

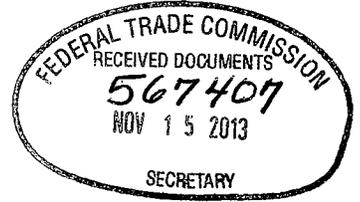
UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF THE ADMINISTRATIVE LAW JUDGES
Washington, D.C.

ORIGINAL

In the Matter of

ECM BioFilms, Inc.,
a corporation, also d/b/a
Enviroplastics International

PUBLIC
Docket No. 9358



**ANSWER AND AFFIRMATIVE DEFENSES OF
RESPONDENT ECM BIOFILMS, INC.**

Pursuant to 16 C.F.R. § 3.12, Respondent ECM BioFilms, Inc. (“ECM”) hereby answers the Federal Trade Commission’s Complaint (“Complaint”). Except as otherwise stated herein, ECM denies every allegation contained in the Complaint, including each allegation and assertion not specifically contained in an enumerated paragraph. Specifically, ECM denies that it violated any laws, regulations, or guidelines of the Federal Trade Commission (“FTC”), including Section 5 of the Federal Trade Commission Act (“FTCA”), the “Green Guides,” and the “Revised Green Guides.” The Complaint disserves the public interest because it is based on an anachronistic and inapplicable scientific model, on flawed consumer surveys, and on policy that is contradicted by generally accepted industry standards reflective of current science. Moreover, the Complaint disserves the public interest because in its first and principal ordering paragraph it demands relief that violates the First Amendment to the United States Constitution. If adopted, the Complaint’s first ordering paragraph will violate the First Amendment by enjoining ECM from communicating truthful and non-misleading commercial speech and by imposing a blanket ban on ECM’s prospective speech concerning biodegradation of plastics when there are obvious, less speech-restrictive alternatives in the form of reasonable claim qualifications. *See Pearson v.*

Shalala, 164 F.3d 650,652-58 (D.C. Cir. 1999); *Peel v. Attorney Registration & Disciplinary Comm'n of Illinois*, 496 U.S. 91, 110 (1990); *In re R. M. J.*, 455 U.S. 191, 206 n.20 (1982); *Shapiro v. Kentucky Bar Assn.*, 486 U.S. 466, 478 (1988); *Whitaker v. Thompson*, 248 F.Supp. 2d 1 (D.D.C. 2002); *Alliance for Natural Health U.S. v. Sebelius*, 714 F.Supp. 2d 48, D.D.C. 2010); *Alliance for Natural Health U.S.*, 786 F.Supp. 2d 1 (D.D.C. 2011). Moreover, the Complaint disserves the public interest because its excessive restrictions on speech concerning biodegradation of plastics stifles a technology essential to reduce harm to the environment caused by plastics contrary to federal environmental law and policy. For those reasons, and the additional reasons set forth below, ECM respectfully responds as follows:

1. ECM admits the allegation contained in Paragraph 1 of the Complaint.
2. ECM admits in part and denies in part the allegations contained in Paragraph 2 of the Complaint. ECM admits that it manufactures, offers for sale, sells, and distributes an additive ("ECM Product") to be included in plastics. ECM admits that it advertises and promotes the ECM Product through its website at www.ecmbiofilms.com to manufacturers that produce plastics which include the ECM Product and to distributors that sell the ECM Product for inclusion in plastics. ECM denies that it advertises or promotes the ECM Product for purchase by the general public, as its customers are exclusively limited to manufacturers that make plastics containing the ECM Product and to distributors that sell the ECM Product for inclusion in plastics. ECM is without sufficient knowledge and/or information either to admit or deny the allegation that manufacturers that make plastics containing the ECM Product and that distributors that sell the ECM Product for inclusion in plastics make any representation on or in association with the plastics so produced to customers and end-use consumers, including representations that the products are "biodegradable;" therefore ECM denies that allegation.

3. ECM denies the allegation contained in Paragraph 3 of the Complaint insofar as Paragraph 3 calls for a legal conclusion to which no response is required.

4. ECM admits in part and denies in part the allegations in Complaint Paragraph 4. ECM admits that it disseminates advertising material concerning its product to independent distributors that sell the ECM Product for inclusion in plastics. ECM disseminates that material to educate those distributors and plastics manufacturers about the additive's uses and characteristics. ECM denies that it disseminates that material to the general public and "end-use consumers" because it only sells the ECM Product to manufacturers that make plastics and distributors that sell the ECM Product for inclusion in plastics. ECM denies any conclusion, inference, characterization, classification, implication, suggestion, and legal argument concerning the FTC's exhibits and materials created through selective or partial excerpting or quotation, and particularly as to any comment added by the FTC. The exhibits should be read as a whole and considered within context, cognizant of the fact that ECM's actual customer base (which consists of plastics manufacturers and those distributors that sell the ECM Product to plastics manufacturers) is highly sophisticated and does not include the general public or "end-use consumers." The vast majority of ECM's interactions with its manufacturer and distributor customers are verbal. ECM has not, and indeed does not, rely on its website and selected excerpts provided by the FTC as its only or even its primary source of promotion or information dissemination to its customer base. The FTC is obliged to consider the net impression of ECM's promotions as a whole, and that includes the direct discussions and sales presentations with its customers, which are not encompassed in the FTC's Complaint.

