

Environmental Assessment

- 1. Date:** November 1, 2023
- 2. Name of Applicant/Petitioner:** Carbios S.A. and its affiliates
- 3. Address:** All communications on this matter are to be sent in care of Counsel for the Notifier:

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4. Description of Proposed Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS), identified as subtilisin from *Alkalihalobacillus clausii* produced by a genetically modified strain of *Bacillus licheniformis* (CAS Reg. No. 9014-01-1), when used in food-contact materials. The FCS is intended for use as an additive in polylactic acid (PLA) polymers that will, in turn, be used in contact with all food types, not including infant formula and human milk, under FDA’s Conditions of Use E (“Room temperature filled and stored (no thermal treatment in the container)”) through G (“Frozen storage (no thermal treatment in the container)”).¹

The subject enzyme offers a technical property that makes it a useful addition to certain food-contact materials. Specifically, the enzyme is capable of facilitating the decomposition of polylactic acid polymers under home and industrial composting conditions. This results in a more rapid and complete breakdown of PLA polymer resulting in a lower accumulation of plastic materials in the environment.

The Notifier does not intend to produce finished food packaging materials from the subject enzyme. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact materials composed of PLA or blends thereof. Food-contact materials produced with the enzyme 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 FCS will occur nationwide. According to the U.S. Environmental Protection Agency’s 2020 update regarding municipal solid waste in the

¹ FDA’s food types and Conditions of Use are defined in Tables 1 and 2, *available at*: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.

United States, it is estimated that, of the 292.36 million tons of municipal solid waste (MSW) generated in 2018, 50.0% of municipal solid waste generally was land disposed, 23.6% was recycled, 11.8% was combusted, 8.5% was composted, and 6.1% was handled through other food management pathways.² For purposes of conservatively estimating the environmental impact resulting from this notification, we have assumed that the FCS will primarily be disposed of through combustion or land-filling (*i.e.*, not recycled, composted, or handled through other food management pathways due to varying participation in composting activities by consumers, the availability of PLA recycling and/or industrial composting facilities across the United States). In advance of the further development and adherence to composting activity in the U.S. in the coming years, we calculate the disposal pattern based on only the quantities of MSW 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

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

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

The FCS that is the subject of this notification is subtilisin from *Alkalihalobacillus clausii* produced by a genetically modified strain of *Bacillus licheniformis* (CAS Reg. No. 9014-01-1).

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 materials. The Notifier is not aware of any information to suggest that there are any extraordinary circumstances that would indicate the potential for significant adverse environmental impacts resulting from the manufacture of the FCS, such as: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State, or local environmental agencies where the emissions may harm the environment; 2) the proposed action threatening a violation of Federal, State, or local environmental laws or requirements; or 3) production associated with a proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or

² *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, accessed March 2023, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.

³ By assuming that none of the FCS is recycled, composted, or handled through other food management pathways, we recalculate the fraction of FCS that is combusted as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% is assumed to be land-disposed.

threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No significant adverse environmental release is expected upon the use of the subject FCS in food-contact materials. In these applications, the enzyme will 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 as part of the food-contact material manufacturer's overall non-hazardous solid waste in accordance with established procedures.

For the sake of conservatism, the disposal of the finished food-contact materials containing the FCS is assumed to occur by conventional rubbish disposal, *i.e.*, sanitary landfill or incineration. Food-contact articles produced from the FCS may ultimately be subject to composting because PLA polymers are compostable. However, the Notifier understands that, while home composting is increasingly prevalent and industrial composting programs are increasing in many markets, they are not yet categorically available in all communities across the U.S.⁴

The subject enzyme consists of amino acids that contain the elements carbon, hydrogen, oxygen, nitrogen, and sulfur. Thus, when properly incinerated, the combustion products are expected to be carbon dioxide, nitrous oxide, SO_x, and water. Based on the elemental composition of the FCS, the potential greenhouse gas (GHG) emissions derived from the combustion of the FCS is below 25,000 metric tons carbon dioxide equivalent (CO₂-e) emissions per MSW combustor on an annual basis.⁵ Thus, the concentration of GHG in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food-contact applications.

