of substantiation for ECM's unorthodox claims, and ECM's proffered substantiation is inadequate.

Second, even if ECM's advertisements also conveyed a different, truthful claim, Complaint Counsel need only prove one reasonable interpretation of the advertisement is false or unsubstantiated to establish liability for deception under the FTC Act.

Third, even accepting ECM's proposition that the testing shows methane generation beyond the negative controls (the untreated plastic and the inoculum blank) or the load rate, this substantiates neither the claims challenged by Complaint Counsel nor the comparative claim that ECM now insists it made.

1. Complaint Counsel Met its Burden to Show ECM's Claims are Both False and Unsubstantiated.

ECM concedes that nothing biodegrades completely in a landfill within five years, thus ECM's express and implied claims that ECM Plastics will completely biodegrade in less than five years in landfills are false. (Compl. Counsel's Amended Post-Tr. Br. at 29-54, 86-88; *see* Resp. Post-Tr. Br. at 56-58 (admitting that it made the claim); FOF ¶ 188 (Dr. Sahu stating it could take 30-100 years for ECM Plastic to completely biodegrade); *see also* Compl. Counsel's Amended Post-Tr. Br. at 55-61.) In addition, well-documented anaerobic tests, including one study published in a peer-reviewed scientific journal (CCX-880), show zero biodegradation, further proving ECM's express and implied claims are false. (FOF ¶¶ 453; 454.)

Even though the evidence establishes that ECM's claims are false, ECM now asserts, without any authority, that Complaint Counsel must rule out various explanations it has proffered for the so-called negative test results to establish ECM lacks substantiation. (Resp. Post-Tr. Br. at 11.) In reality, once ECM satisfies *its* burden to show that it "possessed and relied" on some purported substantiation, Complaint Counsel must do only two things: (1) establish what

evidence the relevant scientific community would consider adequate to substantiate ECM's challenged claims; and (2) demonstrate that ECM's substantiation does not meet the standard laid out by the relevant scientific community. *FTC v. Direct Mktg Concepts*, 624 F.3d 1, 8 (1st Cir. 2010) (*citing Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1498 (1st Cir. 1989)) (internal citations omitted) ("When the FTC brings an action based on the theory that advertising is deceptive because the advertisers lacked a reasonable basis for their claims, the FTC must: (1) demonstrate what evidence would in fact establish such a claim in the **relevant** scientific community; and (2) compare [ ] the advertisers' substantiation evidence to that required by the scientific community to see if the claims have been established.") (emphasis added); *see also FTC v. Garvey*, 383 F.3d 891, 901 (9th Cir. 2004) (applying the same test).

Unlike ECM, which offered the testimony of consultants who are "not polymer scientists,"[8] have never run gas evolution tests,[9] and do not know how the ECM Additive effects plastic on a molecular level,[10] Complaint Counsel put forth the reports and testimony of experts qualified in relevant areas: a landfill expert and two biodegradable polymer experts (one from the plastic polymer perspective and the other from the microbiological perspective). ECM does not contend or cite to any evidence that these pre-eminent experts are not qualified in appropriate fields to evaluate ECM's biodegradability claims.

Collectively, Drs. McCarthy, Tolaymat, and Michel explain the scientific community requires appropriately-analyzed results of independent, well-designed, well-conducted, well-

[8] (FOF ¶ 176; Sahu, Tr. 1949.)

[9] (Sahu, Tr. 1952; Burnette, Tr. at 2449.)

[10] (Sahu, Tr. 1952; Burnette, Tr. at 2449.)

controlled testing to support ECM's claims.[11] The testing should use the appropriate plastic application, load rate, inoculum, test conditions, and sample weight, over an appropriate duration of time.[12] And tests must simulate the claimed disposal conditions.[13] (Compl. Counsel's Amended Post-Tr. Br. at 65.) Drs. McCarthy and Tolaymat reviewed all of ECM's substantiation and explained that ECM's tests are fatally lacking in one or all of these respects. (*See generally* Compl. Counsel's Post-Tr. Br. at 61-76.) For instance, they explained that ECM's tests are insufficient to demonstrate that the plastic, and not just the additive and inoculum, biodegraded. (CCX-891 ¶¶ 19, 44, 83.) And the results also do not necessarily reflect biodegradation of the high-molecular weight carbon backbone as opposed to the small percentage of low-molecular weight monomers. (FOF ¶¶ 135-144; 437-445; COL ¶ 42.) Many tests also do not reflect the recommended load rates, or were conducted under aerobic rather than anaerobic conditions. (*See generally* at Test Index.) Moreover, Drs. McCarthy and Tolaymat explain that biodegradation rates cannot be extrapolated beyond the test results, a fact not in dispute. (FOF ¶ 150; Barlaz, Tr. 2244-2245; RX-855 at 50.) Thus, the evidence unequivocally shows that ECM's tests cannot substantiate its claims. (*See generally* Compl. Counsel's Post-Tr. Br. at 61-76.)

Importantly, ECM's experts concede the inadequacy of ECM's substantiation:

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[11] (FOF ¶ 138.) ECM asserts that gas evolution tests can constitute competent and reliable scientific evidence to support biodegradability claims. However, ECM offers no specific evidence to rebut the testimony of Drs. McCarthy and Tolaymat that the specific tests conducted on ECM Plastic do not substantiate the claims at issue in this case. It merely argues that the type of scientific evidence demanded by our experts is too high. However, as explained, the level of substantiation they outlined is consistent with the reality that ECM's claims run contrary to well-accepted scientific consensus.

[12] (FOF ¶ 138.)

[13] (FOF ¶ 136.)

- Drs. Sahu and Burnette testified that the ASTM D5511 test does not simulate all landfills;[14]
- Drs. Burnette, and Barlaz testified that gas evolution tests like the BMP and ASTM D5511 are not appropriate tests for "slowly degrading" materials like ECM Plastic;[15]
- Dr. Baralz testified that aerobic tests are inapplicable to biodegradation in landfills, thus making almost half of the gas evolution tests irrelevant;[16]
- Dr. Burnette testified the ASTM D5511 test does not have the microbial diversity that would be expected in a landfill;
- Dr. Sahu and Barlaz testified that biodegradation rates cannot be extrapolated from a short-term test;[17]
- Dr. Sahu testified that necessary information that should have been reported was not in many of the reports;[18] and
- All of ECM's experts concede that at least some tests are "inconclusive" and showed "no biodegradation."[19]

ECM nonetheless argues that if methane generation exceeds the amount of the untreated plastic and the load rate of the Additive then it must be that the plastic biodegraded (the "more

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[14] (Sahu, Tr. 1928-1929; Burnette, Tr. 2373; 2439.)

[15] (Burnette Tr. 2372-73; 2388; Barlaz, Tr. 2230, 2267-68.)

[16] (FOF ¶ 182; *see* FOF ¶ 470.)

[17] (Sahu, Tr. 1795-1796; Barlaz, Tr. 2244-2245.)

[18] (Sahu, Tr. 1932-1933; 1940, 1961.)