5. ECM admits in part and denies in part the allegations in Complaint Paragraph 5. ECM admits that it made the statements and depictions contained in Complaint Paragraph 5.

ECM issued the statements and depictions in Complaint Paragraph 5(A) before the FTC revised the Green Guides, but denies that it made all the claims contained in Complaint Paragraph 5 for the use of consumers in the United States after FTC revised the Green Guides. As well, ECM denies any and all implications arising from the FTC's excerpting of such claims from the publication as a whole, apart from the net impression of ECM's advertising as a complete, uniform body of information, to its actual customers as opposed to the general public or end-use consumers. Thus, ECM denies any conclusion, inference, characterization, classification, implication, suggestion, and legal argument concerning the FTC's exhibits and materials created through selective or partial excerpting or quotation, and particularly as to any comment added by the FTC. The exhibits should be read as a whole and considered within context, cognizant of the fact that ECM's actual customer base (which consists of plastics manufacturers and those distributors that sell the ECM Product to plastics manufacturers) is highly sophisticated and does not include the general public or "end-use consumers." Finally, ECM amended its qualified claims found on its website and print materials in response to the Revised Green Guides to ensure ECM remained in compliance with the FTCA and the Revised Green Guides. ECM revised its material in good faith to avoid potential conflict with the FTC's new policies, albeit its prior claims were at all times truthful.

6. ECM is without sufficient knowledge and/or information either to admit or deny the allegation in the first sentence of Complaint Paragraph 6, and therefore denies same. ECM denies the allegation in the second sentence of Complaint Paragraph 6. The FTC relies on an archaic, scientifically invalid conception of conditions in municipal landfills to assert that plastic products manufactured to include the ECM Product will not biodegrade as stated in ECM's qualified advertising claims. ECM plainly reveals that biodegradation occurs at varying rates

depending on environmental conditions in landfills, but all landfills exhibit the general anaerobic conditions necessary for biodegradation. ECM truthfully explains that its products will fully biodegrade under those varying landfill conditions within a reasonably short period of time; that “reasonable” period of time will vary depending on the unique conditions of each landfill site and in context with plastics science generally. That is the plain meaning of the following ECM web content qualification omitted in the FTC’s excerpted Complaint content:

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 – but the time frame of between nine months to five years will give a good general idea for most conditions.

See ECM Ex. No. 1, Attachment A (ECM webpage).¹

The plastic products made with our additives will break down in approximately 9 month (sic) to 5 years in nearly all landfills or wherever else they may end up. 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 to react with the additives and form communities, biofilms...

See ECM Ex. No. 3, Attachment A (ECM Webpage, “ECM Technology for the Biodegradation of Plastic Products”).² ECM conveys information concerning the

¹ Available at <http://www.ecmbiofilms.com/product-info/life-expectancy-of-products-manufactured-with-ecm-masterbatch-pellets/> (last visited November 6, 2013); see also ECM Ex. No. 2, Attachment A (“Reprint of a Letter to an Interested Party” January 16, 2007) (filed “Confidential” and subject to Protective Order).

² Available at <http://www.ecmbiofilms.com/product-info/ecm-technology-for-the-biodegradation-of-plastic-products/> (last visited November 6, 2013); see also ECM Ex. No. 5, Attachment A (“Reprint of a Letter to an Interested Party” December 3, 2008) (filed “Confidential” and subject to Protective Order); ECM Ex. No. 4, Attachment A (“Reprint of a

ECM Product to trade customers mostly through verbal communication, including sales presentations, on-site visits, telephone conversations, and other in-person meetings, which representations must be taken as a whole and within context to portray accurately and completely ECM promotion to its manufacturer and distributor customers.

7. ECM denies the allegations in Complaint Paragraph 7 in their entirety.
8. ECM denies the allegations in Complaint Paragraph 8 in their entirety.

VIOLATIONS OF SECTION 5 OF THE FTC ACT

FALSE OR MISLEADING REPRESENTATIONS

9. ECM hereby responds to the enumerated allegations as follows. To the extent such allegations reference ECM marketing or FTC exhibits, ECM denies any conclusion, inference, characterization, classification, implication, suggestions, and legal arguments concerning the FTC's exhibits and materials created through selective or partial excerpting or quotation, and **particularly as to any comment added by the FTC**. The exhibits should be read as a whole and considered within context, cognizant of the fact that ECM's actual customer base (which consists of plastics manufacturers and those distributors that sell the ECM Product to plastics manufacturers) is highly sophisticated and does not include the general public or "end-use consumers."

A. ECM denies the allegations contained in Complaint Paragraph 9(A). ECM admits that it made representations in advertising concerning the ECM Product to its customers, but denies that its advertising contains unqualified claims. ECM has consistently qualified its

Letter to an Interested Party" October 28, 2005) (filed "Confidential" and subject to Protective Order).

advertising claims to provide its customers accurate and non-misleading information concerning the nature and characteristics of the ECM Product. For example, the following web content, omitted from the FTC Complaint, is reflective of ECM's actual advertising claims in context:

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—but the time frame of between nine months to five years will give a good general idea for most conditions.

