Environmental Assessment

1. **Date** November 27, 2023

2. **Name of Submitter** PJIM Polymer Scientific Co., Ltd.

Counsel for Notifier:

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3. Description of Proposed Action

a. Requested Action

The action requested in this food contact notification (FCN) is to permit for the use of the food contact substance (FCS) identified as Polyglycolic acid, as a base polymer, to be blended with no less than 15 percent by weight Polybutylene adipate terephthalate (PBAT) suitable for food contact use, for making disposable drinking straws and disposable kitchenware (knives, folks and spoons, etc.) for contact with all foods below the temperature of 150 degrees Fahrenheit (70 degrees Celsius), except for use in contact with infant formula and human milk.

b. Need for Action

The FCS is used as a base polymer for making food contact disposable drinking straws. The FCS is a material of ready biodegradable attribute. Such unique attribute makes it an ideal option as a base polymer for reducing plastic waste without the need to use any specialized waste treatment facilities for its decomposition.

Disposable drinking straws and disposable kitchenware are major sources of plastic waste and the resulted microplastics in the environmental. Using biodegradable material will be an ideal solution to this issue.

c. Locations of Use/Disposal

The Notifier does not intend to produce finished food packaging materials from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact disposable drinking straws and disposable kitchenware. 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. The notifier manufactures approximately five thousand metric tons of the notified substance annually in China as a base polymer. Roughly 40% of such polymer is for food contact uses and 60% of them is for non-food contact uses, mainly for other disposable and biodegradable consumers

goods.

It is difficult to assess as to what portion of the materials and articles made of 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).

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) = 8.7%

2) Combusted:

   (5,620,000/35,680,000) = 15.8%

3) Landfilled:

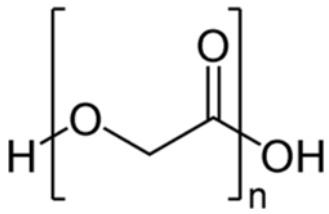
   (26,970,000/35,680,000) x 21% = 75.6%

Therefore, it is anticipated that disposal will occur nationwide, with about 75.6% of the disposed solid waste containing the notified substance being deposited in land disposal sites, about 15.8% combusted, and about 8.7% recycled, composted and managed by other food pathways. Due to the fast biodegradability of the FCS, those subject to land disposal will eventually be naturally biodegraded. Therefore, the total percentage of the notified substance to be biodegraded after disposal would be (75.6 + 8.7)%, or 84.3%, which would be a significant contribution to the reduction of plastic waste in the environment, especially considering disposable drinking straws a major source of plastic waste into the environment.

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

The FCS is Polyglycolic acid (CAS Registry Number 26124-68-5). The molecular structure of the FCS is shown below.

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



The FCS is in the form of off-white granule. Its chemical structure can be identified with the infra-red and nuclear-magnetic resonance spectra as included in the FCN.

5. Introduction of Substances into the Environment

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

Under 21 C.F.R § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants outside of the United States, which otherwise meet local environmental regulations. The Notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and that may harm the environment; 2) the action threatening a violation of Federal, State or local environmental laws or requirements; or 3) production associated with the 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 threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

No environmental release is expected upon the use of the FCS in a food contact article. In these applications, the FCS is expected to be entirely incorporated into the finished food contact article; any waste materials generated in this process, *e.g.*, plant scraps, are expected to be recycled by the manufacturer or disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

The finished disposable drinking straws will be labeled and recommended for being disposed of as a biodegradable material according to the suitable waste treatment measures available locally. However, due to the limited number of compost facilities in the U.S., the fate of most such articles will likely follow the same pattern discussed in Section 3c of this EA, i.e. 8.7% of them will be recycled, composted and managed by other food pathways, 15.8% incinerated and 75.6% landfilled. The latter will eventually lead to full biodegradation of the articles containing the FCS in the environment. The airborne emission of the FCS is

primarily due to the incineration of disposed articles containing the FCS[2]. As the FCS is composed of carbon, oxygen and hydrogen, the combustion products of the articles containing the FCS may include carbon dioxide.

The decomposed product of the FCS, glycolic acid, is expected to enter the environment as a result of the landfill disposal of food contact articles, in light of the Environmental Protection Agency's (EPA) 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 and Appendix 2.

Biodegradability testing was performed by a contract laboratory and the FCS was shown to be readily biodegradable comparably to a cellulose reference material. The report is provided as a confidential attachment (Supplemental Attachment 3) to this EA. Due to the ready biodegradability attribute of the FCS[3] , any finished articles made of the FCS, once discharged directly into the environment, will soon break down to its starting substance, glycolic acid (reviewed in Han and Zhang, 2017[4]). Glycolic acid is a known algal excretory product, represents a potential important energy source for heterotrophic bacteria in marine waters (see von Borzyskowski, L.S. et al[5] and Wright, R.T. and Shah, N.M.[6]). Therefore, we do not envision any particular environmental concern if the finished articles made of the FCS are adventitiously discharged directly into the environment.