[19] (Sahu, Tr. 1937; Barlaz, Tr. 2272-2274; Burnette, Tr. 2440.)

out than in" hypothesis). However, as our experts have explained, there are other possible explanations for these results, and the various tests did not adequately control for them, such as the priming effect.[20] Moreover, given ECM's "unorthodox" contention that conventional plastics can be rendered biodegradable through the addition of 1% biodegradable additive, which is unsupported by any peer-reviewed literature, there is a higher level of substantiation required than just a "more out than in" hypothesis. (CCX-892); *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1097 (9th Cir.1994) ("the standards to which you are held when one is testing an unorthodox theory really have to be quite rigid.").

ECM's conclusory analysis is more suspect because the only labs whose anaerobic results purport to show "more out than in" are Northeast Laboratories and Eden Research Laboratories. But long-term studies conducted by these two labs should be given little weight. Their undocumented, unorthodox modifications to the test utilizing methods such as re-inoculation make their results unreliable.[21] The fact that some tests showed "positive" results does not overcome the fact that the test themselves were flawed. *See FTC v. Pantron I Corp.*, 33 F.3d at 1097; *see also FTC v. QT*, 448 F.Supp.2d 908, 959 (N.D. Ill. 2006); *United States v. An Article . . .Acu–Dot . . .*, 483 F.Supp. 1311, 1315 (N.D. Ohio 1980).

2. ECM Violated the FTC Act Irrespective of the Comparative Claim.

ECM argues that it conveyed a claim that ECM Plastic biodegrades faster than conventional plastic (hereinafter referred to as the "comparative claim"). ECM does not cite to any extrinsic evidence to support the comparative claim. However, even if ECM made this

[20] (CCX-891 ¶¶ 19, 44, 83; 84; 90.)

[21] (FOF ¶¶ 142-143.)

claim, merely arguing that its advertisement is susceptible to another interpretation (even if such claim were truthful) does not absolve ECM for its liability for its deceptive claims.

It is well-settled FTC law that an ad may have more than one reasonable interpretation. *See, e.g., In re Telebrands Corp.*, 140 F.T.C. 278, 290 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006) (*citing Kraft*, 114 F.T.C. at 120-21 n.8)); *Thompson Medical Co.*, 104 F.T.C. 648, 787 n.7 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987) (An advertisement may have more than one reasonable interpretation). A marketer must substantiate all reasonable claims, and that an advertisement that is susceptible to both a misleading and a truthful interpretation will be construed against the advertiser. *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 127 n.6 (D. Conn. 2008) (*quoting Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 148 (2d Cir. 1964) ("Statements susceptible of both a misleading and a truthful interpretation will be construed against the advertiser.")). The evidence establishes that ECM's advertisements conveyed false and unsubstantiated claims that ECM Plastics will completely break down and return to nature within five years in a landfill. Accordingly, ECM's claims violate the FTC Act.

3. ECM's Comparative Claim is False and Unsubstantiated.

While Complaint Counsel does not need to prove the comparative claim is untruthful or unsubstantiated to prevail, the evidence nevertheless establishes that this claim is false and unsubstantiated.[22]

[22] ECM concedes that the comparative claim is material to its customers. (Resp. Post-Tr. Br. at 10.)

a. ECM's comparative claim is false because there is no known mechanism that allows biological organisms to break down large, molecular weight plastic.

ECM's comparative claim is false. First, as explained by Dr. McCarthy and Dr. Michel, two pre-eminent experts in the field of biodegradable polymers, untreated conventional plastics are not susceptible to breakdown by biological organisms. (FOF ¶ 5, 9; Michel Tr. 2097-2098.) A fact that Dr. Barlaz concedes is true. Dr. Barlaz (Barlaz, Tr. 2292 (traditional plastics in general do not biodegrade at all). Dr. McCarthy and Dr. Michel further explained that adding 1% of a known biodegradable polymer to a conventional polymer does nothing to change the underlying molecular structure of conventional plastics to increase their susceptibility to biodegradation.

In order for ECM's comparative claim to be true, the ECM Additive would have to change the largely undisputed scientific fact that conventional plastics cannot be broken down by biological means. But as outlined in Complaint Counsel's Post-trial brief, there is no evidence to support ECM's contentions that the additive "weakens" the carbon-carbon bonds on the main chain of the polymer, or that Additive acts as an attractant. (Compl. Counsel's Amended Post-Tr. Br. at 56-59; 72-73.)

ECM offered the testimony of two purported experts that have no relevant expertise (*see* FOF ¶ 176), who opine that conventional plastics are biodegradable based entirely on a literature search. However, the "opinions" offered by Drs. Sahu and Burnette are not credible. Their opinions are directly contradicted by the scientific literature on which they purportedly rely. (*See, e.g.*, (CCX-892 ¶¶ 10-16 (explaining why the articles cited by Dr. Sahu are irrelevant to ECM's claims); CCX-895 at 12; Michel, Tr. 2874 (explaining that the cited literature demonstrates that only pre-treated polyethylene is susceptible to biodegradation).)

b. ECM's comparative claim is unsubstantiated.

ECM's comparative claim is also unsubstantiated for two reasons: (1) there is no credible evidence in any of the tests that the any of the conventional plastic biodegraded; and (2) assuming biodegradation exceeded the negative controls and the load rate, the testimony of all the experts is unanimous biodegradation rates cannot be extrapolated. Finally, ECM's post-hoc rationalizations for why the more reliable tests showed negative and inconclusive results are meritless. Specifically, its explanations—manufacturing and testing issues—for the lack of results in some tests are illogical and contrary to the evidence.

i. There is no competent and reliable scientific evidence that the conventional plastic biodegraded.

Although ECM claims it has several positive results, there is no reliable evidence that any of the purported "positive" results show that the underlying conventional, non-degradable plastic biodegraded at all. (Compl. Counsel's Amended Post-Tr. Br. at 59-61.) Without competent and reliable scientific evidence that the conventional plastic biodegraded, ECM cannot substantiate a claim that an ECM Plastic will biodegrade comparatively faster than untreated plastic.

ii. There is No Evidence that ECM Plastic Would Continue to Biodegrade (Assuming it Biodegraded At All).

Even assuming that some of the tests showed more methane generation in the treated samples than the untreated samples (which they do not), that assumption does not provide substantiation for ECM's comparative claim. ECM's experts state that determining biodegradation rates is difficult, if not impossible. (Resp. Post-Tr. Br. at 87-91.) Nevertheless, they conclude that ECM Plastic will biodegrade faster than untreated plastic. This conclusion rests on the unsound hypothesis that the "rate" of biodegradation observed in the various tests can be extrapolated to conclusion. (FOF ¶ 149.) However, this proposition is contrary to

generally accepted scientific consensus that prohibits extrapolation of biodegradation rates beyond the four corners of the test. (FOF ¶ 150.)

Dr. McCarthy explains that even if the tests show some biodegradation above the negative controls and load rate, there is no scientific basis to conclude that the entire treated plastic will completely biodegrade faster than untreated plastic. (FOF ¶ 132; *see also* CCX-892 ¶¶ 22-23 (*citing* M. Parikh, R. Gross, and S. McCarthy, The Influence of Injection Molding Conditions on Biodegradable Polymers, Journal Of Injection Molding Technology, Vol. 2, No. 1, pp. 30-36, March (1998).) This is due to the recalcitrance of the underlying plastic. (FOF ¶ 133.) As Dr. McCarthy explained:

> The first material to biodegrade is the amorphous region of a polymer, which biodegrades at a fast rate. If the material were 50% crystalline, then the biodegradation rate would be very rapid until it reached 50% biodegradation. Once the amorphous region was degraded, the crystalline region would be left. The biodegradation rate would severely decrease (or even stop altogether) since the crystalline region is very difficult to biodegrade, as even Dr. Sahu concedes Sahu Report at 30. Therefore, during a biodegradation test, if the biodegradation rate calculated from the first 50% were to be extrapolated to 100%, an unrealistic (or impossible) rate of complete biodegradation would be the result.