See ECM Ex. No. 1 (Attachment A).

The plastic products made with our additives will break down in approximately 9 month (sic) to 5 years in nearly all landfills or wherever else they may end up. 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 to react with the additives and form communities, biofilms...

See ECM Ex. No. 3 (ECM Webpage, "ECM Technology for the Biodegradation of Plastic Products").³ ECM conveys information concerning the ECM Product to its trade customers mostly through verbal communication, including sales presentations, on-site visits, telephone conversations, and other in-person meetings, which representations must be taken as a whole and within context to portray accurately and completely ECM promotion to its manufacturer and distributor customers.

³ *Also available at* <http://www.ecmbiofilms.com/product-info/ecm-technology-for-the-biodegradation-of-plastic-products/> (last visited November 6, 2013); *see also* ECM Ex. No. 5, Attachment A ("Reprint of a Letter to an Interested Party" December 3, 2008) (filed "Confidential" and subject to Protective Order); ECM Ex. No. 4, Attachment A (filed "Confidential" and subject to Protective Order).

B. ECM admits in part and denies in part the allegations contained in Complaint Paragraph 9(B). ECM admits that it has claimed that the ECM Product causes plastics to degrade through biological means. ECM denies that it has made unqualified plastic elimination claims in advertising concerning the ECM Product in landfills; rather, ECM's advertising plainly explains that the rate of plastic degradation is dependent on ambient environmental conditions. *See* Ex. No.'s 1-5. ECM denies that its biodegradable claim is deceptive, false, or misleading in any particular. ECM has proven through competent and reliable testing that plastics manufactured with the ECM Product will fully biodegrade through biological means when exposed to micro-organisms commonly present in the outdoor environment, including in landfills.

C. ECM denies the allegations contained in Complaint Paragraph 9(C) because they depend on a definition of the term "biodegradable" in conflict with the meaning of that term understood by the actual customers of the ECM Product. To the extent the FTC compels adherence to a definition of "biodegradable" in conflict with the meaning understood by the actual customers of the ECM Product, its act of compulsion arbitrarily and capriciously effects speech suppression predicated on an official speech orthodoxy in violation of the Administrative Procedure Act and the First Amendment to the United States Constitution.

D. ECM denies the allegations contained in Complaint Paragraph 9(D) insofar as those allegations depend on the definition of "biodegradable" presented in Complaint Paragraph 9(A), particularly to the extent the FTC erroneously suggests that all plastic products must completely biodegrade within one calendar year after customary disposal before manufacturers can label such products "biodegradable," and to the extent the FTC claims that ECM made unqualified "biodegradable" claims. Per the plain language of the FTC's own regulations, only

unqualified claims must meet the standard of “a reasonably short period of time.” Qualified claims that provide an alternative timeframe are not subject to the “reasonable time” standard.

10. ECM hereby responds to the enumerated allegations in Complaint Paragraph 10 seriatim as follows:

A. ECM denies the FTC’s allegations in Complaint Paragraph 10(A) because they rely on an unworkable definition of “biodegradable,” subject to standards not generally accepted in the scientific community, and they depend upon a falsehood, to wit, that ECM made an unqualified claim in advertising its Product.

B. ECM denies the FTC’s allegations in Complaint Paragraph 10(B) because they rely on an unworkable definition of “biodegradable,” subject to standards not generally accepted in the scientific community, and they depend upon a falsehood, to wit, that ECM made an unqualified claim in advertising its Product.

C. ECM denies the FTC’s allegations in Complaint Paragraph 10(C) because they rely on an unworkable definition of “biodegradable,” subject to standards not generally accepted in the scientific community, and they depend upon a falsehood, to wit, that ECM made an unqualified claim in advertising its Product.

D. ECM denies the FTC’s allegations in Complaint Paragraph 10(D) because they rely on an unworkable definition of “biodegradable,” subject to standards not generally accepted in the scientific community, and they depend upon a falsehood, to wit, that ECM made an unqualified claim in advertising its Product.

11. ECM denies the allegations in Complaint Paragraph 11 because the actual claims made by ECM in advertising and those reasonably implied therefrom are in context, taken as a whole, and as understood by ECM’s customers, truthful and non-misleading. ECM’s advertising

representations are protected commercial speech within the meaning of the First Amendment to the United States Constitution.

UNSUBSTANTIATED REPRESENTATIONS

12. Incorporating its objections and denials described in this Answer, ECM denies the allegations in Complaint Paragraph 12. ECM has at all times possessed a “reasonable basis” for its advertising representations. Its advertising representations are protected commercial speech within the meaning of the First Amendment to the United States Constitution.

13. ECM denies the allegations in Complaint Paragraph 13 because it has possessed and currently possesses a reasonable basis that substantiates its advertising representations. Its advertising representations are protected commercial speech within the meaning of the First Amendment to the United States Constitution.

MEANS AND INSTRUMENTALITIES

14. Complaint Paragraph 14 contains legal argument and conclusions to which no response is required. ECM nevertheless denies the allegations contained in Complaint Paragraph 14, including, but not limited to, every implication that ECM’s advertising is unfair, misleading, deceptive, or false or has caused or induced those in receipt of the advertising to commit deceptive acts or practices.

