Environmental Assessment

1. Date August 16, 2023

2. Name of Submitter Pliith Biomaterials Co. Ltd.

Counsel for Notifier:

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3. Description of Proposed Action

a. Requested Action

The action requested in this Notification is the establishment of a clearance to permit the use of polylactide (PLA), made by Pliith Biomaterials Co. Ltd., as a component of food-contact articles in contact with all types of food under Condition of Use B through H as defined at 21 C.F.R. Section 176.170(c), Table 2. The FCS is not intended for use in contact with infant formula and human milk.

b. Need for Action

The subject polymer offers several technical properties that make it useful in a variety of food and pharmaceutical applications. Particularly, the moisture and oxygen barrier properties of this polymer make it useful in food and pharmaceutical flexible packaging and in certain rigid packaging applications. This polymer can also offer good contact clarity. The food contact articles include food packaging and repeat-use articles.

c. Locations of Use/Disposal

The Notifier does not intend to produce finished food packaging materials from PLA but may manufacture films and sheets from PLA to be supplied as components to finished packaging converters. The polymer 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 either by being deposited into land disposal sites or being combusted. The types of environment present at and adjacent to these disposal locations do not differ from the disposal locations of any other current used food-contact material. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from the PLA polymer.

As the notifier only manufactures the notified substance as an additive, it is beyond their knowledge as to what portion of the materials and articles containing the notified substance would eventually make their ways to the United States, we therefore conservatively assume that 100% of such materials and articles are exported to the U.S..

We consulted the data from EPA's Advancing Sustainable Materials Management: 2018 Tables and Figures updated on December 2020[1]. In 2018, in the United States, approximately 292,360,000 tons of municipal solid waste (MSW) were generated, in which 35,680,000 tons were plastics (Table 1). Further, among these solid waste of plastics, approximately 3,090,000 tons were "recycled, composted and managed by other food pathways: (Table 2); 5,620,000 tons were combusted with Energy Recovery (Table 3); and 26,970,000 tons were landfilled (Table 4). We further that Table 8 of this report provides Total Plastics in MSW, by resin, in which the plastics PP, LDPE and LLDPE, HDPE, and PS together make a total of 70.9% of Total Plastics in MSW.

Taking the EPA data above into account, we then calculate the possible fate of the materials and articles containing the notified substance in MSW as follows:

1) Recycled, composted and managed by other food pathways:

   (3,090,000/35,680,000) x 70.9% = 6.14%

2) Combusted:

   (5,620,000/35,680,000) x 70.9% = 11.17%

3) Landfilled:

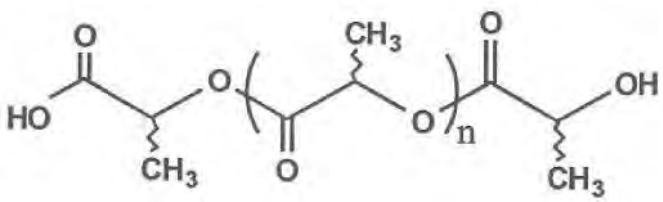
   (26,970,000/35,680,000) x 70.9% = 53.59%

Therefore, it is anticipated that disposal will occur nationwide, with about 6.14% of the disposed solid waste possibly containing the notified substance being recycled, composted and managed by other food pathways, about 11.17% combusted, and about 53.59% deposited in land disposal sites.

4. Identification of Substances that are Subject of the Proposed Action

The subject of this notification is polylactide (PLA), a polymer of lactide, which is the cyclic dimmer of lactic acid. The polymer will be marketed in the United States of America. A detailed confidential manufacture process is in Attachment 12 of this Notification.

The CAS Registry Number is 9051-89-2 and its CAS Registry name 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. The structure may be represented as follows:



[1] Advancing Sustainable Materials Management: 2018 Tables and Figures (epa.gov)

5. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

Under 21 C.F.R. Section 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 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.

No environmental release is expected based on the use of the subject polymer to fabricate packaging materials. In these applications, the polymer will be entirely incorporated into the finished food package. 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.

In addition, the PLA material may be introduced into commercial compost sites, where the polymer degrades into lactic acid and other smaller compounds, and ultimately to carbon dioxide and water. The process takes 45 to 60 days in a controlled compost site operated at 140ºF with the presence of moisture. As lactic acid is widely found in naturally occurring materials, a large number of microorganisms are able to metabolize this substance. Microorganisms in compost and soil consume the lactic acid and other smaller compounds as nutrients. Biodegradability tests were undertaken by Cargill Dow LLC in accordance with European Committee for Standardization (CEN), DIN[2], and American Society for Testing and Materials (ASTM) standards. Summaries of these studies, cited from the FOIA version of FCN No. 178 are provided below.

b. Inherent Biodegradability

Organic Waste Systems N.V. (OWS) Belgium conducted this testing based on ASTM D-5338.92 demonstrating 91% biodegradation after 45 days relative to the cellulose control.

c. Disintegration

Disintegration testing was performed by OWS indicating that the test article exhibited complete disintegration after 12 weeks. The validity of the testing was demonstrated, as the produced compost was similar in quality to the control compost.

d. Ecotoxicity

The compost generated in the disintegration test was subjected to ecotoxicity testing by OWS. No adverse ecotoxicity was observed in summer barley (plant growth) and water cress (seed germination).

