

Environmental Assessment (EA)

1. **Date:** May 28, 2025
2. **Name of Applicant/Notifier:** Versalis, S.p.A.
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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), ethylene/1-butene copolymers (CAS Reg. No. 25087-34-7), containing up to 25 weight percent polymer units derived from 1-butene. The clearance established by this notification would permit the use of the FCS in contact with all food types under Conditions of Use A ("High temperature heat-sterilized (*e.g.*, over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use"). The FCS is not intended for use in contact with infant formula or human milk.

The Notifier does not intend to 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 materials containing 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 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 (MSW) generally.¹ According to the U.S. Environmental Protection Agency's (EPA), it is estimated that, as of 2020,

¹ *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).

of the 292.36 million tons of MSW generated, approximately 50.0% is land disposed, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways.² As the FCS is a resin that is expected to be disposed primarily by land-filling or combustion (*i.e.*, not recovered for recycling, composted, or handled through other food management pathways), we have recalculated the disposal pattern based on only the quantities of plastic waste that are land disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually.³

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

Food Contact Substance: Ethylene/1-butene copolymers, containing up to 25 weight percent polymer units derived from 1-butene.

Other Names: ethylene butane-1 copolymer; ethylene butane-1 rubber; 1-butene polymer with ethane; poly(1-butene-co-ethylene)

CAS Reg. No.: 25087-34-7

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) (“Environmental assessments”), 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 food-contact materials. 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 the FCS in food-contact materials. The FCS will be used as the basic polymer to fabricate all forms of food-contact articles, will be entirely incorporated into the finished food-contact article, and is expected to remain with these materials throughout use/disposal by the consumer. 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 in accordance with established procedures. The FCS will be used in place of currently authorized linear low-density polyethylene (LLDPE) resins.

Disposal by the ultimate consumer of food-contact materials containing the subject FCS will be by conventional rubbish disposal (*i.e.*, sanitary landfill or incineration). The FCS consists of carbon and hydrogen. When properly incinerated, the combustion products are expected to be carbon dioxide and water. Based on the elemental composition of the FCS, the worst-case releases of carbon dioxide from the FCS have been calculated. The concentrations of these

² *Id.*

³ $11.8\% \text{ combusted} \div (11.8\% \text{ combusted} + 50.0\% \text{ land disposed}) = 19.1\% \text{ combusted}$. The remaining 80.9% will be land-disposed.

substances in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food-contact applications.

To evaluate the significance of the environmental impact, we considered whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment. Greenhouse gas (GHG) emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2 (“Who must report?”). The expected carbon dioxide equivalent emissions are below 25,000 metric tons on an annual basis, as detailed in our Confidential Environmental Information Attachment. As the estimated GHG emissions are well below this threshold for mandatory reporting, no significant adverse environmental impacts are anticipated from combustion of food-contact materials containing the FCS in MSW combustion facilities.

EPA regulations require all 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 (“Criteria for Municipal Solid Waste Landfills”)). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the FCS is not expected to reach aquatic or terrestrial environments when disposed via landfill.

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 is not expected to readily volatilize. Further, the FCS is expected to be used as a replacement for other authorized LLDPE polymers. Use and disposal of food-contact materials manufactured with the FCS will not significantly alter the emissions from solid waste combustion facilities operating under 40 C.F.R. Part 60 (“Standards of Performance for New Stationary Sources”).

As indicated above in Item 6, the FCS will replace a portion of the total municipal solid waste currently combusted. Therefore, combustion of the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and the 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 Environmental Information 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 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 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 Confidential Environmental Information Attachment, precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure to terrestrial organisms of 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 subject FCS in the manufacture of food-contact materials.

8. Environmental Effects of Released Substances

No information is needed to address the environmental effects of substances released into the environment as a result of the use and disposal of the FCS in landfills and by combustion because, as discussed under Item 6 above, only very small quantities of substances, if any, are expected to be introduced into the environment due to the intended use of the FCS. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use, and disposal of the FCS involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject FCS in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources because the FCS will replace the use of other packaging materials.

Manufacture of the FCS and the final conversion to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture of chemically related resins. Articles and packaging materials produced from the FCS are expected to be disposed of according to the same patterns when used in place of currently marketed materials. Thus, there will be no impact on current 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 from the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No significant 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 (*e.g.*, LLDPE and similar polyolefin resins already on the market); such action would have no anticipated environmental impact.

12. List of Preparers

David J. Ettinger, J. D., over 24 years of experience related to all aspects of preparing Food Contact Notifications (FCN) and Environmental Assessments to support same, Partner at Keller and Heckman LLP, The Bund Center, Suite 3604, 222 Yan'an Dong Lu, Shanghai, China 200002.

Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington DC 20001. Dr. Manning has over 8 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 28, 2025



David J. Ettinger
Counsel for Notifier

14. References

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).