15. Complaint Paragraph 15 contains legal argument and conclusions to which no response is required. ECM nevertheless denies the allegations contained in Complaint Paragraph 15, including, but not limited to, every implication that ECM’s advertising is unfair, misleading, deceptive, or false or constitutes a deceptive act or practice.

ECM hereby denies all allegations that are contained in the Complaint which were not specifically admitted or denied above.

NOTICE SECTION

The Complaint provides "Notice" to ECM of procedural matters. That Notice contains statements and conclusions of law to which no response is required. To the extent any response is required expressly or by implication, ECM hereby denies that it has violated any laws or regulations which warrant compliance with the Notice requested. ECM denies that this proceeding by the FTC is in the public interest, that this proceeding is lawful under the U.S. Constitution or the Administrative Procedures Act, or that the FTC has satisfied the statutory, regulatory and constitutional requisites for issuance and prosecution of a Complaint against ECM.

ADDITIONAL DEFENSES

ECM hereby reserves the right to present additional defenses as this matter proceeds, particularly with respect to those defenses presently unknown to ECM. ECM hereby asserts the following additional defenses, without assuming any burden of proof on any issue or relieving the Commission of its burden to establish each element of its alleged claims.

**FIRST DEFENSE
(Failure to State a Claim)**

The Complaint fails to state a claim upon which relief can be granted under Section 5 of the FTC Act, 15 U.S.C. § 45. The FTC has not demonstrated that ECM's well-qualified claims are false, have a tendency to deceive, or that Part 3 adjudication is in the public interest.

SECOND DEFENSE
(Complaint Not in Public Interest)

The requested relief, if granted, would not be in the public interest.

THIRD DEFENSE
(Third-Party Causation)

The FTC alleges that it can seek restitution and other forms of redress. However, any relief the FTC impliedly may seek was legally and proximately caused by other persons, entities, or forces, over which ECM exerted no control and for which it had no responsibility. Specifically, ECM marketed and explained its product's qualities with attendant qualifying language, and through sufficient scientific explanation to give its sophisticated plastics manufacturer and ECM Product distributor customers a complete understanding of the scientific limitations of the ECM Product. ECM did not, does not, and cannot control how third-parties market and sell finished plastics products containing the ECM Product as one ingredient. Accordingly, ECM cannot be liable for actions taken by third-parties beyond ECM's dominion and control.

FOURTH DEFENSE
(Good Faith)

ECM has acted in good faith in all of its marketing practices, including qualified claims in support of biodegradability. ECM took affirmative steps to comply with the FTCA after the FTC revised its Green Guides effective October 2012, including the implementation of additional qualifying language. ECM amended claims to follow closely the letter of those Guides. Evidence of good faith prohibits the FTC from applying in its Order a permanent injunction.

FIFTH DEFENSE
(No Reasonable Basis for Requested Relief)

There is no danger of recurrence of alleged similar violations, and the FTC's requested relief is not reasonably related to ECM's alleged violations. The FTC must demonstrate that a "cognizable danger of current violation" exists before an injunction may issue, and there is insufficient evidence that such danger exists. Further, ECM has demonstrated that it affirmatively takes steps to ensure that it does not violate the FTCA or the Revised Green Guides. When determining the likelihood of recurrence, courts consider the deliberate nature of the presently alleged violation and the defendant's past record concerning unfair advertising practices. *See F.T.C. v. Hang-Ups Art Enterprises, Inc.*, CV 95-0027 RMT(JGX), 1995 WL 914179 (C.D. Cal. Sept. 27, 1995). The lack of any deliberate conduct in violation of law and that ECM has no past record of law violation precludes the FTC from relying on injunctive relief.

SIXTH DEFENSE
(Materiality)

The advertising claims excerpted by the FTC in its Complaint include ones not material to the purchasing decisions of ECM customers.

SEVENTH DEFENSE
(Violation of First Amendment Right to Free Speech)

The Complaint ordering paragraphs, if adopted, violate ECM's First Amendment right to communicate truthful commercial speech. The FTC thus lacks authority to impose its requested relief. ECM's claims are truthful and, to the extent the FTC perceives any implication arising from the claims to be misleading, are fully correctible through use of reasonable qualifications, which qualifications are less speech restrictive alternatives and are commanded by the First

Amendment. By requiring complete elimination of plastic within one year as a condition precedent to use of the term “biodegradable,” the FTC precludes truthful disclosure of scientific evidence that supports the degradation of plastics through biological means which can occur at a slower rate depending on ambient environmental conditions, thus censoring truthful speech through an overbroad injunction, reducing public awareness of a product that diminishes harm to the environment, and creating a conflict with national environmental policy in the Environmental Protection Agency’s enabling act.⁴ The FTC also creates an official speech orthodoxy, antithetical to the First Amendment, governing the term “biodegradable” when an obvious, less speech restrictive alternative, in the form of reasonable claim qualification, exists. *See Pearson*, 164 F.3d at 658 (“It is clear ... that when government chooses a policy of suppression over disclosure—at least where there is a showing that disclosure would not suffice to cure misleadingness—government disregards a ‘far less restrictive’ means”).

