

- 1. Date:** February 15, 2018
- 2. Name of Applicant:** Indorama Ventures Química SLU
- 3. Address:** Poligono Industrial Guadarranque, S/N  
San Roque, 11360, Spain

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 isophthalic acid. The finished copolymers must contain 3 to 17 weight percent ethylene isophthalate units. The finished copolymers comply with 21 C.F.R. § 177.1630 (“Polyethylene phthalate polymers”), in food-contact applications. The technical effect of the FCS is to reduce crystal formation in the food-contact material, as well as reduce the processing temperature. It thus makes possible the production of transparent bottles and containers.

The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the food-contact substance (FCS) that is the subject of this Notification will be sold to resin manufacturers who make resins that are ultimately sold to food-contact articles manufacturers. Food-contact articles produced with the food-contact substance 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 resin made with the subject FCS will occur nationwide, with the material being land disposed, combusted or recycled in quantities similar to those reported for municipal solid waste generally.<sup>1</sup>

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

The FCS that is the subject of this Notification is isophthalic acid (CAS Reg. No. 121-91-5). If this Notification were to become effective, the subject monomer may be used in the manufacture of copolymers made from the reaction of dimethyl terephthalate (or terephthalic

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<sup>1</sup> *Advancing Sustainable Materials Management: Facts and Figures 2014*, U.S. Environmental Protection Agency, Accessed October 2017, 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, approximately 52.6% generally was land-disposed, 12.8% was combusted, and 34.6% was recovered (a combination of waste recovered for recycling and for composting).



98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO<sub>2</sub>-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.” In accordance with 40 C.F.R. § 1508.27, the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment.

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.

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 correction action as appropriate.

## **7. Fate of Emitted Substances in the Environment**

### **a. Air**

No significant effect on the concentrations of an exposures to any substances in the atmosphere are anticipated due to the proposed use of the food-contact substance. Polymers manufactured using the food-contact substance do not readily volatilize. Use and disposal of food-contact applications 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 food-contact substance.

As indicated above in Item 6, because polymers manufactured with the FCS monomer 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.

## **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 polymers manufactured with the food-contact substance 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 food-contact substance. In particular, the polymeric, hydrocarbon nature of resin manufactured with the FCS monomer is expected to result in virtually no leaching of components of the finished food-contact substance under normal environmental conditions when these substances are disposed of. Furthermore, the very low production of polymers manufactured with the FCS monomer for use in food-contact applications, 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 food-contact substance.

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. Environmental Effects of Released Substances**

As discussed previously, the only substance that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject monomer 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 articles containing the food-contact substance. 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-contact substance 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**

As is the case with other food packaging materials, the production, use and disposal of the food-contact substance involves the use of natural resources such as petroleum products, coal, and the like. The use of the subject monomer in the manufacture of resins that are subsequently used 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 polymers containing the FCS monomer are anticipated to be used include other dimethyl terephthalate (or terephthalic acid)-ethylene glycol-isophthalic acid copolymers that are currently permitted under Food Contact Notifications (FCN) 4, 211, and 1423.

The partial replacement of these types of materials by the subject food-contact substance is not expected to have any adverse impact on the use of energy and resources. Manufacture of the food-contact substance, polymers containing the food-contact substance, 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 that copolymers that contain isophthalic acid up to the levels requested in this Notification can be used to fabricate bottles, which constitute a significant portion of the PET plastic recycling stream. Thus, where the subject polymers are used to fabricate bottles, they will be replacements for the bottles currently being recovered for recycling and that also are covered by the indicated effective FCNs (FCNs 4, 85, 211, 376, 547, 635, 1064, and 1423). In this way, there is no expectation of an impact on current or future recycling programs. In addition, as polymer resins are typically added to PET, use of the FCS in food-contact applications is not expected to have a negative impact on recyclability.

For these reasons, no 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 food-contact substance. This is primarily due to the minute levels, if any, of leaching of components of the food-contact substance from finished articles employing the food-contact substance, the insignificant impact on environmental concentrations of combustion products of the food-contact substance, and the similarity of the subject food-contact substance to the materials it is intended to replace. Thus, no significant adverse impacts were identified that require 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 food-contact substance would otherwise replace; such action would have no significant environmental impact.

## **12. List of Preparers**

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

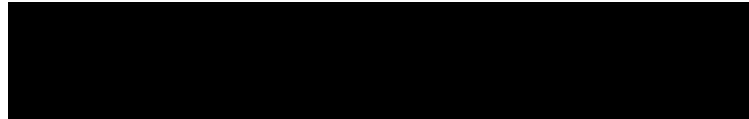
Peter N. Coneski, Ph.D. in Chemistry, Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001.

### **13. Certification**

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

Date: February 15, 2018

Catherine R. Nielsen



Counsel for Indorama Ventures Química SLU

### **14. List of References**

1. *Advancing Sustainable Materials Management: Facts and Figures 2014*, U.S. Environmental Protection Agency, Accessed October 2017, at <https://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report>.

### **15. Attachments**

1. Confidential Attachment – Attachment 14