

Part IV (Environmental Information); Section B (Environmental Assessment)

An EA is required and has been prepared under 21 CFR 25.40 and is attached.

Note: An EA is a public document and should not contain confidential information. Such information should be included in a separate section of the FCN, labeled confidential and summarized to the extent possible in the EA.

1. **Date:** August 2, 2017
2. **Name of Applicant/Notifier:** LyondellBasell Industries
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4. **Description of the Proposed Action**

The action requested in this notification is to permit the use of “poly-1-butene polymers(CAS Reg. No. 9003-28-5)” and “butene/ethylene copolymers (CAS Reg. No. 25087-34-7)” in contact with food. This FCN seeks to cover poly-1-butene polymers and copolymers containing up to 7.5% polymers units derived from ethylene in contact with all types of foods under Conditions of Use A through H. In addition, with respect to permitted uses in contact with infant formula and breast milk, the polymers and copolymers may be used in repeated-use articles (excluding baby bottle nipples) intended for the feeding of infants (e.g., baby bottles). The polymers and copolymers will have a melt index of 0.10-3000 g/10 min, a density of 0.87-0.93 kg/dm³, and a typical intrinsic viscosity of < 3.2 dl/g.

The subject poly-1-butene polymers and copolymers offer several technical properties that make them useful in a variety of food packaging applications. In particular, the FCS is very compatible with polypropylene and, when used in blends with polypropylene, improves its

flexibility, elasticity, and transparency. The properties of the final food-contact article (blends with the subject FCS) are comparable in function to flexible PVC but, unlike PVC, the FCS is a type of polymer that does not require the use of plasticizers; furthermore, the FCS is a type of polymer that does not contain chloride atoms and, thus, may be burned without releasing dioxins.

The Notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the food-contact substance that is the subject of this Notification will be sold to formulators engaged in the production of food-contact articles. 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 will occur nationwide, with about 80.4% of the materials being deposited in land disposal sites, and about 19.6% combusted.¹

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the food-contact substance.

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

The FCS that is the subject of this Notification is: poly-1-butene polymer (CAS Reg. No. 9003-28-5) and butene/ethylene copolymers (CAS Reg. No. 25087-34-7).

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

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 approximately 19.6% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: $12.8\% \text{ combusted} \div (12.8\% \text{ combusted} + 52.6\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.

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 to fabricate packaging materials. In these applications, the FCS (*i.e.*, a polymer) is expected to be entirely incorporated into and 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 a 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 materials produced by the subject polymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

The subject polymer consists of carbon and hydrogen. Thus, carbon dioxide and water are expected to form upon combustion of the FCS. The carbon content of the FCS has been calculated based on the elemental composition of the FCS (available in a confidential attachment to the FCN).

On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance² 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 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, 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 (CO₂-e) emission threshold for required reporting. As can be seen in the Confidential Attachment to the Environmental Assessment, based on the proposed use of the FCS, the anticipated market volume (available in a confidential attachment to the FCN), and calculations regarding the maximum introduced level of carbon dioxide as a combustion product (available in a confidential attachment to the FCN), we have quantified the potential carbon dioxide and CO₂ equivalent emissions resulting from combustion of the FCS. As noted in the Confidential Attachment, the uses of the FCS proposed in this notification will result in small potential increases to greenhouse gas emissions.³

² https://www.energy.gov/sites/prod/files/2016/08/f33/nepa_final_ghg_guidance.pdf.

³ We note that the earlier CEQ draft guidance provided a reference point of 25,000 metric tons of CO₂ emissions below which a GHG analysis is not needed; however, the final guidance no longer includes this threshold. We are not aware that FDA has issued any further guidance on

Based on the proposed use of the FCS, the anticipated market volume (available in a confidential attachment to the FCN), and calculations regarding the maximum introduced level of carbon dioxide and CO₂ equivalent combustion products (available in a confidential attachment to the FCN), we have concluded that the FCS will make up a very small portion of the total municipal solid waste currently combusted, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

Only extremely small amounts, if any, of the polymer 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 groundwater monitoring systems.⁴ 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. The lack of any leaching is especially true considering that the subject substance is a high molecular weight polymer resin that contains only low levels of low molecular weight oligomers, which is the portion of the resin that can potentially be leachable.

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 resin. The polymer is of high molecular weight and does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the resin.

The products of complete combustion of the polymer are carbon dioxide and water; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymer in the amounts utilized for food packaging applications, particularly considering that, as stated above, the expected market volumes for the polymers described herein will be only a minute fraction of the total MSW produced.

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

this point. In the absence of specific guidance from the Agency, we refer to the 25,000 metric tons per year benchmark in assessing the environmental impact of this action. In that regard, we have calculated that carbon dioxide equivalent emissions associated with combustion of the FCS is far below the 25,000 metric tons per year benchmark.

⁴ 40 C.F.R. Part 258.

polymer. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymer, nor upon its disposal in landfills.

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 resin. In particular, the low production of the resin for use in food-contact applications precludes any substantial release to the environment of their 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 resin.

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 resin in the manufacture of articles intended for use in contact with food. Accordingly, the environmental fate of the FCS does not need to be addressed because no significant introduction of substances into the environment was identified as a result of the proposed use of the FCS.

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 polymers consist of extremely small quantities of combustion products and leachate, 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 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

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. However, the use of the subject food-contact substance in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since the food-contact substance is intended to be used in food-contact articles which will be used in place of similar polymers now on the market for use in food-contact applications. Substances currently used in the applications in which the subject food-contact substance is anticipated to be used include those that are permitted under 21 C.F.R. § 177.1570 ("Poly-1-butene resins and butene/ethylene copolymers"), FCN 146, and FCN 1436.

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, and its conversion to finished food-contact materials, will consume energy and resources in amounts comparable to the manufacture and use of the other food-contact substances. Furthermore, the use proposed in this Notification for the subject food-contact substance, which is a family of poly-1-butene polymers butene/ethylene copolymers, is as a replacement for polymers, *i.e.*, other poly-1-butene and butene/ethylene copolymers, that are not currently recovered for recycling. Food-contact materials produced using the subject food-contact substance 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 or future recycling programs.

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, the use of the food-contact substance as proposed is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

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 environmental impact. In view of the fact that the food-contact substance constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from its use, the establishment of an effective Food Contact Notification to permit the use of the subject food-contact substance as described herein is environmentally safe in every respect.

12. List of Preparers

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13. Certification

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

Date: August 2, 2017



Counsel for LyondellBasell

14. References

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>.

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2. See https://www.energy.gov/sites/prod/files/2016/08/f33/nepa_final_ghg_guidance.pdf.
3. We note that the earlier CEQ draft guidance provided a reference point of 25,000 metric tons of CO₂ emissions below which a GHG analysis is not needed; however, the final guidance no longer includes this threshold. We are not aware that FDA has issued any further guidance on this point. In the absence of specific guidance from the Agency, we refer to the 25,000 metric tons per year benchmark in assessing the environmental impact of this action. In that regard, we have calculated that carbon dioxide equivalent emissions associated with combustion of the FCS is far below the 25,000 metric tons per year benchmark.
4. 40 C.F.R. Part 258.

15. Attachments

1. Attachment 11, Confidential Environmental Information (**CONFIDENTIAL**).