EIGHTH DEFENSE
(APA Arbitrary and Capricious Agency Action)

The FTC’s allegations are predicated on arbitrary and capricious regulatory policies that are not based on substantial evidence. The FTC has no legitimate basis to conclude that the term “biodegradable” begets a single meaning for consumers of the ECM Product, to wit: complete

⁴ Title I of the National Environmental Policy Act of 1970 states:

The purposes of this chapter are: To declare a national policy which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation; and to establish a Council on Environmental Quality.

42 U.S.C.A. § 4321 (West).

plastic elimination within one calendar year after disposal. Furthermore, the FTC has no legitimate basis to conclude that the “reasonably short period of time” standard, as applied through the One Year Rule, is material to consumer impression of “degradable claims.” Accordingly, the FTC acts arbitrarily and capriciously in reliance on its Green Guides in this case and in the creation of an official speech orthodoxy, antithetical to the First Amendment, governing the term “biodegradable.”

NINTH DEFENSE
(APA Arbitrary and Capricious Retroactive Application of Green Guides)

The FTC violates the APA by arbitrarily and capriciously enforcing its 2012 revisions to the Green Guides to commercial speech that predated those same guides. To the extent the FTC seeks to hold ECM liable under the so-called One-Year Rule for speech that occurred before the FTC implemented that rule, the FTC acts arbitrarily and capriciously. FTC’s claims are therefore barred by the doctrine of Retroactive Application. Specifically, courts presume that regulations or laws are not to be retroactively applied. The FTC’s “one-year” rule under the revised Green Guides targets advertising by ECM that occurred prior to the promulgation of the revised Guides.

TENTH DEFENSE
(Violation of Due Process-Separation of Functions)

The Commission violates ECM’s right to Due Process under the Fifth Amendment to the United States Constitution by abrogating the Separation of Functions Doctrine. Due Process requires “minimum standards” of protection and fundamental fairness lacking here. *Dunmar v. Ailes*, 348 F.2d 51, 54 (D.C. Cir. 1965). To ensure fairness, the FTC must maintain separate prosecutorial and adjudicative functions. *F.T.C. v. Atl. Richfield Co.*, 567 F.2d 96, 102 (D.C.

Cir. 1977). ECM is entitled to a fair proceeding that requires, at a minimum, a neutral weighing of the evidence and of the charges presented by the charging party; such a neutral weighing is impossible when the ultimate charging party, the Commission, also sits as the ultimate judge of its own charges. *Marshall v. Jerrico, Inc.*, 446 U.S. 238, 242 (1980) (noting that, “The Due Process Clause entitles a person to an impartial and disinterested tribunal in both civil and criminal cases”). By combining the functions of investigator, prosecutor, judge, and appellate tribunal in one body, the Commission, to which final agency review is committed, is incontrovertibly biased, it being judge of the merits of its very own charges.

PRAYER FOR RELIEF

WHEREFOR, ECM respectfully prays for relief as follows:

1. Deny all of the FTC’s claims and request for relief.
2. Dismiss the Complaint in its entirety with prejudice.
3. Award ECM all awards, costs, and fees reasonably associated with this lawsuit pursuant to 3.81 of the FTC Rules of Practice, to the extent applicable, including, but not limited to, attorney fees and expert fees.
4. Award all forms of additional relief as the Administrative Law Judge may deem proper and just.

Respectfully submitted,

ECM Biofilms, Inc.

By: 
Jonathan W. Emord
Peter A. Arhangelsky
Lou F. Caputo
Bethany R. Kennedy

Attorneys for Defendant-ECM Biofilms, Inc.

DATED this 14th day of November, 2013.

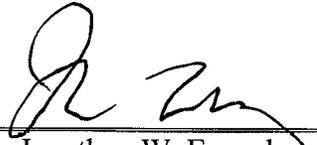
CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2013, a copy of foregoing, **ANSWER AND AFFIRMATIVE DEFENSES OF RESPONDENT ECM BIOFILMS, INC.**, was electronically filed using the FTC's Electronic Filing System and was sent by that system and by certified mail to the following:

Donald S. Clark
Office of the Secretary
Federal Trade Commission
Room H-113
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

Elisa Jillson
Division of Enforcement
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, NW
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Washington, D.C. 20580

Katherine Johnson
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Mail stop M-8102B
Washington, D.C. 20580



Jonathan W. Emord

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

In the Matter of)
)
)

ECM BioFilms, Inc.,)
a corporation, also d/b/a)
Envioplastics International,)
Respondent.)
_____)

DOCKET NO. 9358

PROTECTIVE ORDER GOVERNING DISCOVERY MATERIAL

Commission Rule 3.31(d) states: "In order to protect the parties and third parties against improper use and disclosure of confidential information, the Administrative Law Judge shall issue a protective order as set forth in the appendix to this section." 16 C.F.R. § 3.31(d). Pursuant to Commission Rule 3.31(d), the protective order set forth in the appendix to that section is attached verbatim as Attachment A and is hereby issued.

