Environmental Assessment (EA)

1.	**Date:**	October 17, 2024
2.	**Name of Applicant/Notifier:**	EMS-CHEMIE AG
3.	**Address:**	All communications on this matter are to be sent in care of Counsel for the Notifier: Pamela L. Langhorn, Partner Keller and Heckman LLP 1001 G Street, NW Suite 500 West Washington, DC 20001 Telephone: (202) 434–4291 E-mail: langhorn@khlaw.com

4. Description of Proposed Action

The action requested in this Notification is to establish a clearance for the food-contact substance (FCS) identified as "fatty acids, C18-unsat., dimers, polymers with dodecanedioic acid, isophthalic acid, 4,4'-methylenebis[2-methylcyclohexanamine] and terephthalic acid" (CAS Reg. No. 2014364-77-1), for use in food-contact applications.

The FCS is a random copolyamide, prepared from the following monomers: bis(4-amino-3-methylcyclohexyl) methane (MACM), dodecanedioic acid (DDDA), isophthalic acid (IPA), terephthalic acid (TPA), and fatty acids, C18-unsat., dimers (C36 dimer acids). The FCS will be used in repeat-use applications in contact with all food types, under FDA's Conditions of Use A ("High temperature heat-sterilized (*e.g.*, over 212°F)") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use").[1] The FCS is not intended for use in contact with infant formula and human milk, as such uses were not included as part of the intended use of the substance in the FCN.

The FCS is a transparent polyamide that offers high glass transition temperature, high heat distortion temperature, and chemical resistance. Other desirable properties include high stiffness, mechanical strength, and dimensional stability. The intended use and technical function of the FCS is analogous to other common polyamides regulated under 21 C.F.R. § 177.1500 ("Nylon resins") and effective Food Contact Notifications (FCN). Examples of applications in which the FCS may be used include hot water feed systems for coffee machines,

[1] FDA Food Types and Conditions of Use are defined in Tables 1 and 2 at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

parts in dairy milking machines, drinkware, food containers, cooking utensils, and various parts in food processing equipment.

The Notifier does not intend to produce finished food-contact articles containing the FCS. Rather, the FCS that is the subject of this notification 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 of food-contact materials containing the FCS will occur nationwide, with the material being land disposed, combusted, or recycled in quantities similar to those reported for municipal solid waste (MSW) generally.[2] According to the Environmental Protection Agency (EPA), it is estimated that, as of 2020, of the 292.36 million tons of MSW generated, approximately 50.0% of MSW is deposited in land disposal sites; 11.8% is combusted; 23.6% is recycled; 8.5% is composted; and 6.1% is directed to other food management pathways.[3] As the FCS is expected to be primarily disposed of through combustion or land-filling (*i.e.*, not recycled, composted, or handled through other food management pathways), we recalculate 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.[4]

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

The FCS that is the subject of this notification is "fatty acids, C18-unsat., dimers, polymers with dodecanedioic acid, isophthalic acid, 4,4'-methylenebis[2-methylcyclohexanamine] and terephthalic acid." The CAS Registry Number is 2014364-77-1. The density of the FCS polymer is 1.04 g/cm^3.

The FCS polyamide is manufactured by condensation of the following monomers:

Component	**CAS Reg. No.**
Bis(4-amino-3-methylcyclohexyl) methane (MACM)	6864-37-5
Dodecanedioic acid (DDDA)	693-23-2
Isophthalic acid (IPA)	121-91-5
Terephthalic acid (TPA)	100-21-0

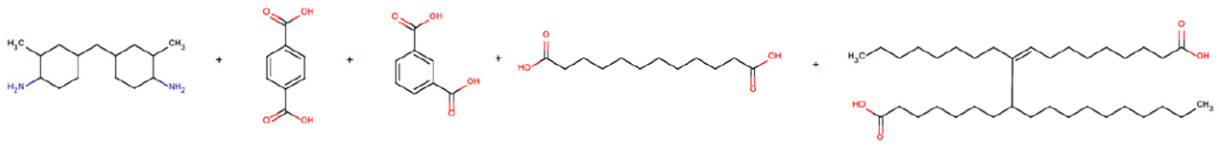
[2] Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Fact Sheet: Assessing Trends in Materials Generation and Management in the United States* (December 2020), *available at*: https://www.epa.gov/sites/default/files/2020-11/documents/2018_ff_fact_sheet.pdf.

[3] *Id.*

[4] By assuming that none of the FCS is recycled, 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% will be land-disposed.

Component	CAS Reg. No.
Fatty acids, C18-unsat., dimers (C36 dimer acids)	61788-89-4

The structures of the FCS monomers are shown below.