(CCX-892 ¶ 23.)

This testimony is uncontroverted. Dr. Sahu concedes in his expert report that extrapolation is inappropriate. (RX-855 at 50 ("I agree trend extrapolation from shorter duration tests is not meaningful."). And both Drs. Barlaz and Sahu testified to the same at trial:

> Or if you wanted to detect in a slowly degradable material [using C-14 testing] what happens over the first month or two and then shut the test down and extrapolate, I suppose one could construct an argument. I wouldn't agree with it. Yeah, I would rather measure it than extrapolate.

(Barlaz, Tr. 2244-2245);

> Q. In the publicly available peer-reviewed literature and in your experience, have scientists ever extrapolated data from gas evolution tests

> that were conducted for less than a year to conclude that plastics will continue to biodegrade in a natural environment?
>
> A. I have not seen any kind of extrapolation to complete biodegradation, you know, in other words, taking a rate derived from a test and then extrapolating that and holding that that rate would remain constant and therefore trying to attempt a time period for complete biodegradation. That would be unusual.

(Sahu, Tr. 1795-1796.)

iii. ECM's post-hoc rationalizations for lack of biodegradation do not substantiate ECM's claims.

To overcome the fact that the most reliable tests reported that ECM Plastic is not biodegradable, ECM offers two post-hoc rationalizations. First, it asserts the Additive's efficacy requires strict adherence to ECM's manufacturing instructions. (Resp. Post-Tr. Br. at 82-86.) ECM cites to testimony by Dr. Sahu about a variety of manufacturing problems, such as scorching, that could negatively affect the efficacy of the Additive. (*See, e.g.*, Sahu, Tr. 1814-1815; 1942-1943.) ECM's suggestion that the ECM Additive could have been rendered inefficacious due to "scorching" or "burning" of the Additive during processing is a red herring. The argument is nothing more than unsupported conjecture; no expert evaluated the inoculum used for the tests or any ECM-containing plastic. Furthermore, no expert evaluated the extrusion procedures of the companies that prepared the samples.

ECM's explanation also runs contrary to its other assertions in this case. Specifically, ECM testified that its customers are "sophisticated plastics' manufacturers" who engage in a lengthy evaluation of the effect of the ECM Additive on the extrusion or injection processes. (Resp. Post-Tr. Br. at 177-182.) According to ECM, it also requires that its customers certify that they will comply with the minimum loading requirements. (Sinclair, Tr. at 783.) Finally, these customers are voluntarily sending these samples for testing to confirm biodegradability.

To suggest that these sophisticated plastics' manufacturers did not prevent scorching or other manufacturing mishaps that could negatively affect a biodegradation test makes little sense. And in the thousands of pages of business records, ECM has not identified one communication in which it notified a customer that a negative test result could be attributed to scorching or burning of the Additive during processing.

Second, ECM argues tests may be inconclusive due to a variety of factors resulting from the test design, as opposed to the Additive's efficacy. (Resp. Post-Tr. Br. at 138-139.) Drs. Sahu, Barlaz, and Burnette testified that closed-system tests, run for long durations, could lead to inhibitory conditions, such as high pH (acidity), that affect the viability of the inoculum. (Sahu Tr. 1928-1931; Burnette, Tr. 2374-75.)

ECM's "closed-system" inhibitory effect explanation is also unsupported. Notably, Dr. Barlaz testified that of the three potential causes of loss of microbial viability: (1) lack of sufficient substrate to support growth; (2) accumulation of inhibitory intermediates; and (3) nutrient depletion, the lack of sufficient substrate would be the most relevant to slowly degradable materials. (RX-943 (Barlaz, Dep. Tr. at 21).) Dr. Barlaz explained that the ratio of test material to inoculum makes accumulation of inhibitory intermediates unlikely. And the inoculum itself is nutrient rich, so he would be "pretty surprised if that is an issue." (RX-943 (Barlaz, Dep. Tr. at 21).) At trial, Dr. Barlaz admitted that inhibitory effects are just "theoretical"—he does not know whether any of the tests actually had these problems. (Barlaz, Tr. 2336-37.)

Dr. Michel's testimony and report further rebut ECM's flimsy conjecture that closed-system tests are inhibitory. Dr. Michel explains that there is incredible bacterial diversity in the inoculant. (Michel, Tr. 2852-2853; *see also* CCX-895 at 5-6.) And closed systems can be

maintained indefinitely. (Michel, Tr. 2958.) This is consistent with other evidence. For instance, Dr. Barlaz testified that he has been running a BMP test for "well over a year." (CCX-943 (Barlaz, Dep. Tr. at 63).) And the ASTM D5526 (a closed-system gas evolution test) has been validated to run for as long as 300 days. (CCX-86.) Finally, no lab identified "death of the microbes" as a possible cause for the lack of results (and in fact, most acknowledge that the positive control conclusively demonstrates a valid test). Dr. Michel's testimony regarding the diversity of microorganisms is unrebutted. (Burnette, Tr. 2470-71.)

C. Dr. McCarthy Does Not Have a Financial Interest in the Outcome of this Case that Affected His Opinion.

ECM's attempt to paint Dr. McCarthy as the hand of the so-called corn lobby is absurd. First, ECM's contention is not backed by any credible evidence that Dr. McCarthy considered anything other than the scientific evidence squarely before him, and rendered an opinion based on his considerable expertise. (*See* McCarthy, Tr. 688 ("Q: Can you tell us whether your opinions in this case have been affected by the -- your university's connection to Metabolix? A. No. Not at all.").) In fact, Dr. McCarthy's testimony is not rooted in a conspiracy to exclude ECM's "revolutionary technology" from the marketplace, but in the simple fact that the ECM Additive does not work as advertised. Indeed, the testimony and tests run by Dr. Barlaz, who presumably would not have been retained by ECM if he were in the pocket of the "nefarious" corn lobby, establishes as much. (FOF ¶¶ 166-169.)

Second, despite going to great lengths to paint Dr. McCarthy as a direct competitor of ECM, he is not. During his deposition, Dr. McCarthy testified that:

- He is the inventor on only one patent related to biodegradable plastics that generates any income at all, the so-called '199 Patent licensed to Metabolix;[23]
- He had no contact with Steve Mojo of BPI at least in the past year;[24]
- He has not worked for BPI for at least two years;[25]
- He has no other contact with BPI members;[26]
- He has no knowledge that either BPI[27] or Metabolix[28] had any contact with the FTC;
- His earnings related to BPI and Metabolix are limited;[29]
- He has no knowledge of the specific products made by Metabolix under the licensed patent, he has never seen a finished product, nor any marketing;[30]
- Prior to his involvement in this case, Dr. McCarthy had seen no document related to ECM;[31] and

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[23] (McCarthy Tr. 534-536.)

[24] (RX-841 (McCarthy, Dep. Tr. at 96).)

[25] (RX-841 (McCarthy, Dep. Tr. at 97).)