ORDERED:



D. Michael Chappell
Chief Administrative Law Judge

Date: October 22, 2013

ATTACHMENT A

For the purpose of protecting the interests of the parties and third parties in the above-captioned matter against improper use and disclosure of confidential information submitted or produced in connection with this matter:

IT IS HEREBY ORDERED THAT this Protective Order Governing Confidential Material ("Protective Order") shall govern the handling of all Discovery Material, as hereafter defined.

1. As used in this Order, "confidential material" shall refer to any document or portion thereof that contains privileged, competitively sensitive information, or sensitive personal information. "Sensitive personal information" shall refer to, but shall not be limited to, an individual's Social Security number, taxpayer identification number, financial account number, credit card or debit card number, driver's license number, state-issued identification number, passport number, date of birth (other than year), and any sensitive health information identifiable by individual, such as an individual's medical records. "Document" shall refer to any discoverable writing, recording, transcript of oral testimony, or electronically stored information in the possession of a party or a third party. "Commission" shall refer to the Federal Trade Commission ("FTC"), or any of its employees, agents, attorneys, and all other persons acting on its behalf, excluding persons retained as consultants or experts for purposes of this proceeding.
2. Any document or portion thereof submitted by a respondent or a third party during a Federal Trade Commission investigation or during the course of this proceeding that is entitled to confidentiality under the Federal Trade Commission Act, or any regulation, interpretation, or precedent concerning documents in the possession of the Commission, as well as any information taken from any portion of such document, shall be treated as confidential material for purposes of this Order. The identity of a third party submitting such confidential material shall also be treated as confidential material for the purposes of this Order where the submitter has requested such confidential treatment.
3. The parties and any third parties, in complying with informal discovery requests, disclosure requirements, or discovery demands in this proceeding may designate any responsive document or portion thereof as confidential material, including documents obtained by them from third parties pursuant to discovery or as otherwise obtained.
4. The parties, in conducting discovery from third parties, shall provide to each third party a copy of this Order so as to inform each such third party of his, her, or its rights herein.
5. A designation of confidentiality shall constitute a representation in good faith and after careful determination that the material is not reasonably believed to be already in the public domain and that counsel believes the material so designated constitutes confidential material as defined in Paragraph 1 of this Order.

6. Material may be designated as confidential by placing on or affixing to the document containing such material (in such manner as will not interfere with the legibility thereof), or if an entire folder or box of documents is confidential by placing or affixing to that folder or box, the designation "CONFIDENTIAL – FTC Docket No. 9358" or any other appropriate notice that identifies this proceeding, together with an indication of the portion or portions of the document considered to be confidential material. Confidential information contained in electronic documents may also be designated as confidential by placing the designation "CONFIDENTIAL – FTC Docket No. 9358" or any other appropriate notice that identifies this proceeding, on the face of the CD or DVD or other medium on which the document is produced. Masked or otherwise redacted copies of documents may be produced where the portions deleted contain privileged matter, provided that the copy produced shall indicate at the appropriate point that portions have been deleted and the reasons therefor.

7. Confidential material shall be disclosed only to: (a) the Administrative Law Judge presiding over this proceeding, personnel assisting the Administrative Law Judge, the Commission and its employees, and personnel retained by the Commission as experts or consultants for this proceeding; (b) judges and other court personnel of any court having jurisdiction over any appellate proceedings involving this matter; (c) outside counsel of record for any respondent, their associated attorneys and other employees of their law firm(s), provided they are not employees of a respondent; (d) anyone retained to assist outside counsel in the preparation or hearing of this proceeding including consultants, provided they are not affiliated in any way with a respondent and have signed an agreement to abide by the terms of the protective order; and (e) any witness or deponent who may have authored or received the information in question.

8. Disclosure of confidential material to any person described in Paragraph 7 of this Order shall be only for the purposes of the preparation and hearing of this proceeding, or any appeal therefrom, and for no other purpose whatsoever, provided, however, that the Commission may, subject to taking appropriate steps to preserve the confidentiality of such material, use or disclose confidential material as provided by its Rules of Practice; sections 6(f) and 21 of the Federal Trade Commission Act; or any other legal obligation imposed upon the Commission.

9. In the event that any confidential material is contained in any pleading, motion, exhibit or other paper filed or to be filed with the Secretary of the Commission, the Secretary shall be so informed by the Party filing such papers, and such papers shall be filed *in camera*. To the extent that such material was originally submitted by a third party, the party including the materials in its papers shall immediately notify the submitter of such inclusion. Confidential material contained in the papers shall continue to have *in camera* treatment until further order of the Administrative Law Judge, provided, however, that such papers may be furnished to persons or entities who may receive confidential material pursuant to Paragraphs 7 or 8. Upon or after filing any paper containing confidential material, the filing party shall file on the public record a duplicate copy of the paper that does not reveal confidential material. Further, if the protection for any such material expires, a party may file on the public record a duplicate copy which also contains the formerly protected material.

