Environmental Assessment

1. Date	November 9, 2020
2. Name of Applicant	Kuraray Co., Ltd.
3. Address	Agent for Notifier: Joan S. Baughan, Partner Steptoe & Johnson LLP 1330 Connecticut Avenue, NW Washington, DC 20036

4. Description of Proposed Action

a. Requested Action

The action identified in this food contact notification (FCN) is to provide for the use of the food contact substance (FCS) identified as ethylene-vinyl acetate-vinyl alcohol (EVOH) copolymers modified with up to 8 mol% 1,2-epoxypropane (CAS Reg. No. 482589-30-0).

The FCS is intended for use in packaging articles that may contact infant formula and/or breast milk. It is intended for use as an internal, non-food-contact layer separated from food by one or more layers having a suitable regulatory status for use in direct contact with food in single service and repeated-use food-contact articles both at levels of up to 25% in blends with EVOH.

The maximum thickness of the internal layer containing the FCS will be 50 μm. The finished food-contact articles may be used in contact with infant formula and/or breast milk under FDA's Conditions of Use A ("High temperature heat-sterilized (e.g., over 212 deg.F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use"), as defined in the FDA's Food Types & Conditions of Use Table 2.

b. Need for Action

The FCS is used as a component of finished food contact articles. The FCS reduces the cycle processing time and improves the physical properties of the polyolefin article. The food contact articles include food packaging and repeat-use articles, as well as articles such as utensils, plastic cups and plastic plates.

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 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 will occur nationwide, with about 80.4% of the materials being deposited in land disposal sites, and about 19.6% combusted.[1]

[1] See the U.S. Environmental Protection Agency's (EPA) "Advancing Sustainable Materials Management: 2017 Fact Sheet Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery

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

The subject of the FCN is ethylene-vinyl acetate-vinyl alcohol (EVOH) copolymers modified with up to 8 mol% 1,2-epoxypropane (CAS Reg. No. 482589-30-0). Other chemical names for the FCS include ethenol polymer with ethane, 1(vinyloxy) propan-2-ol, and 2-(vinyloxy)propan-1-ol, and) and acetic acid ethenyl ester, polymer with ethene, hydrolyzed, 2-hydroxymethylethyl ether.

6. 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. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

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

No significant environmental release is expected upon the use of the subject FCS to fabricate packaging materials. In these applications, the FCS (i.e., a polymer) is expected to be entirely incorporated into and remain with the finished food-contact article. Any waste materials generated in this process, e.g., plant scraps, are expected to be disposed of as a part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials produced by the subject FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration.

The subject FCS consists of carbon, oxygen, and hydrogen. Thus, carbon dioxide (which is a greenhouse gas (GHG)) and water are expected to form upon combustion of the FCS. The

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and Landfilling in the United States " EPA530-F-19-007 (November 2019), at: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

As noted in Table 1 of EPA's fact sheet, of the total 267.79 million tons of municipal solid waste (MSW) generated in 2017, 52.13% was land disposed, 12.71% was combusted, 25.1% was recycled and 10.1% was composted. As the FCS is expected to be disposed primarily by land-filling 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 19.6% of food-contact articles containing the FCS will be combusted annually. This amount is calculated as follows:
12.71% combusted ÷ (12.71% combusted + 52.13% land disposed) = 19.6% combusted. The remaining 80.4% will be land-disposed.

carbon content of the FCS has been calculated based on the elemental composition of the FCS (available in a confidential attachment to the FCN).

In accordance with 40 C.F.R. § 1508.27 the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context the greenhouse gas (GHG) emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 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 to GHG emissions under EPA's GHG reporting program (GHGRP), and sets an annual 25,000 metric ton carbon dioxide equivalent (CO2-e) emission threshold for required reporting. As can be seen in the Confidential Attachment to the Environmental Assessment, based on the proposed use of the FCS, the anticipated market volume (available in a confidential attachment to the FCN), and calculations regarding the maximum introduced level of carbon dioxide equivalent as a combustion product (available in a confidential attachment to the EA), we have quantified the potential carbon dioxide and CO2 equivalent emissions resulting from combustion of the FCS.

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 from the combustion of the FCS in MSW combustion facilities. Therefore, we have concluded that the FCS will make up a very small portion of the total municipal solid waste currently combusted, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

Only extremely small amounts, 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 Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills (40 C.F.R. Part 258). 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. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate. The lack of any leaching is especially true considering that the subject substance is a high molecular weight polymer resin that contains only low levels of low molecular weight oligomers, which is the portion of the resin that can potentially be leachable.

7. Fate of Emitted Substances in the Environment

As described above, articles manufactured with the FCS are expected to be either land-disposed or incinerated as municipal solid waste. These mechanisms of disposal are managed by local state and federal regulations. Thus, no significant quantities of any substances will be

released into the atmosphere or into freshwater, estuarine marine ecosystems upon the use and proper disposal of food-contact articles manufactured with the FCS.

Therefore, there is no expectation of any meaningful substance exposure to terrestrial or aquatic organisms as a result of the use and disposal of the FCS as notified.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the FCS consist of extremely small quantities of combustion products and leachate, if any. Thus, no significant adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the food-contact substance.

9. 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. The manufacture of the FCS and use of the FCS in the food-contact applications will consume comparable amounts of energy and resources as similar currently marketed products. The raw materials used in the production of the FCS are commercially manufactured chemicals that are produced for use in various chemical reactions and production purposes. Therefore, the partial replacement of these materials by, and their use in food-contact applications with, the subject FCS is not expected to have any adverse impact on the use of energy and resources.

Food-contact materials produced using the subject FCS are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future recycling programs.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the FCS; therefore, the FCS is not expected to result in environmental issues that require mitigation measures.

11. Alternatives to the Proposed Action

No significant 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.

12. List of Preparers

Patricia Kinne, Environmental Specialist, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036 with over 8 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Joan Sylvain Baughan, Partner, Steptoe & Johnson LLP, 1330 Connecticut Ave., NW, Washington, DC 20036 with 29 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: November 9, 2020 

Joan S. Baughan, Partner

14. References

U.S. Environmental Protection Agency's (EPA) "Advancing Sustainable Materials Management: 2017 Fact Sheet Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States " EPA530-F-19-007 (November 2019), at: https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

15. Attachments

Confidential Attachment to the Environmental Assessment