[26] (RX-841 (McCarthy, Dep. Tr. at 96).)

[27] (RX-841 (McCarthy, Dep. Tr. at 100).)

[28] (RX-841 (McCarthy, Dep. Tr. at 67-68).).

[29] Dr. McCarthy testified that the only income he presently earns from biodegradable plastics is through the Metabolix patent, for which he has only earned approximately $28,000 total over the lifetime of the patent (RX-841 (McCarthy, Dep. Tr. at 60); *see also* McCarthy Tr. 612) since the patent was issued in 1997 (*see* RX-362 ('199 Patent).). Moreover, he testified that his income through his certification work at BPI was only about $30,000 over 10 years, (RX-841 (McCarthy, Dep. Tr. at 97)). He also identified another approximately $5,000 as an expert witness for Metabolix in two patent infringement cases (in 2002 and 2005). (RX-841 (McCarthy, Dep. Tr. at 62).)

[30] (RX-841 (McCarthy, Dep. Tr. at 66).)

[31] (RX-841 (McCarthy, Dep. Tr. at 66).)

- Over 20 years, Metabolix has funded about $1.7 million in research at UMass—an annual rate of about $85,000;[32] but Dr. McCarthy does not receive any personal financial remuneration from project funding accounts where he is principal investigator.[33]

ECM's contention that Dr. McCarthy may benefit financially from the outcome of this case is simply untrue. In fact, Dr. McCarthy testified in detail regarding the nature of Metabolix's relationship with the University of Massachusettes, including testimony that Metabolix has suffered a financial setback (loss of its single source resin supplier) that has severely reduced the financial arrangements between the University and Metabolix. As Dr. McCarthy described it, Metabolix is "going out of business." (McCarthy, Tr. 603-606.) And because the '199 patent is "timing out soon," the University of Mass Lowell (who owns the patent) will likely be unable to license it to another entity. (McCarthy, Tr. 605.)

D. ECM's Policy Arguments are Meritless.

Left without viable legal or factual arguments, Respondent resorts to challenging the Administrative process. Specifically, ECM argues that this case is not in the public interest and violates its due process. For the reasons explained below, these arguments are meritless.

1. This Proceeding is in the Public Interest.

ECM makes two supposed "public interest" arguments. First, it argues that it did not market directly to consumers, but rather to sophisticated customers, who could not have been misled.[34] Second, ECM argues that Complaint Counsel has not shown injury to the public, and,

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[32] (RX-841 (McCarthy, Dep. Tr. at 66.)

[33] (RX-841 (McCarthy, Dep. Tr. at 54.) Dr. McCarthy also explained that, until this year, the research funding he brings into UMass had no bearing on his ability to get an increase in pay. (RX-841 (McCarthy, Dep. Tr. at 55).) And, now, at most, he could obtain a ½% increase in his salary for merit. *Id.* 55:13-22.

[34] Although this is a legal argument, we address it here because ECM raised this as a public interest argument.

in fact, the action is against the public interest because it will result in bad environmental policy. (Resp. Post-Tr. Br. at 195-200.) Neither position has merit.

a. ECM Deceived Customers and End-Use Consumers.

ECM's "sophisticated customer" argument is meritless for two reasons. First, there is no evidence that ECM's customers are more sophisticated than end-use consumers regarding the relevant topic: biodegradability of plastics. (Compl. Counsel's Post-Tr. Br. at 23; 29-54; 86.)

Second, ECM misapprehends the law and relies on inapposite cases. ECM relies on *Harad*[35] and *Arnold Stone*[36] for the proposition that there is no public interest where the representation is between a sophisticated buyer and purchaser. However, ECM misstates the holdings of these cases. In both *Harad* and *Arnold Stone*, the courts held that the public interest is not served where there is no deception, or potential for deception, of the intended audience. *In the Matter of Harad*, 50 FTC 300, 315 (1953); *Arnold Stone Co. v. FTC*, 49 F.2d 1017, 1018 (5th Cir. 1941). In both cases, the evidence failed to show that respondent's customers and consumers were deceived could have been deceived. *Harad*, 50 FTC at 315; *Arnold Stone Co. v. FTC*, 49 F.2d at 1018.

Here, there is substantial evidence that (1) ECM's customers and end-use consumers understand ECM's unqualified biodegradable marketing term to mean complete breakdown within one year in a landfill;[37] (2) ECM's customers and end-use consumers understood the express nine month to five year claim to mean precisely what it said;[38] and (3) ECM's customers

[35] *In the Matter of Harad*, 50 FTC 300, 315 (1953).

[36] *Arnold Stone Co. v. FTC*, 49 F.2d 1017, 1018 (5th Cir. 1941).

[37] (FOF ¶¶ 191-413.)

[38] (FOF ¶ 35; FOF ¶ 43.)

and end-use consumers were, or could be deceived, by ECM's marketing claims.[39] Finally, unlike *Harad* and *Arnold Stone*, the "existence of a public interest here rests on the deception practiced upon the public . . . . The 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." *FTC v. Irwin*, 36 FTC 626, 635 (1944). ECM provided the means and instrumentalities to pass the deceptive claims to downstream to end-use consumers. (Compl. Counsel's Post-Tr. Br. at 83-86.) Therefore, *Harad* and *Arnold Stone* are inapposite.

b. Effect on Environmental Issues is Not Relevant to Whether this Case is in the Public Interest.

ECM also argues that the consuming public has an understanding of the word biodegradable that, if enforced, will lead to more methane emission into the atmosphere. First, ECM has no evidence that allowing ECM to deceptively market its product has an environmental benefit. Moreover, Dr. David Stewart, ECM's consumer perception expert agreed that prohibiting claims like "nine months to five years" would serve the public interest unless they have scientific support. (FOF ¶ 191.)

Third, this argument assumes that the product works, and in a manner that could reduce methane emissions, but the evidence shows it does not. Additionally, assuming ECM can substantiate any efficacy, it could qualify its claim in a number of ways to make it non-deceptive.[40]

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[39] (FOF ¶ 25.)

[40] (*See* Compl. Counsel's Amended Post-Tr. Br. at 92, 93 (discussing scope of Notice Order provisions).)

Finally, even assuming the proposed order caused some negative environmental impact, the Supreme Court has previously rejected the argument that environmental impact is a license to deceive:

> Finally, the argument is made that the restraining orders are not necessary to protect the public interest (see *Federal Trade Commission v. Royal Milling Co.*, supra), but to the contrary that the public interest will be promoted by increasing the demand for pinus ponderosa, though it be sold with a misleading label, and thus abating the destruction of the pine forests of the east.
>
> The conservation of our forests is a good of large importance, but the end will have to be attained by methods other than a license to do business unfairly.

FTC v. Algoma Lumber Co., 291 U.S. 67, 81 (1934). Preventing methane from being emitted into the atmosphere is a laudable goal. But that does not mean ECM can deceive its customers and end-use consumers to achieve it.

2. The Action Against ECM is Not Ultra Vires or Unlawful Trade Regulation.

ECM argues that this action is *ultra vires* because it is, in effect, setting nationwide environmental policy, a power delegated to the EPA.[41] ECM also criticizes consumers' understanding of biodegradable because, it says, that understanding is at odds with the well accepted "scientific" definition of biodegradable. Both of these arguments misapprehend the relevant law.

