

Environmental Assessment

1. **Date** March 8, 2022
2. **Name of Applicant/Notifier** The Dow Chemical Company
3. **Address** All communications on this matter are to be sent to Mrs. Alicia M. Fitzpatrick, The Dow Chemical Company, 310 George Patterson Blvd, Suite 100, Bristol, PA 19007.
Telephone: (215) 785-7033
4. **Description of the Proposed Action**

The action requested in this Notification is the establishment of a clearance to permit the use of ethylene/butene copolymers, containing up to 10 weight percent butene, in the manufacture of articles for contact with all types of food under Conditions of Use A through H, as set forth in Table 2 of 21 C.F.R. § 176.170(c). The FCS is not for use in contact with infant formula and human milk.

The subject copolymers offer similar technical properties to other Linear Low Density Polyethylene (LLDPE) copolymers made from ethylene and other comonomers that make them useful in a variety of food-contact applications. For purposes of this Environmental Assessment, subject materials will be designated as E/B copolymers.

While the petitioned for polymers are intended to compete with other alpha-olefin-based copolymer films, coatings, and molded articles, it is expected that these E/B polymers will primarily replace other LLDPE copolymers.

The Notifier does not intend to produce finished food packaging materials from the subject polymers. Rather, the polymers will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the use of the polymers will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. According to the U.S. Environmental Protection Agency's 2018 data on municipal solid waste in the United States, 16.9% of plastics used for containers and packaging will be combusted while 69.5% and 13.6% will be landfilled or recycled respectively.¹

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared the subject copolymers. Only extremely small amounts, if any, of the

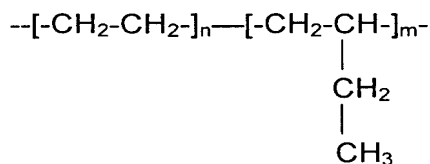
¹ *Advancing Sustainable Materials Management: 2018 Fact Sheet Assessing Trends in Materials Generation and Management in the United States*. December 2020 *Advancing Sustainable Materials Management: 2018 Fact Sheet* (epa.gov)

polymer constituents 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. 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). Therefore, no significant environmental introductions resulting from landfill disposal of articles manufactured with the FCS are anticipated.

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

The FCS that is the subject of this Notification is a copolymers of ethylene and butene, CAS Reg. No. 25087-34-7. Specifically, the subject of the FCN are copolymers produced by the polymerization of the two monomers such that the finished copolymers will contain up to 10 weight percent butene units.

The FCS is represented by the structure below:



6. Introduction of Substances into the Environment

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. 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 E/B copolymers. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject polymers to fabricate food-contact materials. In these applications, the polymers will be entirely incorporated into the finished food package. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials produced by the subject copolymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill, recycling or incineration. The subject copolymers consist of carbon and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the polymers. As the FCS is substitutional for already regulated LLDPE used in contact with food, there will be no net change in the disposal of LLDPE used in contact with food. The subject copolymers consist of carbon and hydrogen, elements that are commonly found in municipal solid waste. The main combustion

products of polyethylene are carbon dioxide (CO₂), carbon monoxide, water and small amounts of various hydrocarbons.²

Additionally, 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 CFR 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 CFR 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. Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA³, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting regulated under 40 CFR 98 and because the operation of and emissions from MSW combustion facilities are regulated under 40 CFR 60, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

7. 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 E/B copolymers. The polymers are of high molecular weight and do not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with these polymers.

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Format Item 6. Consequently, evaluation of the environmental fate of the FCS or its combustion products is not required.

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 the subject copolymers. No significant introductions of substances into the aqueous environment is anticipated as a result of the proposed use of the FCS as discussed in Format Item 6.

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 copolymers. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the copolymers.

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 E/B copolymers in the manufacture of articles intended for use in contact with food.

² David R. Weise, Heejung Jung, Javier Palarea-Albaladejo & David R. Cocker (2020) Compositional data analysis of smoke emissions from debris piles with low-density polyethylene, *Journal of the Air & Waste Management Association*, 70:8, 834-845, DOI: 10.1080/10962247.2020.1784309

³ Confidential Attachment A

8. Environmental Effects of Released Substances

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified under Format Item 6. Consequently, evaluation of the environmental effects of the proposed use of the FCS is not required.

Based on these considerations, no adverse effect on organisms in the environment is expected because of the disposal of articles containing the copolymers. In addition, the use and disposal of the copolymers are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. parts 60 and 258.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of E/B copolymers involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymers in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since the copolymers are intended to be used in place of similar polymers now on the market for use in food packaging applications.

The replacement of these types of materials by E/B copolymers is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymers and conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture of other similar polyolefins. Moreover, E/B copolymers will replace food-contact articles that are not currently recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration.

These copolymers will be used for single and repeat use food-contact articles such as finished food-packaging films and rigid containers that could contact all types of food. While the E/B copolymers are suitable for contact with all food types, there are cost and technical limitations that will limit the types of food-packaging applications. While the copolymers might find limited use in beverage bottling, they will be limited in that application both by cost and function. These copolymers will have a negative cost basis versus high density polyethylene used in milk bottles and they do not have the high gas barrier property of polyethylene terephthalate used in carbonated beverage bottles. Thus, we would not expect any impact on current or future recycling programs as a result of the use of these copolymers.

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 from the subject FCS. Thus, no mitigation is required.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not clearing the action proposed herein would simply result in the continued use of the materials, which the subject copolymers would otherwise replace; such action would have no environmental impact.

12. List of Preparers

Alicia M. Fitzpatrick, Senior Product Regulatory Manager, B.S. in Chemistry with ten years experience in FCN submissions and environmental assessment, The Dow Chemical Company, 310 George Patterson Blvd, Suite 100, Bristol, PA 19007

13. Certification

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

Date: March 8, 2022



Alicia M Fitzpatrick
Senior Product Regulatory Manager
The Dow Chemical Company