Attachment 12

Environmental Assessment

1. Date: May 27, 2020

2. Name of Applicant/Notifier: DuPont Industrial Biosciences LLC

3. Address:

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Wilmington, Delaware 19803

All communications on this matter are to be sent in care of Counsel for Notifier:

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4. Description of the Proposed Action:

The action requested in this Notification is to permit the use of the Notifier's food contact substance (FCS), poly(ethylene furandicarboxylate) (CASRN 52733-28-5), at levels of up to 16% in blends with polyethylene terephthalate (PET) for direct contact with food. The FCS will be used in contact with all food types under Conditions of Use C ("Hot filled or pasteurized above 150°F") through G ("Frozen storage (no thermal treatment in the container)").[1] The FCS has gas barrier properties and is for use in imparting reduced permeation to articles for O_2, C_2, and water amongst other permeants.

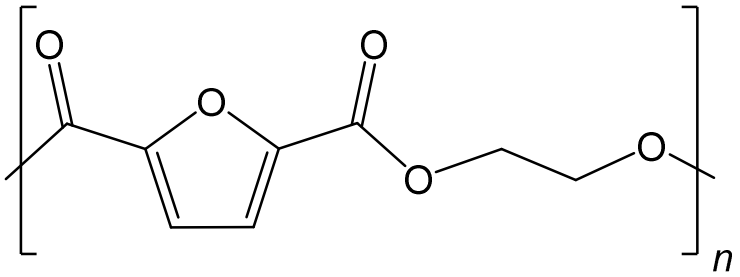
The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the FCS that is the subject of this Notification will be sold to food-contact article manufacturers. Food-contact articles produced with the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal of the subject resin will occur nationwide, with

[1] FDA's Food Types and Conditions of Use for FCNs are set forth at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste generally.[2]

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

The FCS that is the subject of this Notification is a polyester polymer identified as poly(ethylene furandicarboxylate) (PEF) (CASRN 52733-28-5). The FCS is a high molecular weight polymer. The polymer cannot be represented by a discrete chemical structure due to the presence of multiple monomeric repeating units. A generalized chemical structure of this substance may be represented as follows:



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 significant 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 significant environmental release is expected upon the use of resins containing the FCS. In these applications, the FCS is expected to be entirely incorporated into 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

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[2] *Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States,* U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, November 2019, *available at*: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf. As noted in Table 1 of EPA's fact sheet, of the total 267.8 million tons of municipal solid waste (MSW) generated in 2017, 52.1% was land disposed, 12.7% was combusted with energy recovery, 10.1% was composted, and 25.1% was recovered for recycling.

nonhazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS resin is provided in the confidential attachment to the EA.

Disposal by the ultimate consumer of food-contact articles containing the subject FCS will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. For food-contact articles that contain the FCS that are determined to be recyclable *(e.g.*, PET bottles), recycling processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated. We estimate that approximately 31% of PET bottles are recycled.[3] ASTM standard number D7611 "Standard Practice for Coding Plastic Manufactured Articles for Resin Identification" provides a guide for plastics manufacturers to mark the final plastic article with an identification code that informs users/recyclers of the identity of the resin with which the final plastic article is made.[4] We anticipate the articles manufactured with the FCS would be so marked and thus coded for recycling.

The FCS is composed of carbon, oxygen, and hydrogen. Thus, the combustion products of the FCS may include carbon dioxide. The carbon content of polymers manufactured with the FCS has been calculated based on the elemental composition of the FCS (available in the confidential attachment to the EA).

Greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 98.1, which "establishes mandatory greenhouse gas (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 GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to 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." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors.

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[3] *See* http://www.container-recycling.org/index.php/factsstatistics/plastic. In 2013, the National Association for PET Container Resources (NAPCOR) statistics for U.S. PET polymer generation and final disposition indicate 1,798 million pounds recycled + 5,764 million pounds total x 100% = 31% recycled.

[4] ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. 60 and/or relevant state and local laws).

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 polymers containing the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, hydrogen, and oxygen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

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 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 groundwater 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 collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

7. Fate of Emitted Substances in the Environment

(a) Air

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. Because the FCS is a high molecular weight polymer, the FCS does not readily volatilize. Use and disposal of food-contact materials manufactured with the FCS will not significantly alter the emissions from municipal solid waste combustion facilities operating under 40 C.F.R. Part 60. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the FCS.