First, ECM misleadingly characterizes this case as "setting" a definition of biodegradable. However, the actual issued presented, and the only relevant issue on this front, is whether consumers' understanding of ECM's unqualified biodegradability claim is reasonable even if inconsistent with the scientific definition. *See, e.g.*, *Pantron*, 33 F.3d at 1099-1100;

[41] To the extent that ECM asserts that the effect of the injunction will be to prevent ECM from marketing its product, this argument is addressed elsewhere in our Reply.

Algoma Lumber, 291 U.S. at 74-76. On this issue, Dr. Frederick explained, the population of American consumers whom a false biodegradable claim might deceive includes many consumers whose understanding of "biodegradation" is mistaken or incomplete according to scientists, and consumers who believe "biodegradability" is a positive attribute even if they do not know precisely why. (FOF ¶ 349; Compl. Counsel's Amended Post-Tr. Br. at 46-47.) Indeed, Dr. Stewart reluctantly concurred that a consumer might purchase a product "because he or she thinks biodegradation is a positive attribute even if his or her understanding of the term is scientifically incorrect," and such a consumer "can still be misled if the product doesn't biodegrade as he or she understands the term[.]" (FOF ¶ 350.) Any alleged conflict with either environmental policy or the scientific definition is irrelevant to the question of whether the interpretation is reasonable. *See generally FTC v. Algoma Lumber Co.*, 291 U.S. at 77-81 (holding that marketing of lower grade pine as "California White Pine" where consumers and retailers understood white pine to refer to a more durable wood was deceptive, despite that the Bureau of Standards used the term "California White Pine").

3. This Action Does Not Violate Due Process.

a. The FTC Proceeding Does Not Violate the Separation of Functions Doctrine.

Respondent contends that Part III administrative proceedings violate the separation of functions doctrine and, therefore, deprive Respondent of due process. (Resp. Post-Tr. Br. at 211-213.) Not so. This argument ignores decades of established law that the Commission's combined investigative and judicial functions do not violate due process. *See, e.g.*, *Kennecott Copper Corp. v. FTC*, 467 F.2d 67, 79 (10th Cir. 1972) ("[C]ourts have uniformly held that [the Commission's combination of the investigator, prosecutor, and judge functions] does not make out an infringement of the due process clause of the Fifth Amendment."); *FTC v. Cinderella*

Career & Finishing Schools, Inc., 404 F.2d 1308, 1315 (D.C. Cir. 1968) (noting the Commission's practice of reviewing the recommendations of subordinate investigative employees of the Commission and then making the decision to initiate a complaint is clearly excepted from the Administrative Procedure Act) (emphasis added). Moreover, the Commission is entitled to a presumption of regularity and good faith in the exercise of its administrative duties. *FTC v. Owens-Corning Fiberglas Corp.*, 626 F.2d 966, 975 (D.C. Cir. 1980) (citations omitted).

ECM's due process argument also fails factually for at least three reasons. First, Respondent has not presented (and could not present) any evidence that the Commission or its staff acted in bad faith or engaged in impropriety at any point in these proceedings. Second, Respondent has had a full opportunity to defend itself throughout each stage of this litigation and will continue to receive such an opportunity during any post-trial proceeding that may arise. *See, e.g.*, Rule 3.52 (providing procedures for parties to appeal the initial decision); Rule 3.55 (providing procedures for parties to petition the Commission for reconsideration of its decision). Finally, as explained in Complaint Counsel's post-trial brief, Complaint Counsel's proposed relief would still permit Respondent to make truthful unqualified or qualified biodegradability claims as long as the claims were truthful and supported by a reasonable basis.[42] For these reasons, Respondent's separation of function argument fails.[43]

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[42] (*See* Compl. Counsel's Amended Post-Trial Brief at 92-94.) Even if the effect of the order might be to put ECM out of business, its due process violation argument fails. *Slough v. F.T.C.*, 396 F.2d 870 (5th Cir. 1968) (5th Circuit held that operator of collection service was not denied due process of law even though effect of Commission's order might be to put operator out of business),

[43] Citing *Leer Elec., Inc. v. Penn. Dep't of Labor and Indus.*, 597 F. Supp. 2d 470 (M.D. Pa. 2009), Respondent claims that the Commission has an interest in the outcome of the litigation sufficient to violate the separation of functions doctrine. But *Leer Elec., Inc.* addressed

b. Complaint Counsel Did Not Engage in Abusive Discovery Practices.

Respondent asserts that Complaint Counsel engaged in multiple instances of discovery abuse that denied it due process. (Resp. Post-Trial Brief at 213-217.) These arguments are baseless. In the two resolved discovery disputes Respondent refers to (and for one of the disputes, attempts to relitigate), Respondent was given meaningful opportunities to fully brief and argue its positions, and as it notes, even received a favorable ruling on one of the issues.[44] Thus, Respondent cannot persuasively contend that it was denied sufficient due process during those matters. Furthermore, although Respondent bewails the number of depositions taken by Complaint Counsel in this case, the associated costs of those depositions, and the evidentiary value of deposition testimony, those arguments are likewise unconvincing for at least two reasons. First, Respondent has offered no evidence (and could not offer any evidence) that Complaint Counsel scheduled and conducted the depositions in bad faith.[45] Second, Respondent participated in each of the depositions, including making objections and cross-examining deponents as it saw fit, and stipulated to the admissibility in the evidentiary record of all

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whether the plaintiffs in the case sufficiently pled due process violations under a civil rights statute and did not concern a Commission enforcement action. Accordingly, *Leer Elec., Inc.* is unavailing to Respondent.

[44] *In re ECM Biofilms*, Dkt. No. 9358, Order Granting In Part And Denying In Part Respondent's Motion for Sanctions (March 21, 2014), *available at* http://www.ftc.gov/system/files/documents/cases/140321orderrespsanctions.pdf; *In re ECM Biofilms*, Dkt. No. 9358, Order Denying Respondent's Motion for Sanctions for Unauthorized Dissuasion of Response to Subpoena Duces Tecum (April 9, 2014), *available at* http://www.ftc.gov/system/files/documents/cases/140409orderdenysanctions.pdf.

[45] Indeed, Complaint Counsel scheduled all depositions in this case *in coordination with* Respondent.

deposition testimony.[46] Thus, Respondent's discovery abuse argument falls flat and the Court should reject it outright.

c. There Was No Unfair Surprise.

Respondent claims that it was denied due process through unfair surprise based on the participation of Complaint Counsel's rebuttal expert, Dr. Frederick Michel, and the denial of its request to call Dr. Steven Grossman as a surrebuttal witness. (Resp. Post-Tr. Br. at 217-220.) Respondent is merely attempting to relitigate discovery disputes that the Court has already resolved and in which Respondent had the full opportunity to argue and present evidence.[47] Moreover, because Respondent was permitted to depose Dr. Michel before trial (which it did) and cross-examine him at trial (which it did), and make an offer of proof as to Dr. Grossman's expected testimony (which it made), it can hardly claim that it was not afforded adequate due process to challenge Dr. Michel's opinions and defend itself. Respondent's argument is therefore groundless.

III. CONCLUSION

For the reasons stated above, Respondent's practices, as alleged in the Complaint, constitute unfair or deceptive acts or practices, in or affecting commerce, in violation of Sections

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[46] *See* JX-1-A (including all deposition transcripts in this matter).

