Environmental Assessment for Food Contact Notification FCN 2384

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Environmental Assessment

1. **Date:** August 15, 2024 *

2. **Name of Notifier:** Ingenia Polymers Corporation

3. **Address:** Agent for Notifier: Joan Sylvain Baughan Steptoe LLP
30 Connecticut Avenue, N.W. Washington, DC 20036-1795

4. **Description of the Proposed Action**

The action requested in this Notification is the establishment of a clearance to permit the use of polylactide (polylactic acid; PLA) polymers optionally containing up to 16 weight percent D-lactic acid polymer units, (CAS Reg. No. 9051-89-2), supplied by Ingenia Polymers Corporation, as a component of food-contact articles in contact with all types of food under Conditions of Use A through H.[1]

The subject polymer offers several technical properties that make it useful in a variety of food contact applications. The thermal and mechanical properties of this polymer make it useful in flexible packaging and in certain rigid packaging applications.

The Notifier does not intend to produce finished food packaging materials from PLA but may manufacture masterbatches using PLA to be supplied as components for finished packaging. The polymer pellets, film, and sheets will be sold to manufacturers who produce food-contact materials. Those food-contact materials will be utilized in patterns corresponding to the national population density and will be widely distributed across the United States of America. Therefore, it is anticipated that disposal will occur nationwide, with material being land disposed, combusted, composted, or recycled.

Therefore, it is anticipated that disposal will occur nationwide, with about 80.9% of the materials being deposited in land disposal sites, and about 19.1% combusted.[2]

As noted in the U. S. Environmental Agency's (US EPA) 2018 update regarding municipal solid waste in the United States report, food-contact materials manufactured from PLA are not expected to be collected for recycling (see data excerpted from this report in the below table).

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[1] https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances

[2] See the U.S. Environmental Protection Agency's (EPA) "Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Material Generation and Management in the United States" EPA530-F-20-009 (December 2020). Available at: https://www.epa.gov/sites/production/files/2021-01/documents/2018_ff_fact_sheet_dec_2020_fnl_508.pdf

As noted in Table 1 of EPA's fact sheet, of the total 292.36 million tons of municipal solid waste (MSW) generated in 2018, 50.0% was land disposed, 11.8% was combusted, and 32.1% was recovered (a combination of waste recovered for recycling and for composting). As the FCS is expected to be disposed primarily by landfilling or combustion (i.e., not recovered for recycling), we re-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. This amount is calculated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land-disposed.

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several corrections to harmonize the EA to the final FCN regulatory language, make edits of an editorial nature, and to format the text for conformance with Section 508 assistive technologies.

Table 1: 2018 Municipal Solid Waste Generation Data for PLA[3]

Waste Type	Generation (US short tons)	Recovery (%)
PLA plastic in plates & cups	30,000	0
PLA plastic in other plastic packaging	20,000	0
Total	**50,000**	**0**

Additionally, even though the FCS is compostable, these materials are not likely to be recovered for composting given that commercial composting (i.e., at monitored sites operating at the elevated temperatures, with mixing and aeration, etc.) is not a widely used disposal option in the United States. Excluding these means of disposal and assuming that all food-contact articles manufactured with the FCS are land disposed or combusted, it is estimated that approximately 80.9% of the materials will be deposited in land disposal sites and about 19.1% will be combusted.[4] Using these disposal rates and the EPA's 2018 MSW generation data for PLA provided in Table 1, we estimate the amount of PLA combusted and land disposed in 2018 was 8,662 and 36,688 metric tons (mT), respectively, as is shown below.

$$50{,}000 \text{ US short tons} \times \frac{0.907 \text{ mT}}{\text{US short ton}} = 45.350 \text{ mT PLA disposed}$$

19.1% MSW combustion rate × 45,350mT PLA Disposed = 8,662 mT PLA combusted

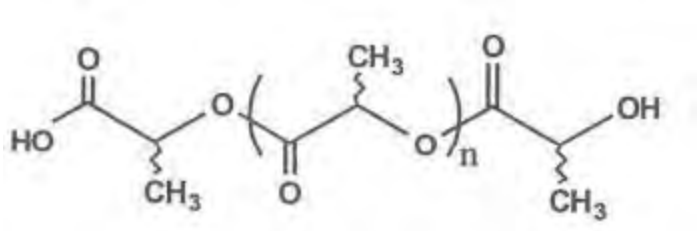
80.9% MSW land disposal rate × 45,350mT PLA Disposed = 36,688 mT PLA land disposed

We anticipate that the FCS will replace a portion of this waste.

5. Identification of the Subject of the Proposed Action

The subject of this notification is (3R,6R)-3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione (known as polylactide (PLA) polymers), (CAS Reg. No. 9051-89-2). Polylactide is a polymer of lactide, which is the cyclic dimer of lactic acid.

The structure may be represented as follows:



[3] See footnote 2, Table 8, Plastics in Products in MSW, US EPA 2015.

