Environmental Assessment

1. Date: March 24, 2017

2. Name of Applicant/Notifier: Newlight Technologies, LLC

3. Address:

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4. Description of the Proposed Action:

The action requested in this notification is to permit the use in food-contact applications of a polyhydroxyalkanoate polymer (PHA) produced by bacterial fermentation using methane as the feedstock. The resulting PHA is butanoic acid, 3-hydroxy-, (R)-, homopolymer (CAS Reg. No. 29435-48-1). The primary applications for the FCS are housewares applications, including disposable cutlery and clamshells, as well as other similar types of food-contact articles. The polymer is intended for use as a component of food-contact materials under FDA's Conditions of Use B ("Boiling water sterilized.") through H ("Frozen or refrigerated storage: Ready prepared foods intended to be reheated in container at time of use.") as described in Table 2 of FDA's "Food Types and Conditions of Use for Food Contact Substances," available at http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/default.htm).

The food contact substance (FCS) is a "biopolymer", and is intended as an alternative to traditional petroleum based polymers that currently serve the housewares market. The properties of the FCS are expected to be similar to existing PHA polymers already authorized by FDA for use in food-contact applications (*see, e.g.,* FCNs 1119 and 1398). One of the unique features of the FCS is the manner in which it is produced. More specifically, the FCS is produced by microbial fermentation using methane as the carbon feedstock. Notably, the methane that is fed to the microorganisms may be recovered from the environment to produce the PHA polymer. Thus, it is possible to produce the FCS using a greenhouse gas as the carbon source.

The FCS is intended for use in a wide variety of food-contact applications. These food-contact materials will be utilized in patterns corresponding to the national population density and

will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80.4% of the materials being deposited in land disposal sites, and about 19.6% combusted.[1] The FCS will not be used in applications that are subject to a significant level of recycling, such as blow-molded beverage bottles. Although PHA polymers are biodegradable, composting programs for articles such as cutlery that are likely to be produced from the FCS do not appear to be widely available at this time in the U.S.[2] In addition, some composting facilities may have source controls in place that may result in the rejection of articles

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[1] *See* EPA's 2014 internet summary of "Advancing Sustainable Materials Management: Facts and Figures", November 2016, available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures. *See also* "Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States", November 2016 at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

According to this report, of the total 258 million tons of municipal solid waste (MSW) generated in 2014, 52.6% was land disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting). As the FCS is expected to be disposed primarily by land-filling or combustion (*i.e.,* not recovered for recycling), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.6% of food-contact articles containing the FCS will be combusted annually. This amount is calculated as follows:

12.8% combusted ÷ (12.8% combusted + 52.6% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.

[2] The Environmental Protection Agency's (EPA) "Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States", November 2016, pages 8 and 11, available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report, confirms that food, yard trimmings, and other MSW organic materials are the categories of waste that are composted in the U.S.; plastics are not included among the materials reported to be composted.

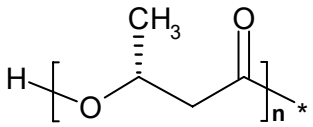
In addition, EPA directs composters to contact the commercial composting facility to determine whether compostable plastic is accepted. They also advise consumers against adding "compostable" plastics to their home composting bins, unless the packaging specifically states that the material is acceptable for "home composting." They further suggest that compostable plastics are generally intended to be composted at industrial composting sites. *See* https://www.epa.gov/trash-free-waters/frequently-asked-questions-about-plastic-recycling-and-composting.

composed of the FCS.[3] With this in mind, the Notifier expects the FCS to be disposed of almost entirely by landfill.[4]

No significant environmental impact is anticipated due to the landfilling or incinerating of compostable PHA. We did not account for composting in our quantitative CO_2 assessment because the value determined based on incineration provides a worst-case scenario with respect to greenhouse gas emissions. In any event, should some composting of the FCS occur, the Notifier does not expect this to adversely impact the environment.[5]

5. Identification of Substance that is the Subject of the Proposed Action

The FCS is produced by bacterial fermentation using methane (CAS Reg. No. 74-82-8) as the feedstock. The resulting PHA is a butanoic acid, 3-hydroxy-, (R)-, homopolymer (CAS Reg. No. 29435-48-1). The FCS is composed of the elements carbon, hydrogen, and oxygen. The chemical structure for the FCS is provided below:



The FCS is a relatively high molecular weight polymer and, therefore, it is inherently non-volatile. The molecular weight of the FCS is set out in the confidential attachment to the Environmental Assessment.

