

## Environmental Assessment

1. **Date:** July 25, 2025

2. **Name of Applicant/Notifier:** TotalEnergies Corbion BV

3. **Address:**

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**

### A. Requested Action

The action proposed in this Notification is to provide for the use of long-chain branched polylactic acid as a component of food-contact articles. Finished articles made with the food-contact substance may contact all types of food, except beverages containing more than 15 percent alcohol, under Conditions of Use B through H, as described in Tables 1 and 2. The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

### B. Need for Action

The linear, straight-chain structure of standard polylactic acid (PLA; CAS Reg. No. 9051-89-2) results in a polymer with low melt strength and low melt elasticity. Melt strength and melt elasticity are crucial properties for processes requiring significant elongational flow such as film blowing, blow molding, fiber spinning, and foaming. Such processes therefore are difficult to perform with a standard PLA. The linearity of standard PLA also results in high crystallinity which leads to lower impact strength and relatively low heat distortion temperatures. The low melt strength and crystalline properties of PLA are the primary barriers to marketing polylactide (PLA) into broader food-contact applications. The subject FCS (long-chain branched polylactic acid) has improved melt strength, crystallinity, and heat resistance relative to standard PLA which allow greater flexibility with polymer processing such as film blowing, blow molding, and foaming.

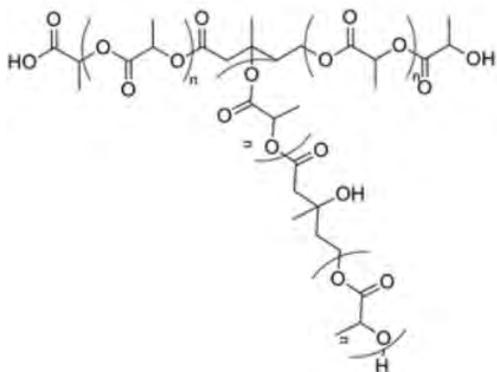
### C. Location of Use and Disposal

The Notifier does not produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this Notification will be sold to manufacturers engaged in the production of food-contact materials. Food-contact articles containing the FCS will be used in patterns corresponding to the national population density and will be widely distributed across

the country. It is therefore anticipated that disposal of food-contact materials containing the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste generally.

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

The FCS that is the subject of this Notification is long-chain branched polylactic acid. The structure of the base polymer is depicted as follows:



The Figure above illustrates the standard PLA backbone as the horizontal chain across the top and the long-chain branch coming off of a carbon atom of that backbone on the more or less diagonal.

**Molecular Formula:**  $(C_3H_4O_3)_n$

## 6. Introduction of Substances into the Environment

### A. Manufacture

Title 21 C.F.R. § 25.40(a) states that an environmental assessment should focus on relevant environmental issues relating to the use and disposal rather than the production of FDA-regulated articles. Moreover, information available to the Notifier is not suggestive of any extraordinary circumstances that would indicate a potential for significant adverse environmental impacts resulting from the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided.

### B. Use

No significant environmental release is expected upon the use of the FCS in food-contact materials. The FCS is expected to be entirely incorporated into the finished food-contact article in these applications. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the food-contact material manufacturer's overall nonhazardous solid waste disposal plan in accordance with established procedures.

### C. Disposal

Disposal of food-contact materials containing the subject FCS by the ultimate consumer will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. Food-contact articles containing the FCS will be used in patterns corresponding to the national population density and will be widely distributed across the country. According to U.S. Environmental Protection Agency (EPA) data for 2018, approximately 50.0% of municipal

solid waste is currently deposited in land disposal sites, 11.8% is combusted with energy recovery, 23.6% is recycled, and 8.5% is composted.<sup>1</sup> The use of the FCS in food-contact articles will not impact the disposal patterns of the articles in which it is used.

These disposal patterns are recalculated here based on only the quantities of municipal solid waste (MSW) that are land disposed or combusted because, although the FCS is recyclable, current waste infrastructure does not fully support its recycling. Therefore, approximately 19.1% of food packaging materials containing the FCS will be combusted annually. This amount is estimated as follows:  $11.8\% \text{ combusted} \div (11.8\% \text{ combusted} + 50.0\% \text{ land disposed}) = 19.1\% \text{ combusted}$ . Therefore, it is anticipated that disposal will occur nationwide, with approximately 19.1% combusted. The remaining 80.9% will be land-disposed.

The FCS is composed of carbon, oxygen, and hydrogen; elements that are commonly found in municipal solid waste. We compared the projected fifth year market volume for the FCS, contained in a confidential attachment to this Environmental Assessment, to the annual MSW production (292 million tons MSW in 2018), and to the portion of that total that is landfilled, and conclude that the FCS will constitute an insignificant portion of the total MSW, as well as the amount of that total that is landfilled. Therefore, we expect no extraordinary circumstances that would suggest a significant environmental impact resulting from post-consumer disposal of packaging that contains the FCS. Further, the proposed use of the FCS and corresponding projected 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, estimated to be 11.8% of the 292 million tons total waste generated, or 34.5 million tons, as of 2018.<sup>2</sup> Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant municipal solid waste combustors, and incineration of food-contact articles containing the FCS will not cause municipal solid 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).