[4] 11.8% combusted ÷ (12.8% combusted + 50.0% land disposed) = 19.1% combusted. The remaining 80.9% will be land disposed.

6. Introduction of Substances into the Environment

A. **Resulting from manufacture of the FCS**:

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 production, of FDA-regulated articles. Current information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any significant adverse environmental impact since the manufacture of PLA will not take place in the United States. Hence, information on the manufacturing site and compliance with relevant emission requirements is not provided in this Notification.

B. **Resulting from use of the FCS**:

No significant environmental release is expected based on the use of the subject polymer to fabricate food-contact materials. In these applications, the polymer will be entirely incorporated into the finished food-contact article. Any waste materials generated in this process are expected to be disposed as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

C. **Resulting from disposal of the FCS**:

As noted previously, disposal by the ultimate consumer of food-contact materials produced with PLA will be by conventional trash disposal and primarily by sanitary landfill or incineration. Materials manufactured with the FCS may also be composted although as commercial composting of plastic polymers is not a widely used disposal option in the U.S., we assume there are no environmental introductions resulting from commercial composting of materials manufactured with the FCS. Additionally, recycling of materials manufactured with the FCS is not anticipated.

We compared the projected fifth year market volume for the FCS, contained in a confidential attachment to this environmental assessment, to the annual municipal solid waste (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.[5] Further, the proposed use of the FCS and corresponding market volume (provided in the confidential attachment) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, which was estimated to be 11.8% of the 292 million tons of total MSW generated (or 34.5 million tons) in 2018. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant municipal solid waste combustion facilities, nor cause them to threaten a violation of applicable emissions laws and regulations (i.e., 40 C.F.R. Part 60 and/or other relevant state and local laws).

Land disposal: The FCS is composed of carbon, hydrogen and oxygen, elements that are commonly found in municipal solid waste. Under aerobic conditions, PLA decomposes to lactic acid and other smaller compounds, ultimately to carbon dioxide and water. Under anaerobic conditions and an aqueous medium, PLA will hydrolyze to lactic acid.[6]

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

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[5] *Ibid.*

[6] Henton, D.E., et al., "Polylactic Acid Technology," in Natural Fibers, Biopolymers, and Biocomposites. Mohanty, A.K. et al., eds. (2005). Available at: https://www.researchgate.net/publication/289599648_Polylactic_Acid_Technology

water and to have ground-water monitoring systems (40 C.F.R. Part 258). These requirements are enforced by state solid-waste management programs. Therefore, 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.

Incineration: As we anticipate incineration of articles containing the FCS, and because the FCS, which has the molecular formula ($C_3H_4O_2$), contains carbon and oxygen, we expect the release of carbon dioxide, a greenhouse gas (GHG).

The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of materials containing the FCS in MSW combustion facilities. Such facilities are regulated by the EPA under 40 C.F.R. Part 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 GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we consider whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

In this context, the U.S. EPA, under 40 C.F.R. Part 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 environmental adverse 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.

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 PLA. As indicated above in Item 6, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with PLA polymer. Carbon dioxide and water are the ultimate products of complete combustion of PLA. The concentrations of these two substances in the environment will not be significantly altered by the proper incineration of PLA in the amounts utilized for food-contact materials. The FCS will make up a very small portion of the municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60 compliant operating municipal solid waste combustors to threaten a violation of applicable emission 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 PLA. As indicated above in Item 6, no significant quantities of any substances will be added to these water systems upon the proper incineration of PLA, nor upon its disposal in landfills due to the regulations governing emissions from landfills.

C. Land:

Considering the factors discussed above, no significant introductions of the FCS to terrestrial ecosystems are anticipated as a result of the proposed use and disposal of the subject polymer. As discussed above, EPA's regulations for new and expanding landfills require implementing preventive measures to significantly reduce or eliminate leachate. Furthermore, the low production of the FCS for use in food-contact applications, as supported by the market volume provided to the FDA in the confidential attachment, precludes any substantial release to the environment of the components. Finally, if finished food-contact materials made with the FCS are introduced into commercial composting sites, the polymer is expected to biodegrade. In this regard, the FCS has been shown to fulfill the evaluation criteria for inherent biodegradability, disintegration, and compostability as defined in ASTM D5338-98[7] and EN13432 (2000).[8] Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

Herein, we respectfully state that there is no reasonable expectation of a significant impact on any substance in the environment due to the proposed use of the FCS in articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed previously, the substances that may be released to the environment upon the use and disposal of food-contact articles made with PLA are extremely small quantities of combustion products, extractables and the product of commercial composting. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of PLA-containing food-contact articles. The use and disposal of PLA food-contact articles are not expected to violate applicable laws and regulations, e.g., the EPA regulations in 40 C.F.R. Parts 60 and 258. Finally, PLA exhibited complete disintegration under controlled composting conditions and the compost generated indicated no adverse ecotoxicity.

9. Use of Resource and Energy

The manufacture of food-contact articles using PLA manufactured by Ingenia is not expected to result in a net increase in the use of energy and resources since the use of this PLA is intended to be used in place of other competitive PLA polymers, currently on the market to manufacture food packaging.