10. If counsel plans to introduce into evidence at the hearing any document or transcript containing confidential material produced by another party or by a third party, they shall provide advance notice to the other party or third party for purposes of allowing that party to seek an order that the document or transcript be granted *in camera* treatment. If that party wishes *in camera* treatment for the document or transcript, the party shall file an appropriate motion with the Administrative Law Judge within 5 days after it receives such notice. Except where such an order is granted, all documents and transcripts shall be part of the public record. Where *in camera* treatment is granted, a duplicate copy of such document or transcript with the confidential material deleted therefrom may be placed on the public record.

11. If any party receives a discovery request in any investigation or in any other proceeding or matter that may require the disclosure of confidential material submitted by another party or third party, the recipient of the discovery request shall promptly notify the submitter of receipt of such request. Unless a shorter time is mandated by an order of a court, such notification shall be in writing and be received by the submitter at least 10 business days before production, and shall include a copy of this Protective Order and a cover letter that will apprise the submitter of its rights hereunder. Nothing herein shall be construed as requiring the recipient of the discovery request or anyone else covered by this Order to challenge or appeal any order requiring production of confidential material, to subject itself to any penalties for non-compliance with any such order, or to seek any relief from the Administrative Law Judge or the Commission. The recipient shall not oppose the submitter's efforts to challenge the disclosure of confidential material. In addition, nothing herein shall limit the applicability of Rule 4.11(e) of the Commission's Rules of Practice, 16 CFR 4.11(e), to discovery requests in another proceeding that are directed to the Commission.

12. At the time that any consultant or other person retained to assist counsel in the preparation of this action concludes participation in the action, such person shall return to counsel all copies of documents or portions thereof designated confidential that are in the possession of such person, together with all notes, memoranda or other papers containing confidential information. At the conclusion of this proceeding, including the exhaustion of judicial review, the parties shall return documents obtained in this action to their submitters, provided, however, that the Commission's obligation to return documents shall be governed by the provisions of Rule 4.12 of the Rules of Practice, 16 CFR 4.12.

13. The provisions of this Protective Order, insofar as they restrict the communication and use of confidential discovery material, shall, without written permission of the submitter or further order of the Commission, continue to be binding after the conclusion of this proceeding.

EXHIBIT 1

Life Expectancy of Products Manufactured with ECM MasterBatch Pellets™

The life expectancy of plastic products that are manufactured with at least a one percent (1%) load, by weight, of our ECM MasterBatch Pellets can be explained through two types of life expectancies. The first type of life expectancy is the life expectancy of the plastic when it is on the warehouse or store shelf, in regular usage as packaging or other normal plastic usage. The second type of life expectancy has to do with the situation when the same plastic has been put in conditions wherein it has constant contact with other materials that are biodegrading.

Plastic products manufactured with ECM MasterBatch Pellets will have the same life expectancy as the same plastic product manufactured without our additives under all but the conditions mentioned above wherein they are placed in constant contact with other materials that are biodegrading (i.e. on or buried in the ground). This is a major reason why our technology for having biodegradable* plastic products is so successful.

The principles concerned with the degradation* of plastics that make use of our additive technology are truly involved with "bio"-degradation*. Our technology does not rely on the use of photosensitivity or thermal sensitivity to photodegrade or thermally break down the plastics. For this reason, a blow-molded HDPE shampoo bottle or motor oil bottle manufactured with one of our additives will last in the warehouse and on the store shelf as long as it would without our additives. There is a considerable amount of interest in our additives for the plastics for the automotive and aviation industries for this reason.

There is the real concern for the technologies that make use of thermal or photodegradation that they are simply leaving smaller particles of plastic in the soil rather than having the material truly become the organic components of soil. This is especially of concern in the agricultural industry and for those needing erosion control products. Agricultural films, erosion control nettings, and other such products manufactured with our additives will last long enough to get the required use but will completely biodegrade into the soil; such plastic products completely biodegrade in a period of from 9 months to 5 years or less. It is not a "poof, it's gone" system but simply makes the plastic product biodegrade as if it were a stick or a branch off a tree rather than "sticking around"

independent laboratories by independent scientists. 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.

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 – but the time frame of between nine months to five years will give a good general idea for most 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 one year is a reasonable expectation.

Petrochemical plastics would normally take hundreds or thousands of years or even longer to "biodegrade"; with our additives, these same plastic formulas biodegrade in a hundredth of that time or less.

Do not be confused by the claims of some companies that say that their resins fully biodegrade in 2 months or 3 months. They are speaking of biodegradation under very specific conditions. This has led to some confusion when the plastic products are in the end-consumers' hands, such as in the Kassel project in Germany when the bags and other plastic products marked with a "compostable" label were found not to be compostable by the town's citizens in their backyard compost heaps (they were only "compostable" under the very specific commercial composting standards where there is high heat, oxygenation, moisture control and high levels of microorganisms). When I spoke at the Biodegradable Plastics Conference in Frankfurt, Germany a few years ago, I argued with the companies involved in that project that they should be careful in not trying to confiscate generic terms for too specific conditions (i.e. they should label items as "Commercially Compostable" rather than simply "Compostable" when such conditions are required). As the use of our technology continues to grow to become the world's leading technology for the production of biodegradable* plastics, our viewpoint will continue to gain more and

for hundreds of years.

more adherents.