[47] *See In re ECM Biofilms*, Dkt. No. 9358, Order Denying Complaint Counsel's Motion for Leave to Call Rebuttal Fact Witnesses and Respondent's Request to Bar Rebuttal Expert Witness (Sept. 5, 2014) at 5, *available at* http://www.ftc.gov/system/files/documents/cases/571791.pdf ("As to whether Dr. Michel's testimony constitutes fair rebuttal to the opinions of Respondent's proffered experts, it has already been held in this case that Dr. Michel's report constitutes fair rebuttal."); *In re ECM Biofilms*, Dkt. No. 9358, Order on Respondent's Combined Motion for Sanctions, to Exclude Expert Witness and for Leave (June 23, 2014) at 4, *available at* http://www.ftc.gov/system/files/documents/cases/571095.pdf (denying Respondent's request for leave to offer surrebuttal expert testimony as unjustified and untimely).

5(a) and 12 of the FTC Act. Complaint Counsel respectfully requests that the Court enter the relief proposed in the Commission's Notice Order.

Dated: October 16, 2014

Respectfully submitted,

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TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
1	OWS PFR-1 (CCX 161)	1998	Aerobic Biodegradation under controlled composting conditions (ISO 14855 and ASTM D5338)	45 days	5% black film 5% natural film	4.5%± 9.6% 2.6%±4.4%	• Aerobic tests irrelevant to Anaerobic biodegradation (RX-853 at 7 (Barlaz, Tr. 2299-2300)). • Load rate exceeds recommended load rate (CCX-891 at 14). • Well-documented, "Well-conducted scientific testing" (CCX-891 at 13); (McCarthy, Tr. 465-470); (Sahu, Tr. 1932-1933; 1940, 1961); *See also* Complaint Counsel's FOF 453. • Conclusion stated in test: "No biodegradation significantly different than zero." (CCX-161 at 3.)
2	OWS PFR-2 (CCX-162)	1998	Aerobic Biodegradation under controlled composting conditions (ISO 14855 and ASTM D5338)	45 days	50% Load Film (60 days) 5% Load ECM film 10% Load ECM Film	19.1%±4.3% 0%±2.7% 1.1± 1.1%	• Cellulose achieved 120% biodegradation which "can result if a 'priming effect' has occurred." (CCX-162 at 28; *see also* CCX-891 at 8). • Aerobic tests irrelevant to Anaerobic biodegradation

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
							(RX-853 at 7 (Barlaz, Tr. 2299-2300)). • Load Rate exceeds recommended load rate (CCX-891 at 14). • Well-documented, "Well-conducted scientific testing" (CCX-891 at 13); (McCarthy, Tr. 465-470); (Sahu, Tr. 1932-1933; 1940, 1961); *See also* Complaint Counsel's FOF 453. • Conclusion stated in test: "biodegradation for two film samples [5% and 10% Load films] were biodegradation significantly different from zero." (CCX-162 at 3.)
3	McLaren/Hart (RX 269)	1999	Scientific Evaluation and Review of existing study data (anaerobic/aerobic report)	15 days 22 months	ECM Pellet 5% ECM Film	24% (pellet) Qualitative evidence of biodegradation (film)	• Summary of faulty tests. Does not independently evaluate ECM Plastic (CCX-891, 13-16). • Unclear where the underlying tests are (RX-269). • Load Rate exceeds recommended load rate (CCX-891 at 14). Qualitative tests (CCX-891, 33-34) *See also* (CCX-891 at

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
							13).
4	OWS PFR-4 (RX 265)	1999	High Solids Anaerobic Digestion (HSAD) concept test	15 days	ECM pellet	24.0%	• Load Rate exceeds recommended load rate "ECM Pellet 100%" (CCX-891 at 14). • Wrong temperature (CCX-891 at 15). • 15-day test too short (CCX-891, 15-16).
5	OWS PFR-5 (CCX-159)	2000	Aerobic Biodegradation Under Controlled Composting Conditions (40 Gal Trash Bag)	45 days	Treated bag	5.2%±8.3%	• Aerobic tests irrelevant to Anaerobic biodegradation (RX-853 at 7 (Barlaz, Tr. 2299-2300)). • Load rate unreported (CCX-891 at 14). • Plastic type unreported (CCX-891, 13-14). • Conclusion stated in test: "biodegradation measurement does not indicate whether or not any other breakdown of the sample has taken place" (CCX-159 at 21).

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
6	AMC Environmental, Material, and Product Evaluation (CCX-160)	2000	ASTM D5338 for Robert Sinclair	Unreported	PP Meshing 1% Resin Tape 1% PE Pallet Wrap 1%	Weight loss test	• Aerobic tests Irrelevant to Anaerobic biodegradation (RX-853 at 7 (Barlaz, Tr. 2299-2300)). • Conclusion stated in test: "In our opinion, based on the weight loss values from all samples, this test indicated all the samples had poor aerobic compostability" (CCX-160 at 3).
7	Univ. of NM Electron Microscopy (RX-270)	2006	Scanning Electron Microscope (SEM) images of treated test samples	n/a	Treated bubblewrap	Qualitative evidence of biodegradation	• Does not conclude item will completely biodegrade (RX-270, 2-3). • Origin of sample is unknown (CCX-891, 13-14) • Load rate is unknown (CCX-891 at 14). • Exposure time unknown (CCX-891, 15-16). • Environmental conditions of test unknown (CCX-891 at 15). Qualitative tests (CCX-891, 33-34) *See also* (CCX-891 at 13). • Conclusions are limited to observation of pitting on

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
							surface and states that it is "probably" related to microbial breakdown, but compares it to pitting on rocks caused by microbial attachment (RX-270, 2-3).
8	Univ. of NM Electron Microscopy (RX-271)	2006	Scanning Electron Microscope (SEM) images of treated test samples	n/a	PET bottles	Qualitative Analysis	• Insufficient information: Origin of sample is unknown (CCX-891, 13-14). • Load rate is unknown (CCX-891 at 14) • Exposure time unknown (CCX-891, 15-16). • Environmental conditions of test unknown (CCX-891 at 15). Qualitative tests (CCX-891, 33-34) *See also* (CCX-891 at 13). • Does not conclude item will completely biodegrade (RX-270, 2-3). • Conclusions are limited to observation of pitting on surface and states that it is "probably" related to microbial breakdown, but compares it to pitting on rocks caused by microbial

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
							attachment (RX-270, 2-3).
9	Univ. of NM Electron Microscopy (RX-271)	2006	Scanning Electron Microscope (SEM) images of treated test samples	n/a	PVC Foam	Qualitative Analysis	• Qualitative tests (CCX-891, 33-34) *See also* (CCX-891 at 13).
10	Univ. of NM Electron Microscopy (RX-271)	2007	Scanning Electron Microscope (SEM) images of treated test samples	n/a	Treated PS foam	Qualitative	• Does not conclude item will completely biodegrade (RX-271 at 2). • Origin of sample is unknown (CCX-891, 13-14). • Load rate is unknown (CCX-891 at 14). • Exposure time unknown (CCX-891, 15-16). • Environmental conditions of test unknown (CCX-891 at 15). Qualitative tests (CCX-891, 33-34) *See also* (CCX-891 at 13). • Conclusions are limited to observation of pitting on surface and states that it is "probably" related to microbial breakdown, but compares it to pitting on rocks caused by microbial attachment (RX-271 at 2).
11	Environ (RX 254)	2008	Anaerobic study	9 months	Amended PVC	2.7% weight loss	• Weight loss studies are "not competent and reliable scientific evidence of

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
							biodegradation" (CCX-891 at 18). • Underlying data not reported • No statistical data reported (CCX-891 at 13). • Uses wrong kinetic model to determine a half-life (RX-853, 9-13) *See also* (Barlaz, Tr. 2293-2296). • Load rate unreported (CCX-891 at 14). • No biodegradation after month 7 (plateau) (CCX-891 at 28).
12	NCSU (CCX-954)	2009	Anaerobic BMP for WMA	61	ECM - Additive 2 Cutlery Plates	.17 ml CH4/gm .41 ml CH4 /gm Weight loss	• Conclusion stated in report: average methane production for both ECM samples are "not statistically different from negative control" (CCX-954 at 2). • Weight loss: "no weight losses were different from the negative control" (CCX-954) *See also* Weight loss studies are "not competent and reliable scientific evidence of biodegradation" (CCX-891 at 18).