An analysis of the significance of environmental impacts should include the degree to which the action may violate relevant federal, state, or local laws imposed or policies designed for the protection of the environment in accordance with 40 C.F.R. § 1501.3(d)(2)(iii).<sup>3</sup> Title 40

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<sup>1</sup> *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States*, U.S. Environmental Protection Agency, Office of Land and Emergency Management, Dec. 2020, see [Advancing Sustainable Materials Management: 2018 Fact Sheet \(epa.gov\)](https://www.epa.gov/advancing-sustainable-materials-management-2018-fact-sheet).

<sup>2</sup> *Id.*

<sup>3</sup> 40 C.F.R. Parts 1500-1508 have been rescinded pursuant to a February 25, 2025 interim final rule issued by Council on Environmental Quality (CEQ). 90 Fed. Reg. 10,610 (Feb. 25, 2025) available at <https://www.federalregister.gov/documents/2025/02/25/2025-03014/removal-of-national-environmental-policy-act-implementing-regulations>. This EA references these rescinded regulations pursuant to FDA's existing NEPA implementing procedures provided in 21 C.F.R. § 25 and related guidance. See U.S. Food and Drug Admin., *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN*, May 2006 (current as of Sept. 20, 2018), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical->

C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO<sub>2</sub> equivalents (CO<sub>2</sub>-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (EPA). Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). 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 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. Subsection 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 (CO<sub>2</sub>-e) emission threshold for required reporting.

The expected carbon dioxide emissions resulting from combustion of the FCS were estimated in the confidential attachment to the Environmental Assessment from the fifth-year confidential market projection. These expected emissions are far below 25,000 metric tons annually. No significant environmental impacts are anticipated to result from combustion of the FCS in MSW combustion facilities because the estimated GHG emissions are far below the threshold for mandatory reporting.

Only extremely small amounts, if any, of the FCS are expected to enter the environment via landfill disposal of food-contact articles consequent to the EPA's 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).

## **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 does not readily volatilize.

The FCS will make up a very small portion of the total municipal solid waste currently combusted. Therefore, combustion of the FCS will not significantly alter the emissions from 40 C.F.R. § 60-compliant municipal solid waste combustors, and the incineration of food-contact materials containing the FCS will not cause municipal solid waste combustors to threaten a

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[exclusion-or-environmental-assessment-submission-cfsan#III](#). CEQ has advised that “agencies should apply their current NEPA implementing procedures with any adjustments needed to be consistent with the NEPA statute as amended by the [Fiscal Responsibility Act].” Exec. Office of the President, CEQ, Chief of Staff, Katherine R. Scarlett, *Memorandum for Heads of Federal Departments and Agencies*, February 19, 2025, available at <https://ceq.doe.gov/docs/ceq-regulations-and-guidance/CEQ-Memo-Implementation-of-NEPA-02.19.2025.pdf>.

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. No significant quantity of any substance will enter water systems upon the proper incineration of the polymer nor upon its disposal in landfills due to negligible levels of migration of polymer components. The fate of finished food-contact articles containing 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 exposure to any substances in terrestrial ecosystems are anticipated due to the proposed use of the subject FCS. The polymeric nature of the FCS is expected to result in virtually no leaching of the FCS components under normal environmental conditions when articles containing the FCS are disposed. Thus, there is no expectation of any meaningful exposure of polymer-borne substances to terrestrial organisms due to the proposed use of the FCS.

Considering the foregoing, 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 subject FCS in the manufacture of food-contact materials.

## **8. Environmental Effects of Released Substances**

The only substances that may be expected to be released to the environment upon the use and disposal of food-contact articles fabricated with the subject polymer consist of extremely small quantities of combustion products and negligible levels of migrating polymer components. Thus, no adverse effect on organisms in the environment is expected due to the disposal of food-contact articles containing the FCS. No information needs to be provided on the environmental effects of substances released into the environment due to use and/or disposal of the FCS because only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of food-contact articles containing the FCS. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, *e.g.* the Environmental Protection Agency's regulation in 40 CFR Parts 60 and 258.

## **9. Use of Resources and Energy**

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

Manufacture of the FCS, and its conversion to use in a food-contact article, will consume energy and resources in amounts comparable to the manufacture and use of other similar food-contact substances. Furthermore, the finished food-contact articles in which the FCS is used are

not currently recovered for recycling. Food-contact materials 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 or future recycling programs.

**10. Mitigation Measures**

No significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials containing 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 (*i.e.*, straight-chain polylactide). 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 the 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**

Cynthia B. Lieberman, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Washington, DC 20001. Juris Doctorate; many years of experience preparing environmental assessments related to food-contact notifications.

Mark A. Hepp, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001. Ph.D. (Chemistry); many years of experience preparing environmental assessments related to food-contact notifications.

**13. Certification**

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

Date: July 25, 2025



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Cynthia B. Lieberman  
Counsel for Notifier

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

1. Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations, Appendix V, Table 2: Conditions of Use. Available at:

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081818.htm>.

2. *Advancing Sustainable Materials Management: 2018 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 2020, available at:

[https://www.epa.gov/sites/production/files/2020-11/documents/2018\\_ff\\_fact\\_sheet.pdf](https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf).

#### **15. List of Attachments**

1. Confidential Environmental Assessment (Attachment 11)