To summarize the concept, the key to our technology is that the right conditions for biodegradation are not those found when the plastic product is in use, is on the store shelves or is being warehoused somewhere. Just like a wood bowl or a piece of wood furniture, which can be used for a lifetime or more, a plastic product with our additives can be used for essentially the same period of time as the same plastic product without our additives could be used.

Plastics manufactured with our additives will fully biodegrade in home compost heaps, commercial composting operations (both high heat and low heat, or even in vermiculture, processes), buried in the ground, buried in landfills, tilled into the soil, having been littered, etc. Most importantly, our process is by far the least expensive, most widely applicable, proven technology for the biodegradation of plastics in the world.

Concerning the life expectancy of the plastic products manufactured with our additives once they are placed in constant contact with other biodegrading materials, we 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. Our additives have been tested in all of the types of polyolefins, EVAs, PVCs, PETs, PSs, PUs and combinations thereof, with much of the testing having been performed using the various world-standardized tests in

Again, we certify the biodegradation* of polyolefins (any of the polyethylenes and polypropylenes), EVAs, PVCs, PETs, PSs, PUs and any combination of these resins, manufactured with at least a 1% load of our additives. We base this certification on more than ten years of testing worldwide by us, by universities, by customers, by prospects and by competitors.

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BIODEGRADABLE* PLASTICS QUALIFIER

* Plastic products manufactured with ECM BioFilms' additives will biodegrade in any biologically-active environment (including most landfills) in some period greater than a year.

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Biodegradable Plastics

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Products Plastic Resins Renewable Natural Gas Sustainable

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EXHIBIT 2

REDACTED

EXHIBIT 3

ECM Technology for the Biodegradation of Plastic Products

The technology is an additive which, when combined in small quantities with any of the popular plastic resins, renders the end products biodegradable* while maintaining their other desired characteristics. It is sold as ECM MasterBatch Pellets and our Company has developed the technology to the point where most plastic products manufacturers can use the additive without having to modify their existing methods of production any more than if they were changing the product's color. The resulting plastic products exhibit the same desired mechanical properties, have effectively similar shelf-lives, and yet, when disposed of, are able to be metabolized into biomass by the communities of microorganisms commonly found almost everywhere on this planet. This biodegradation process can take place aerobically and anaerobically. It can take place with or without the presence of light. These factors allow for biodegradation even in landfill conditions which are normally inconducive to any degradation of other technologies. Our technology differs significantly from other "degradable plastics" emerging in the market today because it does not attempt to replace the currently popular plastic resin formulations but instead enhances them by rendering them biodegradable*. Recognizing the environmental concerns related to plastics and the market potential, the corporate and scientific communities have long sought to develop degradable plastics. However, the Company believes that degradable plastics introduced to date possess several weaknesses that have prevented wide-spread acceptance in the marketplace. Photo-degradable products, for example, do not degrade in landfills due to the lack of sunlight (they are typically covered with another layer of trash before the degradation can occur). At the same time these photo-degradable products present difficult circumstances for storage before use due to their reactivity to light. Similarly, plastic products manufactured with PLA and such "renewable" replacement resins fail to biodegrade as litter or in a landfill, are very expensive to manufacture, and often do not achieve the requisite physical properties. ECM's technology is a process which enables the microorganisms in the environment to metabolize the molecular structure of plastic products into humus that is beneficial to the environment. Our process utilizes several

ECM engaged several renowned testing laboratories to independently establish the biodegradability of plastic products made with ECM's additives. The tests concluded that the products were biodegradable* under both aerobic and anaerobic conditions. In addition, the tests concluded that their biodegradation did not produce any toxic residue harmful to living organisms in land or water.

Technology Explanation

The plastic products made with our additives will break down in more than one year but less than a hundred plus years in nearly all landfills or wherever else they may end up. 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 to react with the additives and form communities, biofilms, which create the enzymes and acids that can attack the longchain hydrocarbon molecules and break them down to the point that the microbes' natural acids and enzymes are then effective and the microbes can metabolize the simple hydrocarbons with CO₂ and water or methane being the waste products. This process continues until all the plastic product is fully biodegraded.

Material treated with ECM has been tested and proved as biodegradable* and safe for the environment by using the following:

- ASTM D5209 "Standard Test Method for Determining the Aerobic Biodegradation of Plastic Materials in the Presence of Municipal Sewage Sludge";
- ISO 14855 / ASTM D5338 "Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials under Controlled Composting Conditions"; and
- ASTM 5511 "Standard Test Method for Determining Anaerobic Biodegradation of Plastic Materials Under High-Solids Anaerobic Digestion Conditions".

Where will it biodegrade*?

- Home composting
- Commercial composting
- Landfills
- Buried in, or in contact with the soil
- Erosion / Agricultural netting & film

proprietary compounds that are combined into a masterbatch pellet that is easily added to plastic resins using existing technology.

- Litter
- Where won't it degrade?
- Warehouses
- Store shelves
- Offices & Home

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BIODEGRADABLE* PLASTICS QUALIFIER

* Plastic products manufactured with ECM BioFilms' additives will biodegrade in any biologically-active environment (including most landfills) in some period greater than a year.

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