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
13	O.W.S. (CCX-163)	2009	Anaerobic ASTM D5511-02 for Masternet	15 days	Unreported	-3.7%±0.3%	• Wrong temperature (CCX-891 at 15). • 15-day test too short (CCX-891, 15-16). • Well-documented, "Well-conducted scientific testing" (CCX-891 at 13); (McCarthy, Tr. 465-470); (Sahu, Tr. 1932-1933; 1940, 1961); *See also* Complaint Counsel's FOF 453. • Conclusion states: "The test item plastic netting cannot be regarded biodegradable under dry anaerobic conditions" (CCX-163 at 6).
14	NE Labs N0843980 (RX 399)	2008	ASTM D5511 study for Bio-Tec Environmental LLLC	14 days	PP Sheet	8.4% weight loss	• Wrong temperature (CCX-891 at 15). Load rate unreported (CCX-891 at 14). • Weight loss test inaccurate, *See* Weight loss studies are "not competent and reliable scientific evidence of biodegradation" (CCX-891 at 18). • No underlying data; gas data collected but unreported (CCX-891 at 13). • Gas data reported as "inconclusive" (RX-399 at 2)

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
15	NE Labs N0946510-01 (RX 398)	2009	ASTM D5511 study for Masternet Ltd.	15 days	PE/1%	4.91%	• Wrong temperature (CCX-891 at 15). 15-day test too short (CCX-891, 15-16). • No statistical analysis (CCX-891 at 13). • Within the error margin of the analytical equipment ((CCX-891 8, 16-17, 36) *See also* CCX-891 at 28)
16	SSCCP (RX 465)	2009	UNI EN 14043/2003, aerobic degradation test of Italcom product	91 days	PET PVC Film	4.95% (PET) 50.09% (PVC) 4.80 (Film)	• Load rates unreported (CCX-891 at 14). • Underlying data unreported (CCX-891 at 13). • Aerobic tests Irrelevant to Anaerobic biodegradation in landfill conditions (RX-853 at 7 (Barlaz, Tr. 2299-2300)).
17	Clemson Univ. Study (RX 388-91)	2009	*In situ* testing of various treated samples for Dispozo Products Inc.	477 days	EcoPure	Qualitative evidence of biodegradation	• Qualitative study sponsored by Dispoz-o, Qualitative tests (CCX-891, 33-34) *See also* (CCX-891 at 13).
18	NE Labs 1048742-01 (RX 405)	2010	ASTM D5511 study for Eco SmartPlastics	45 days	LDPE/1.5%	7.37%	• Unclear whether contains ECM Additive (RX-405) *See also* CCX-891, 13-14. • Wrong temperature (CCX-891 at 15). • No statistical analysis (CCX-891 at 13).

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
19	NE Labs 1048819 (RX 396)	2010	ASTM D5511 study for Eco SmartPlastics	45 days	PET	7.01%	• Unclear whether contains ECM Additive (RX-396) *See also* CCX-891, 13-14. • Wrong temperature (CCX-891 at 15). • No statistical analysis (CCX-891 at 13).
20	NE Labs 1048215 (RX 863)	2010	ASTM D5511 test for Dansko	15 days	Rubber/2.5%	1.5%	• Wrong temperature (CCX-891 at 15). • No statistical analysis (CCX-891 at 13).
21	Ecologia Applicata s.r.l. (CCX-741)	2010	UNI EN ISO 14855, aerobic degradation, for Co.ind. s.c.	180 days	PP/1%	19.3%	• Aerobic tests Irrelevant to Anaerobic biodegradation (RX-853 at 7 (Barlaz, Tr. 2299-2300)). • No underlying data; No statistical analysis (CCX-891 at 13). • Does not reach above 60% (CCX-891 15-16).
22	OWS BFI-1 (RX 268)	2010	High Solids Anaerobic Digestion (HSAD) Test for Covidien	15 days	PP	3.9%	• Wrong temperature and moisture shows 3.9±1.1% (CCX-891 at 15). • Concludes that plateau was reached after 15 days and that "no further biodegradation is expected. It seems that only a minor component or some minor

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
							residual chemicals (monomers) are degradable" (RX-268 at 7) *See also* CCX-891 at 28.
23	Eden MicroTek (RX-861/CCX-534)	2011	ASTM D5511 test for MicroTek	811 days	PE	17.9%	•
24	Sondor (RX 274)	2011	Sondor Biofoam degradation test	775 days	Various/2%	Qualitative evidence of biodegradation (mass loss, etc.)	• Qualitative analysis with limited data (CCX-891, 33-34) *See also* (CCX-891 at 13); not all data reported (CCX-891 at 13). Unclear what the underlying plastic is made of; conclusion by author that at least one of the plastics (SPX) was more degradable without the additive (CCX-891, 13-14).
26	Ecologia Applicata s.r.l. (RX 276)	2011	UNI EN ISO 14855, aerobic degradation, for Colplast S.r.l.	180 days	Polyammide & Nylon/% unknown	46.67%	• Aerobic tests Irrelevant to Anaerobic biodegradation in landfills (RX-853 at 7 (Barlaz, Tr. 2299-2300)). • Load Rate Unknown (CCX-891 at 14). • Positive control exceeds 100% biodegradation; author concludes that it is a result of the "Priming Effect" *See also* (CCX-891 at 8).

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
26	Eden 092511B (RX 248)	2011	ASTM D5511, for FP International	120 days	Airbag film/1% Samples 223-224	11.5% 15.2%	• Wrong temperature (CCX-891 at 15). • Does not show complete biodegradation (CCX-891 at 8). • Does not have statistical analysis of data (CCX-891 at 13). • Does not control for priming effect (CCX-891 at 8).
27	Eden FPI (CCX 1097)	2011	ASTM D5511 for FP International	977 days	Air bag (TKN)/1% Air bag (HOP)/1% Samples 223-224	36.7% 39.8%	• States the test was conducted outside of ASTM D5511 protocol, but does not indicate what method was followed (RX-403 at 2). • Wrong temperature (CCX-891 at 15). • Does not show complete biodegradation (CCX-891 at 8). • Does not have statistical analysis of data (CCX-891 at 13). • Does not control for priming effect (CCX-891 at 8).
28	NE Labs 1150851 (RX 395)	2011	ASTM D5511 study for Sweet Tape Enterprise (M) Sdn. Bhd.	45 days	PP	4.54%	• Unclear whether contains ECM Additive (RX-395) *See also* CCX-891, 13-14. • Wrong temperature (CCX-891 at 15).