Disposal by the ultimate consumer of food-contact materials produced by PLA will be by conventional rubbish disposal and primarily by sanitary landfill or incineration. The subject polymer PLA consists of only carbon, oxygen and hydrogen, thus no toxic combustion products are expected as a result of the proper incineration of PLA.

Only extremely low levels, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the EPA's regulations governing municipal

[2] DIN CENTRO Gesellschaft fur Konformitätsbewerung mbH is the certification organization of DIN, the German Institutes for Standardization.

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 ground-water monitoring systems (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 food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

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.

PLA may decompose into lactic acid, which can and will be generated into methane in an anaerobic environment. According to a research article Biodegradability and methane fermentability of polylactic acid by thermophilic methane fermentation[3], in an optimized environment, the yield of methane (CH_4) is estimated to be 321 – 343 mL CH_4 / g PLA consumed. According to the data from Methane Tracker 2021, the total emission of methane from waste as a result of human activities is roughly 68 Mt[4]. On the other hand, we believe there is no significant impact on total methane emission resulted from the use of food contact materials containing the FCS, primarily because the production volume of the FCS (as expressed in the confidential attachment) is very limited compared with the total amount of methane emitted into the environment.

No significant effect on the concentrations of and exposure 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 exposures to any substances are anticipated as a result of the proposed use of the subject FCS.

Pursuant to the FDA's review of FCN No. 178, the Agency requested information on littering. In addition, FDA has indicated that products manufactured from PLA would be labeled as "#7" plastic (i.e., "Other" plastic), which has no relevance to the degradability of a polymer itself. This label alone should not lead to a public misconception about the consequences of littering articles made from PLA[5]. The customers may label products made from PLA as "compostable" if the final product meets the criteria for compostability under the Federal Trade Commission's requirements for environmental marketing claims. However, labeling a material as "compostable" should not indicate that it will degrade under the environmental conditions associated with litter. Rather, composting is a process that requires specific conditions in order for the materials to biodegrade. For example, commercial composting facilities generally operate at elevated temperatures and involve mixing and aeration in order to accelerate the composting process. Accordingly, an increase in the littering of articles made from PLA is not anticipated, as compared to articles made from other types of plastics.

The usage levels for adjuvants used in the manufacture of PLA are all within relevant limitations. These substances are present at low levels comparable to other polymers using these adjuvants. Finished food packaging materials manufactured from PLA generally will be disposed of by means of landfill and incineration. The minimal levels of adjuvants from the proposed use of PLA polymers are expected to result in municipal solid waste and captured by EPA regulations

3 https://www.sciencedirect.com/science/article/abs/pii/S2589014X19302178

4 https://www.iea.org/reports/methane-tracker-2021/methane-and-climate-change

5 https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-green-guides/greenguides.pdf

governing emissions from landfills and municipal waste incinerators outlined in 40 C.F.R. Parts 258 and 60, respectively. Thus, Environmental introduction of adjuvants through these routes, if any, would be extremely low.

6. Fate of Emitted Substances in the Environment

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of Pliith's PLA. The PLA polymer has high molecular weight and is not volatile. No significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with PLA polymer.

The FCS consists of carbon and hydrogen. These are elements that are commonly found in municipal solid waste. Considering the proposed use and use level of the FCS described under 4(a)., it can be concluded that the FCS will make up an insignificant portion of the plastic containers and packaging presented in the total municipal solid waste (MSW) currently combusted. The products of complete combustion of the FCS are CO2, and water, materials commonly generated in these facilities. Because the release of CO2, a greenhouse gas (GHG) analysis was performed. This analysis is presented in the confidential attachment to the EA and is based upon the elemental composition of the FCS and assumes that 19.1% (described under 4(c)) of the annual market volume will be combusted.

MSW combustion facilities are regulated by the U.S. EPA under 40 CFR 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG" and sets an annual 25,000 metric tons carbon dioxide equivalent (CO2-e) emission threshold for required reporting at 40 CFR 98.2 of this regulation. From this analysis (contained in the confidential attachment to the EA), the expected CO2-e emissions are below 25,000 metric tons on an annual basis and mandatory reporting would not be required.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 CFR § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. In particular, 40 CFR § 1508.27(b)(10) states that, when evaluating the intensity of an impact, one should consider "whether the action threatens a violation of federal, state, or local law or requirements imposed for the protection of the environment." As noted above, GHG emissions from MSW combustion facilities are regulated under 40 CFR § 98.2. Based on the confidential market volume information, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from the combustion of the FCS in MSW combustion facilities.