The replacement of these types of polymers by PLA is not expected to have a significant adverse impact on the use of energy and resources. This PLA is not manufactured in the United States, but its manufacture and conversion to finished food packaging materials within the United States will consume energy and resources in amounts comparable to the manufacture and use of the other polymers with similar physical properties.

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[7] ASTM D5338-92. Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials Under Controlled Composting Conditions, Incorporating Thermophilic Temperatures. Edition superseded – See ASTM D5338-15 (2021). Available at: https://www.astm.org/d5338-15r21.html. See also: https://cdn.standards.iteh.ai/samples/108135/78c217c0ea5b4c7a890b9d6cb0044310/ASTM-D5338-15-2021-.pdf

[8] EN-13432 Standard (2000). Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging. Available at: https://www.en-standard.eu/bs-en-13432-2000-packaging.-requirements-for-packaging-recoverable-through-composting-and-biodegradation.-test-scheme-and-evaluation-criteria-for-the-final-acceptance-of-packaging/. See also: https://docs.european-bioplastics.org/publications/bp/EUBP_BP_En_13432.pdf

While PLA may be used to produce bottles, articles manufactured with the FCS would be marked with a different resin ID code than that of PET or HEDP bottles, which are routinely recycled. Also, as the carbon dioxide transmission rate for PLA makes it unsuitable for use in the manufacture of PET carbonated soft drink bottles, PLA bottles would not be present in those processing streams. Finally, as previously noted, food-contact materials manufactured from PLA are not expected to be collected for recycling (EA Table 1). As such, use of the FCS is not anticipated to significantly impact recycling processes.

One important difference between the manufacture of PLA and most other polymers is that PLA is not manufactured from petroleum derived substances as the basic raw material. It uses lactic acid, which is derived from sugarcane derived sugars, or grain derived sugars that are fermented and distilled.

Sugarcane and corn are currently the sources of lactic acid, although alternatives sources may be other grains, such as wheat, sugar beets, and rice. Thus, the FCS is manufactured from a renewable source. In this regard, Section 101(b)(6) of the National Environmental Policy Act (NEPA) (42 U.S.C. Section 4331(b)(6)) states that:

> *In order to carry out the policy set forth in this chapter, it is the continuing responsibility of the Federal Government to use all practicable means, consistent with other essential considerations of national policy, to improve and coordinate Federal plans, functions, programs, and resources to the end that the Nation may…*
>
> *(6) enhance the quality of renewable resources and approach the maximum attainable recycling of depletable resources.*

Thus, the replacement of other polymers by PLA will have a net decrease in the use of depletable resources. For all of the foregoing reasons, the use of the FCS as described in this Notification will not have a significant adverse impact on energy and resources.

10. Mitigation Measures

No significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles made from PLA. This is primarily due to the minute levels of potential migrants from the finished article, the insignificant impact on environmental concentrations of combustion products, and the use of renewable resources involved in the manufacture of PLA. Thus, the use of PLA is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

As no potential significant adverse environmental effects are identified, it is therefore unnecessary to propose alternative actions to that proposed in the Notification. If the proposed action is not approved, food packaging manufacturers would simply continue the use of those materials which this PLA would otherwise replace, resulting in no significant environmental impact.

12. List of Preparers

Patricia Kinne, Environmental Specialist, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, DC 20036, with over 10 years of experience with food-contact compliance matters, including FCN submissions and chemical registration submissions.

Joan Sylvain Baughan, Partner, Steptoe LLP, 1330 Connecticut Avenue, N.W., Washington, DC 20036, with over 30 years of experience with Food Additive Petitions, 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 her knowledge.

Date: August 15, 2024

Joan Sylvain Baughan, Partner

14. References

Henton, D.E., et al., Polylactic Acid Technology. In *Natural Fibers, Biopolymers, and Biocomposites.* Mohanty, A.K., et al., eds., CRC Press (2005).
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U.S. Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet, Assessing Trends in Materials Generation and Management in the United States,* (EPA530-F-20-009) December 2020. Available at:
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ASTM D5338-92. Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials Under Controlled Composting Conditions, Incorporating Thermophilic Temperatures. Edition superseded – See ASTM D5338-15 (2021). Available at: https://www.astm.org/d5338-15r21.html. See also: https://cdn.standards.iteh.ai/samples/108135/78c217c0ea5b4c7a890b9d6cb0044310/ASTM-D5338-15-2021-.pdf

EN-13432 Standard (2000). Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging. Available at: https://www.en-standard.eu/bs-en-13432-2000-packaging.-requirements-for-packaging-recoverable-through-composting-and-biodegradation.-test-scheme-and-evaluation-criteria-for-the-final-acceptance-of-packaging/. See also: https://docs.european-bioplastics.org/publications/bp/EUBP_BP_En_13432.pdf

15. Attachments

Confidential Attachment to the Environmental Assessment.