6. Introduction of the Substances into the Environment

Under 21 C.F.R. § 25.40(a) ("Environmental assessments"), an environmental assessment (EA) ordinarily 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[5] in this case indicative of any significant 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.

No significant adverse environmental release is expected upon the use of the subject FCS in food-contact materials. The FCS will be used in polymer articles to fabricate food-contact materials or components thereof, and the FCS is expected to remain with these materials throughout use in the food-contact applications and use/disposal by the consumer. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures. The annual projected market volume of the FCS for food-contact use in the U.S. is provided in the Confidential Environmental Information attachment.

Disposal by the ultimate consumer of food-contact articles containing the subject FCS will be by conventional rubbish disposal, and, hence, primarily by sanitary landfill or incineration. For food-contact articles that contain the FCS that are determined to be recyclable,

[5] Such extraordinary circumstances would include: (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 threatened, or wild fauna or flora that are entitled to special protection under some other federal law.

recycling processes will compete with conventional rubbish disposal and, therefore, reduce the amount of the FCS that is landfilled or incinerated.

The FCS consists of the elements carbon, hydrogen, oxygen, and nitrogen. Thus, the combustion products may include carbon dioxide, water, and nitrous oxide. The carbon and nitrogen content of the FCS have been calculated based on the elemental composition of the FCS (available in the Confidential Environmental Information attachment). Further, the carbon and nitrogen contents of the FCS have been used to calculate the potential greenhouse gas (GHG) emissions derived from combustion of the confidential annual market volume of the FCS for food-contact use in the U.S. (available in the Confidential Environmental Information attachment).

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, 40 C.F.R. § 98.2(a)(3) requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO_2 equivalents (CO_2-e) or more per year to report their GHG emissions to the EPA. Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 C.F.R. § 98.30(a). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities.

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the Confidential Environmental Information attachment, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Further, the FCS will not significantly alter the emissions from properly operating MSW combustors as the FCS contains carbon, hydrogen, oxygen, and nitrogen, elements that are commonly found in MSW. Therefore, incineration of the FCS will not cause MSW combustors to threaten a violation of applicable emission laws and regulations (*i.e.*, 40 C.F.R. Part 60 and/or relevant state and local laws).

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, and 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 effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. The analysis discussed above in

Item 6 demonstrates that no significant adverse environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact materials manufactured with the FCS.

B. Water

No significant effects on the concentrations of and exposures to any substance 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. Thus, the fate of finished food-contact materials containing the FCS in the aqueous environment does not need to be addressed because no 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 polymeric nature 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 low production volume anticipated for the FCS in food-contact applications 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. The use and disposal of the subject substance in landfills or by combustion are not expected to threaten a violation of applicable laws and regulation, *e.g.*, the EPA's regulations in Part 258 ("Criteria for Municipal Solid Waste Landfills") that pertain to landfills and 40 C.F.R. Part 60 ("Standards of Performance for New Stationary Sources") that pertain to MSW combustors.

9. Use of Resources and Energy

As is the case with other food-contact materials, the production, use, and disposal of the FCS involves 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 and resources because the FCS will used in place of similar polymers that are already on the market for use in the same or similar applications.

Manufacture of the FCS and the final conversion to finished food-contact materials will consume energy and resources in amounts comparable to the manufacture of chemically related polyamide resins. Articles and packaging materials produced from the FCS are expected to be disposed of according to the same patterns when used in place of currently marketed polyamide materials. Thus, there will be no impact on current recycling programs.

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 using the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished materials employing the FCS, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similarity of the subject FCS to the material it is intended to replace (*i.e.*, competitive polyamide resins regulated under 21 C.F.R. § 177.1500 and effective FCNs). 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

Pamela L. Langhorn, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington DC 20001. Ms. Langhorn has over 25 years of experience counseling and representing corporate entities on food additive petitions and FCNs, including Environmental Assessments.

Steven J. Manning, Ph.D. in Chemistry, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington DC 20001. Dr. Manning has over seven years of experience drafting 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: October 17, 2024

Counsel for EMS-CHEMIE AG

14. References

1. FDA's Food Types and Conditions of Use for FCNs are set forth at https://www.fda.gov/food/packaging-food-contact-substances-fcs/food-types-conditions-use-food-contact-substances.

2. *Advancing Sustainable Materials Management: 2018 Fact Sheet. Assessing Trends in Materials Generation and Management in the United States,* U.S. Environmental Protection Agency, Office of Land and Emergency Management, Dec. 2020, *see* Advancing Sustainable Materials Management: 2018 Fact Sheet (epa.gov).

3. *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.