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 packaging.

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. No significant quantities of any substances will be added to these water systems upon the proper incineration of PLA, nor upon its disposal in landfill due to the extremely low levels of migration of PLA components.

As reference in the summary provided in the FOIA version of FCN No. 178, PLA exhibited complete disintegration at the end of 12 weeks under controlled commercial composting conditions. No adverse ecotoxicity was observed in summer barley (plant growth) and water cress (seed germination).Thus, no significant effect on the concentrations of and exposures to any substance in

terrestrial ecosystems are anticipated due to the proposed use of PLA.

The precise environmental effects of breakdown products of littered PLA articles is not predictable since it is unknown how readily PLA degrades under conditions associated with littered materials. However, either one of two situations will result: 1) If the material is littered and does not degrade, there is no potential for adverse environmental effects resulting from degradation products; 2) If the material is littered and does degrade, then based on the ecotoxicity tests in FCN 178, we do not expect the degradation products to be toxic.

The low annual production volume of the FCS is not expected to result in significant introductions of landfill leachate. The presence of PLA in controlled commercial composting sites is not anticipated to result in introductions of adverse substances into terrestrial ecosystems. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of PLA.

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 PLA in the food-contact articles intended for use in contact with food.

7. Environmental Effects of Released Substances

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. None of the potential migrating substances of PLA presents any toxicological concern at the minute levels at which it could be extracted upon use and disposal, as discussed in Attachment 8. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of PLA-contained food-contact articles. The use and disposal of PLA food packaging 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 commercial composting conditions and the compost generated indicated no adverse ecotoxicity.

8. Use of Resource and Energy

Same as other food packaging materials, the production, use and disposal of PLA involves the use of natural resources such as petroleum products, coal and the like, although the production of PLA actually does not take place in the United States. The manufacture of food-contact articles using PLA is not expected to result in a net increase in the use of energy and resources since PLA is intended to be used in place of other food packaging polymers currently in the market. Polymers currently used in the applications in which PLA is anticipated to be used include polyethylene terephthalte (PET), cellophane, polystyrene and PLA manufactured in accordance with effective FCN No. 178.

The replacement of these types of polymers by PLA is not expected to have any adverse impact on the use of energy and resources. Although Pliith's PLA is not manufactured in the United States, we note that the energy and resources consumed during its manufacture are similar to those required to produce PET, cellophane, polystyrene and the PLA polymer manufactured pursuant to effective FCN No. 178. In fact, PLA articles manufactured of in the U.S. will consume no more energy or resources than will PET, cellophane or polystyrene. While Pliith's PLA will be used to produce bottles, this substance will not be used in the manufacture of carbonated soft drinks. This is due to the fact that, as discussed in FCN No. 178, the transmission rate for carbon dioxide for PLA is substantially higher than that for PET. Therefore, the use of PLA will not have any impact on the recycling of containers used to package carbonated soft drink.

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 solely from the fermentation of grain derived sugars. Corn is currently the sole source of lactic acid and Pliith does not intend to use alternative sources in the near future. Thus, PLA 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 PLA as described in this Notification will not have an adverse impact on energy and resources.

9. 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.

10. Alternatives to the Proposed Action

As no potential adverse environmental effects are identified, it therefore unnecessary to propose alternative actions to that proposed in the Notification. Were Pliith’s PLA not to obtain approval from FDA, food packaging manufacturers would simply continue the use of those materials which this PLA would otherwise replace, and likewise resulting in no environmental impact. Accordingly, the proposed use of Pliith’s PLA product which is the subject of this Notification may properly be considered to be environmentally safe in every respect.

11. List of Preparers

Mr. Wilfred Feng, Dentons Law Offices LLP (Shanghai), 9th/24th/25th Floor, Shanghai World Financial Center, No.100 Century Avenue, Shanghai, China 200120.

Mr. Feng joined Dentons Shanghai Office as Senior Counsel in 2019. His practice focuses on global food and drug, agricultural and environmental laws, advising clients in the sectors of food, food packaging, dietary supplements, drug, medical device, tobacco products, cosmetics, pesticides, feed, veterinary drug, biotechnology, and chemicals.

Before joining Dentons, Mr. Feng spent 14 years at Keller and Heckman, an international regulatory law firm. As the first Chinese member joining its Shanghai Office, Mr. Feng has made significant contribution to its establishment and growth.

Before working at law firms, Mr. Feng gained extensive experience in regulatory affairs, government affairs, marketing and R&D at DuPont.

Mr. Feng earned B.Sc. (biology) from Fudan University, and master degrees in agriculture and law from Chinese Academy of Agricultural Sciences and East China University of Law and Political Sciences. He is qualified to practice law in China.

12. Certification

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

Date: August 16, 2023

Wilfred Feng

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