6. Fate of Emitted Substances in the Environment

a. Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. The FCS does not volatilize and will not combust. The FCS is non-volatile and with its biodegradable status, is not anticipated to have a significant impact on landfill establishments, nor is it anticipated to significantly impact MSW combustion operations or emissions. As stated above, the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the FCS in the amounts utilized for food contact material applications.

b. Water

No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use

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[2] Utilizing the EPA Advancing Sustainable Materials Management: 2018 Tables and Figures (Assessing Trends in Materials Generation and Management in the United States) (revised December 2020) https://www.epa.gov/sites/default/files/2021-01/documents/2018_tables_and_figures_dec_2020_fnl_508.pdf: pg. 14 – 360,000 US tons (plastics in containers and packaging generated in MSW) x 0.907 mT/US ton x 0.158 incineration rate x 0.85 max FCS utilization rate in the finished polymer x 0.316 carbon in the FCS x (44g CO2 / 12g C) x (1 CO2-e/CO2) = 50,809 mT CO2-e. Considering at minimum 100 MSW incineration facilities nation-wide, 5,100 mT CO2-e is anticipated.

[3] Biodegradability testing was performed by a contract laboratory and the FCS was shown to be readily biodegradable comparably to a cellulose reference material. This report is provided as a confidential attachment to this EA.

[4] X. Han and X. Zhang. Modelling degradation of biodegradable polymers. Science and Principles of Biodegradable and Bioresorbable Medical Polymers. (2017). https://doi.org/10.1016/B978-0-08-100372-5.00015-5

[5] Schada von Borzyskowski, L., Severi, F., Krüger, K. et al. Marine Proteobacteria metabolize glycolate via the β‐hydroxyaspartate cycle. Nature 575, 500–504 (2019). https://doi.org/10.1038/s41586‐019‐1748‐4

[6] Wright, R.T., Shah, N.M. The trophic role of glycolic acid in coastal seawater. I. Heterotrophic metabolism in seawater and bacterial cultures. Marine Biology 33, 175–183 (1975). https://doi.org/10.1007/BF00390723

of the FCS. As stated above, ultimate disposal is expected to be in a permitted municipal solid waste (MSW) landfill, or MSW combustion facility. Therefore, we do not expect disposal of the FCS to cause any significant impact to the aquatic environment.

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 FCS. In particular, the extremely low levels of maximum migration of components of the FCS, demonstrated by its insolubility, indicate that virtually no leaching of the components may be expected to occur under normal environmental conditions when finished food-contact materials are disposed. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the FCS as a result of its proposed use.

7. Environmental Effects of Released Substances

As discussed previously, we do not expect the FCS to be significantly released to the environment. Even when any finished articles made of the FCS, once discharged directly into the environment, they will soon break down to its starting substance, glycolic acid. Glycolic acid is a known algal excretory product, represents a potential important energy source for heterotrophic bacteria in marine waters (see von Borzyskowski, L.S. et al[7] and Wright, R.T. and Shah, N.M.[8]).

Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS.

8. Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some degree replace similar substances already on the market. In particular, the FCS already is permitted for the same uses as those proposed in this Notification, most notably, effective FCN 574 and 958. The manufacture of the FCS will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes. Thus, the energy used for the production of the FCS is not significant.

9. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials containing the FCS. Therefore, mitigation is not required.

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[7] Schada von Borzyskowski, L., Severi, F., Krüger, K. et al. Marine Proteobacteria metabolize glycolate via the β‐hydroxyaspartate cycle. Nature 575, 500–504 (2019). https://doi.org/10.1038/s41586‐019‐1748‐4

[8] Wright, R.T., Shah, N.M. The trophic role of glycolic acid in coastal seawater. I. Heterotrophic metabolism in seawater and bacterial cultures. Marine Biology 33, 175–183 (1975). https://doi.org/10.1007/BF00390723

10. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed materials that the subject FCS would replace. Such action would not have significant impacts.

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 200120, China.

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. References

Schada von Borzyskowski, L., Severi, F., Krüger, K. et al. Marine Proteobacteria metabolize glycolate via the β-hydroxyaspartate cycle. Nature 575, 500–504 (2019). https://doi.org/10.1038/s41586-019-1748-4

Wright, R.T., Shah, N.M. The trophic role of glycolic acid in coastal seawater. I. Heterotrophic metabolism in seawater and bacterial cultures. Marine Biology 33, 175– 183 (1975). https://doi.org/10.1007/BF00390723

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13. Certification

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

Date: November 27, 2023

Wilfred Feng, Senior Counsel