Importantly, and as alluded to above, the PHA polymer is produced through a bacterial fermentation process that relies on a biocatalyst. Specifically, the biocatalyst works by combining air with methane, and assembling the carbon, hydrogen, and oxygen molecules therein into a PHA-based thermoplastic polymer that is, by weight, approximately 40% oxygen

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[3] For example, some composting facilities only accept yard waste and/or food scraps. *See, e.g.*, Yard Waste Composting Facility, Prince George's County Maryland, http://www.princegeorgescountymd.gov/583/Yard-Waste-Composting-Facility; Balls Ford Road Composting Facility, Prince William County Virginia, http://www.pwcgov.org/government/dept/publicworks/trash/pages/compost.aspx.

[4] This is further supported by the EPA's "Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States", November 2016, pages 8 and 11, at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

[5] Environmental Protection Agency's (EPA) "Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States", November 2016, available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

from air and 60% carbon and hydrogen from methane emissions. Thus, the production process for the PHA polymer results in the sequestration, rather than emission, of greenhouse gas (*i.e.*, methane).

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject FCS. In these applications, the FCS (*i.e.*, a polymer) is expected to remain with the finished food-contact article. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact articles containing the subject FCS will occur by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

As noted above, the FCS is composed of carbon, hydrogen and oxygen, elements that are commonly found in municipal solid waste. Accordingly, the disposal of the FCS does not threaten a violation of 40 C.F.R. Part 60, which establishes emissions requirements for certain stationary sources, because the FCS is composed of elements commonly found in MSW. In addition, the regulations at 40 C.F.R. Part 258 prevent leaching of the FCS from sanitary landfills. More specifically, only extremely small amounts, if any, of the FCS constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems (40 C.F.R. Part 258). Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

As secondary support that disposal of the FCS will not significantly impact the environment, we compared the market volume information for the FCS, contained in a confidential attachment to this Environmental Assessment, to the annual municipal solid waste (MSW) production (258 million tons MSW in 2014), and conclude that the FCS will constitute a very small portion of the total MSW. Therefore, we do not expect there are any extraordinary circumstances that would otherwise suggest a significant environmental impact resulting from post-consumer disposal of food-contact articles that contain the FCS. Further, the proposed use

of the FCS and corresponding market volume (available in the Confidential Attachment) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, which EPA has indicated to be 33.1 million tons, as of 2014.[6]

On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance[7] to agencies regarding addressing greenhouse gas (GHG) emissions and climate change impacts in NEPA documents. As stated in the guidance, the document is "intended to help Federal agencies ensure their analysis of potential GHG emissions and effect of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action." The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by the EPA under 40 C.F.R. § 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report to GHG emissions under EPA's GHG reporting program (GHGRP), and sets an annual 25,000 metric ton carbon dioxide equivalent (CO_2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents.
40 C.F.R. § 1508.27(b)(10) states, that when evaluating intensity of an impact, one should consider "whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment." MSW combustion GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

Incineration of food-contact articles containing the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws) because the FCS contains elements commonly found in MSW, and the amount of the FCS combusted represents a marginal amount of combusted MSW, as shown in the confidential attachment to the EA.

7. Fate of Emitted Substances in the Environment

(a) Air

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[6] *See* Footnote 1.

[7] Council on Environmental Quality (CEQ) Final Guidance for Federal Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Review, dated August 1, 2016, *available at:* https://www.energy.gov/sites/prod/files/2016/08/f33/nepa_final_ghg_guidance.pdf

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS, as the FCS is a high molecular weight polymer and thus non-volatile.

The composition of the FCS is similar to other MSW incinerated at MSW combustion facilities, and the analysis in the confidential attachment to the EA supports the use of the FCS as described in the Notification will not exceed the EPA GHGRP threshold of 25,000 metric tons.