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
							• Does not have statistical analysis of data (CCX-891 at 13).
29	NE Labs 1150851 (RX 394)	2011	ASTM D5511 study for Tycoplas Sdn Bhd	15 days	PS foam	5.89%	• Wrong temperature (CCX-891 at 15). • Does not have statistical analysis of data (CCX-891 at 13). • Load Rate unreported (CCX-891 at 14).
30	NE Labs 1048036 (RX 392)	2011	ASTM D5511 study for Transilwrap Co.	233 days	Film Laminate	7.85% 8.53%	• Unclear whether contains ECM Additive (RX-395) *See also* CCX-891, 13-14. • Wrong temperature (CCX-891 at 15). • Does not have statistical analysis of data (CCX-891 at 13).
31	NE Labs 1149980 (RX 838)	2011	ASTM D5511 & D6579 tests for Minigrip	365 days	LDPE/LLDPE/1.5 %	17.07%	• Wrong temperature (CCX-891 at 15). • Does not have statistical analysis of data (CCX-891 at 13). • Load Rate exceeds recommended load rate (CCX-891 at 14).
32	NE Labs 1253020 (RX 393)	2012	ASTM D5511 study for National Tree Co.	15 days	PVC PE	9.89% 5.75%	• Eden tests unreliable. FOF ¶ 144. • Unclear whether contains ECM Additive (RX-395) *See also* CCX-891, 13-14. • Wrong temperature (CCX-891 at 15).

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
							• Does not have statistical analysis of data (CCX-891 at 13).
33	Eden 070312C (RX 839)	2012	ASTM D5511, for Shields Bag & Printing	22 weeks	Film/1%	7.9%	• Unclear whether contains ECM Additive (RX-395) *See also* CCX-891, 13-14. Wrong temperature (CCX-891 at 15). Does not have statistical analysis of data (CCX-891 at 13).
34	Eden Fellows (RX 403)	2012	ASTM D5511 for Fellows	197 days	Amended film/1%	71.8% 16.1%	• Eden tests unreliable. FOF ¶ 144. • States the test was conducted outside of ASTM D5511 protocol, but does not indicate what method was followed (RX-403 at 2). • Biodegradable polymer tested, not a conventional untreated plastic (CCX-805 (Poth, Dep. at 104, 148-149). • Does not state temperature (CCX-891 at 15). • No statistical analysis (CCX-891 at 13).
35	Environ (RX 275)	2012	Environ PS & PE testing for FP International (modeled after ASTM D5338 & D5511)	120 days	PS & PE/1%	>5%	• Wrong temperature (CCX-891 at 15). Weight loss studies are "not competent and reliable scientific evidence of biodegradation" (CCX-891 at 18).

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
36	Intertek India (RX 277)	2012	D5511, ISOE Printpack Industries, PVT, LTD, sample sheet	45 days	Sample sheet unknown	Qualitative evidence of biodegradation; gas data; no negative control	• Unclear whether contains ECM Additive (RX-277) *See also* CCX-891, 13-14. • Qualitative tests (CCX-891, 33-34) *See also* (CCX-891 at 13). Wrong temperature (CCX-891 at 15). • Weight loss studies are "not competent and reliable scientific evidence of biodegradation" (CCX-891 at 18).
37	SSCCP (RX 467)	2013	ISO 14855, UNI EN 14046, aerobic degradation ,Colplast	91 days	Unknown	11.9%	• Unclear whether contains ECM Additive (RX-277) *See also* CCX-891, 13-14. • Load rate not reported (CCX-891 at 14). • Wrong temperature (CCX-891 at 15).
38	SSCCP (RX 468)	2013	ISO 14855, UNI EN 14046, aerobic degradation, Colplast	91 days	Unknown	6.96%	• Unclear whether contains ECM Additive (RX-277) *See also* CCX-891, 13-14. Load rate not reported (CCX-891 at 14). Wrong temperature (CCX-891 at 15).
39	Eden FPI (CCX 548)	2013	Modified ASTM D5511 for FPI EPS Samples	291 days	Expanded PS/1%	30.4%	• Eden tests unreliable. FOF ¶ 144. • Temperature not reported (CCX-891 at 15). • Load rate exceeds that specified (CCX-891 at 14).

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
							• States the test was conducted outside of ASTM D5511 protocol, but does not indicate what method was followed (CCX-548 2, 10, 12).
40	Eden Smithers (RX 401)	2013	ASTM D5511 for Smithers Oasis	148 days	Foam/1.1% Foam/3%	2.4% 5.8%	• Temperature not reported (CCX-891 at 15). Load rate exceeds that specified (CCX-891 at 14). • States the test was conducted outside of ASTM D5511 protocol, but does not indicate what method was followed (CCX-548 2, 10, 12).
41	NE Labs N1048340 (RX 836)	2013	ASTM D5511 study for Pregis (PPC)	900 days	PE Poly Bags	49.28%	• Positive control exceeded 100% biodegradation. • Load rate unreported. • Does not show 60% biodegradation. (CCX 891 ¶ 83.) • Wrong temperature (CCX-891 at 15). • Does not show complete biodegradation (CCX-891 at 8). • Does not control for priming effect (CCX-891 at 8).
42	Eden EcoLab (RX-862)	2013	ASTM D5511 test for EcoLab	452 days	Film	19.6% 46.5%	• Eden tests unreliable. FOF ¶ 144. • Not well documented • Load rate unreported.

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
							• Does not show 60% biodegradation. (CCX 891 ¶ 83.) • Wrong temperature (CCX-891 at 15). • Does not show complete biodegradation (CCX-891 at 8). • Does not control for priming effect (CCX-891 at 8).
43	Eden FPI (RX 402)	2014	Updated ASTM D5511 standard for FP International	290 days	1% ECM film 1.75% ECM film	5.5% 11.5%	• Eden tests unreliable. FOF ¶ 144. • CCX 891 ¶ 83 ("the results of these tests are dubious because of the poor methodologies (*e.g.*, refreshing of inoculum, which reinvigorates the priming effect)." • Does not show 60% biodegradation. (CCX 891 ¶ 83.) • Wrong temperature (CCX-891 at 15). • Does not show complete biodegradation (CCX-891 at 8). • Does not have statistical analysis of data (CCX-891 at 13). • Does not control for priming effect (CCX-891 at 8).

TEST INDEX

	Test	Year	Method	Duration	Plastic/ECM	% Biodeg.	Issues
44	Case Western (RX 278)	n/a	Prof. Morton Litt SEM Examination of ECM plastic in	n/a/	n/a/	Qualitative evidence of biodegradation	• Qualitative tests (CCX-891, 33-34) *See also* (CCX-891 at 13).

CERTIFICATE OF SERVICE

I hereby certify that on October 16, 2014, I caused a true and correct copy of the foregoing to be served as follows:

One electronic copy to the **Office of the Secretary**, one hard copy, and one copy through the FTC's e-filing system:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Room H-159
Washington, DC 20580
Email: secretary@ftc.gov

One electronic copy and three hard copies to the **Office of the Administrative Law Judge:**

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., NW, Room H-110
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