Further, to evaluate the significance of the environmental impact, we have considered whether the action threatens a violation of Federal, State, or local laws or requirements imposed for the protection of the environment (*i.e.*, 40 C.F.R. Part 60, 40 C.F.R. Part 98.2, and/or relevant state and local laws). In this context, the U.S. EPA, under 40 C.F.R. § 98, “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG.” This regulation describes that facilities must report GHG emissions and sets an annual 25,000 metric ton CO₂-e threshold for required reporting (40 C.F.R. 98.2) and identifies MSWCs as an included stationary fuel combustion source under 40 C.F.R. 98.30(a). As the estimated GHG emissions are below the threshold for mandatory reporting, no significant adverse environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations.

⁴ See <https://www.findacomposter.com/public/search>, which lists industrial composting facilities capable of processing MRF Processed or Unsorted MSW in only 20 states nationwide.

⁵ U.S. estimated 75 MSWCs. See US EPA: Energy Recovery from the Combustion of Municipal Solid Waste (MSW), available at: <https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw>.

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 materials, in light of the EPA regulations governing MSW landfills. EPA's regulations require new MSW 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, "to have ground water monitoring systems to take corrective action as appropriate (40 C.F.R. Part 258)." 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 the aquatic or terrestrial environment when disposed of 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 high molecular weight, the FCS is not expected to readily volatilize. Thus, no significant quantities of any substances will be release upon the use and disposal of food-contact materials manufactured with the FCS.

As indicated above in Item 6, the FCS will replace a portion of the total MSW currently combusted. Therefore, combustion of the FCS will not significantly later the emissions from properly operating MSW combustors, and the incineration of food-contact materials containing the FCS will not cause MSW combustors to threaten a violation of applicable emissions laws and regulations.

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 FCS. No significant quantities of any substance will be added to these water systems upon the proper incineration of the FCS, nor upon its disposal in landfills. Similarly, no significant effects on the concentrations of and exposure to any substances are anticipated as a result of the proposed use of the subject FCS. Thus, the fate of finished food-contact materials containing the FCS in the aqueous environment does not need to be addressed because 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 high molecular weight 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 materials 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 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 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 subject substance 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. Thus, use and disposal of 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 ("Standards of Performance for New Stationary Sources") that pertain to MSW combustors and Part 258 ("Criteria for Municipal Solid Waste Landfills") 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. 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 or resources since the FCS will replace the use of other food-contact materials.

Production of the enzyme will consume energy and resources in amounts comparable to other additives that are used in the production of finished food-contact materials.

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 from the FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished materials employing the FCS and the insignificant impact on environmental concentrations of combustion products of the FCS. Thus, no significant adverse impacts were identified that require mitigation measures.

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; such action would have no anticipated environmental impact.

12. List of Preparers

Mark Thompson, J.D., Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Over fifteen years of experience in preparing Food Contact Notifications and Environmental Assessments in support of the same.

Peter N. Coneski, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Ten years of experience preparing FCN submissions, including their Environmental Assessments.

13. Certification

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

Date: November 1, 2023

Signature:



14. References

1. FDA's food types and Conditions of Use are defined in Tables 1 and 2, available at: <https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances>.
2. *Advancing Sustainable Materials Management: Facts and Figures 2018*, U.S. Environmental Protection Agency, accessed June 2022, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_ff_fact_sheet.pdf.
3. <https://www.findacomposter.com/public/search>
4. US EPA: Energy Recovery from the Combustion of Municipal Solid Waste (MSW), available at: <https://www.epa.gov/smm/energy-recovery-combustion-municipal-solid-waste-msw>.

15. Appendices

1. Confidential Addendum to Environmental Assessment.