(b) Water

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject polymer. The fate of the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Item 6.

(c) Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. EPA's regulations at 40 C.F.R. 258 require MSW owners to operate their facilities to prevent leaching from sanitary landfills. Furthermore, the polymeric nature of the FCS is expected to result in virtually no leaching of FCS components under normal environmental conditions when food-contact articles containing the FCS are disposed in sanitary landfills. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the polymer in the manufacture of food-contact articles. Therefore, the environmental fate of substances does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject polymer consist of extremely small quantities of combustion products and leachables, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of food-contact articles containing the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the FCS. Therefore, the use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, *e.g.,* the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resources and Energy

The production of the FCS involves the sequestration of carbon gases from the atmosphere, such methane, as well as the use of a biocatalyst and other substances derived from natural resources. Importantly, the use of the subject FCS is not expected to result in a net increase in the use of energy and resources, since the FCS will be used in place of other polymers on the market.

Manufacture of the FCS, and its conversion to use in food-contact articles, will consume energy and resources in amounts comparable to the manufacture and use of other, similar FCSs. Food-contact articles produced using the subject FCS are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current recycling programs. Further, the FCS is intended primarily for use in applications not subject to recycling, such as single-use utensils, clamshells, and similar food-contact articles. Currently, polyolefins, polystyrene and polylactic acid (PLA) are most commonly used in these types of applications. Importantly, none of these types of products are recycled and would instead be removed from the recycling stream based on source control procedures.[8] Similarly, the FCS would be removed using such procedures, in the event that the FCS inadvertently became part of a recycling process stream.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in environmental problems requiring mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject FCS would otherwise replace; such action would have no environmental impact.

12. List of Preparers

Devon Wm. Hill, B.S. and M.S. in Chemistry, J.D., Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, DC 20001; 20 years of experience counseling and representing corporate entities on Food Additive Petitions and Food Contact Notifications, and assisting in the preparation of same, including Environmental Assessments.

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[8] *See* NatureWorks LLC, "The Ingeo Journey", pages 9-12 at: http://www.natureworksllc.com/~/media/News_and_Events/NatureWorks_TheIngeoJourney_pdf.pdf, detailing a near-infrared method for sorting biopolymers from traditional plastic resins.

Jason P. Schmidt, Ph.D. in Chemistry, Senior Staff Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, DC 20001; 7 years of experience evaluating and preparing Food Contact Notifications, including Environmental Assessments.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: March 24, 2017

[redacted]

Devon Wm. Hill
Counsel for Newlight Technologies, LLC

14. List of References

1. Advancing Sustainable Materials Management: Facts and Figures, Materials and Waste Management in the Unites States Key Facts and Figures (internet summary), U.S. Environmental Protection Agency, November 2016, available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures.

2. Advancing Sustainable Materials Management: 2014 Fact Sheet, Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, EPA530-R-17-01, U.S. Environmental Protection Agency, Office of Land and Emergency Management (5306P), November 2016, available at: https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report.

3. EPA's Frequently Asked Questions (FAQ) about Plastic Recycling and Composting, https://www.epa.gov/trash-free-waters/frequently-asked-questions-about-plastic-recycling-and-composting

4. Yard Waste Composting Facility, Prince George's County Maryland, http://www.princegeorgescountymd.gov/583/Yard-Waste-Composting-Facility

5. Balls Ford Road Composting Facility, Prince William County Virginia, http://www.pwcgov.org/government/dept/publicworks/trash/pages/compost.aspx

6. Council on Environmental Quality (CEQ), *Final Guidance for Federal Departments and Agencies on Consideration of Climate Change in National Environmental Policy Act Reviews*, August 1, 2016, available at https://www.energy.gov/sites/prod/files/2016/08/f33/nepa_final_ghg_guidance.pdf

7. NatureWorks LLC, "The Ingeo Journey", pages 9-12, http://www.natureworksllc.com/~/media/News_and_Events/NatureWorks_TheIngeoJourney_pdf.pdf.

15. List of Attachments

1. Confidential Attachment