As indicated above in Item 6, the FCS will make up a very small portion of the total municipal solid waste currently combusted, such polymers will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of food-contact materials containing the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. See Confidential Attachment for additional details.

(b) Water

No significant effects on the concentrations of and exposures to any substance in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS. The fate of finished food-contact articles manufactured with 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. In particular, the polymeric nature of the FCS is expected to result in virtually no leaching of components of the finished FCS under normal environmental conditions when these substances are disposed. Furthermore, the estimated production of finished food-contact articles with the FCS, as discussed in the corresponding confidential attachment, precludes any substantial release to the environment of its components. 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 resins containing the FCS in the manufacture of articles intended for use in contact with food. 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. <u>Environmental Effects of Released Substances</u>

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 small quantities of combustion products and leachables, if any. Thus, no significant adverse effect on organisms in the environment is expected as a result of the disposal of 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 FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Parts 60 and 258.

9. <u>Use of Resources and Energy</u>

As is the case with other food packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. The use of the subject polymer in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, because polymers manufactured with the FCS are intended to be used in food-contact articles in place of similar polymers already on the

market in food-contact applications. Polymers currently used in the applications in which the FCS polymer is anticipated to be used include articles comprised of 100% PET.

The partial replacement of this type of material by the subject FCS is not expected to have any significant adverse impact on the use of energy and resources. Manufacture of the FCS, polymers containing the FCS, and the final conversion of the polymer to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture and use of the other food-contact substances.

In general, we understand that the FCS that is the subject of this Notification is intended for use as a component of PET beverage bottles. When the FCS is used to fabricate bottles, we expect them to be replacements for bottles that currently are comprised of 100% PET.

One important facet of the manufacture of PEF that is different from most other polymers is that PEF is not manufactured from monomers that are petroleum-derived substances as the basic raw materials. The monomers from which PEF is manufactured are ethylene glycol (CASRN 107-21-1) and dimethyl furan-2,5-dicarboxylate (CASRN 4282-32-0). The ethylene glycol used in the manufacture of the FCS is prepared by the fermentation of sucrose from renewable resources (*e.g.*, from sugar cane), followed by steps to convert the ethanol fermentation product to ethylene glycol. Dimethyl furan-2,5-dicarboxylate also is obtained from renewable resources; plant-sourced glucose is converted in several steps to dimethyl furan-2,5-dicarboxylate. Thus, PEF is manufactured from renewable resources.

According to Section 101(b)(6) of the National Environmental Policy Act (NEPA) (42 U.S.C. § 4331(b)(6)),

> (b) In order to carry out the policy set forth in [NEPA], it is the continuing responsibility of the Federal Government to use all practicable means, consistent with other essential considerations of national policy, to improve and coordinate Federal plans, functions, programs, and resources to the end that the Nation may...(6) enhance the quality of renewable resources and approach the maximum attainable recycling of depletable resources. [emphasis added]

Thus, as PEF is manufactured from renewable resources, the replacement of other polymers by PEF will have a net effect of reduction of the use of depletable resources.

For these reasons, no significant adverse impacts on the use of natural resources and energy are expected as a result of this Notification becoming effective.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated using the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished articles employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similarity of the subject FCS to the material it is intended to replace. Thus, no significant adverse impacts were identified that require mitigation measures.

11. Alternatives to the Proposed Action

No significant 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 material that the subject FCS would otherwise replace; such action would have no significant environmental impact.

12. List of Preparers

George G. Misko, J.D., Partner, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Mr. Misko has over 30 years of experience drafting food additive petitions, FCN submissions, and environmental assessments.

Peter N. Coneski, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Dr. Coneski has over 5 years of experience drafting FCN submissions and 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: May 27, 2020

[redacted]

George G. Misko
Counsel for DuPont Industrial Biosciences LLC

14. References

1. FDA's Food Types and Conditions of Use for FCNs are set forth at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. *Advancing Sustainable Materials Management: 2017 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States,* U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, November 2019, *available at*: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf.

3. *Container Recycling Institute's Plastics Facts & Statistics* are available at http://www.container-recycling.org/index.php/factsstatistics/plastic.

4. ASTM, Standard Practice for Coding Plastic Manufactured Articles for Resin Identification, 2020. D7611/D7611M-20.

15. Attachments

1. Confidential Attachment – Attachment 13