

Environmental Assessment

1. **Date:** March 27, 2026*
2. **Name of Applicant/Notifier:** Billions Europe Ltd
3. **Address:** All communications on this matter are to be sent in care of Counsel for Notifier:

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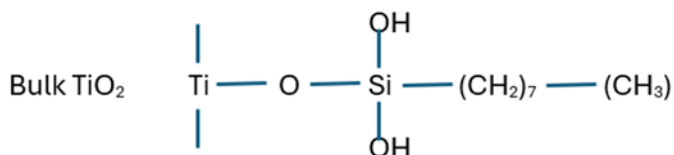
4. **Description of the Proposed Action**

The action requested in this Notification is to authorize the use of the Notifier's food-contact substance (FCS), octyltriethoxysilane (OTES)-modified titanium dioxide, in which the silane-modified component will not exceed 1.6 percent by weight of the FCS.

Specifically, the FCS is intended for use as a pigment in food-contact polymers at levels not to exceed 25 percent by weight of the food-contact article under 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 for use in contact with infant formula and human milk. Such uses are not included as part of the intended use of the substance in the FCN.

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

The FCS that is the subject of this Notification is octyltriethoxysilane (OTES)-modified titanium dioxide. The proposed structure of the FCS is as follows:



¹ FDA's food types and Conditions of Use are defined in Tables 1 and 2 at <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsof Use/default.htm>.

*Subsequent to this date, this EA was edited using the Adobe text editor tool to make corrections of an editorial nature and to remove reference to a withdrawn CEQ guidance document.

6. Introduction of Substances into the Environment

Under 21 C.F.R. § 25.40(a) (“Environmental assessments”), 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 materials. The Notifier is not aware of any information to suggest that there are any extraordinary circumstances that would indicate the potential for significant adverse environmental impacts resulting from the manufacture of the FCS, such as: 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. 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 materials containing the FCS. In these applications, the FCS will be entirely incorporated into the finished food-contact article. 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 is provided in the confidential attachment to the EA.

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. Food-contact articles containing the FCS will be used in patterns corresponding to the national population density and will be widely distributed across the country. According to the United States Environmental Protection Agency’s 2020 update of data regarding municipal solid waste in the United States, of the total 292 million tons of municipal solid waste (MSW) generated in 2018, approximately 50.0% was land disposed, 11.8% was combusted, and 32.1% was recovered for recycling or composting. We recalculate the disposal pattern here based on only the quantities of MSW that are land disposed or combusted because the FCS is not recovered for recycling. We therefore estimate that approximately 19.1% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows: $11.8\% \text{ combusted} \div (11.8\% \text{ combusted} + 50.0\% \text{ land disposed}) = 19.1\% \text{ combusted}$. Therefore, it is anticipated that disposal will occur nationwide, with approximately 19.1% combusted. The remaining 80.9% will be land-disposed.

The FCS consists of carbon, hydrogen, oxygen, silicon, and titanium. These are elements that are commonly found in municipal solid waste. The organic constituents of the FCS are composed of carbon, oxygen, and hydrogen. Thus, the products of complete combustion of the FCS are titanium dioxide, SiO₂, CO₂ (considered a greenhouse gas (GHG)), and water, materials commonly generated in these facilities. The carbon content of the FCS has been calculated based on the elemental composition of the FCS (available in a confidential attachment to the EA).

40 C.F.R. § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO₂ equivalents (CO₂-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (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. 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 GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO₂-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we considered whether the action threatens a violation of federal, state or local law requirements imposed for protection of the environment.² Further, the FCS will not significantly alter the emissions from properly operating MSW combustors. Therefore, incineration of the FCS will not cause MSW to threaten a violation of applicable emission laws and regulations (i.e., 40 C.F.R. 60 and/or relevant state and local laws).

When combusted, there is nothing to suggest the FCS would threaten a violation of 40 C.F.R. Parts 60 and 62, the regulations governing municipal waste combustors, as carbon, hydrogen, and oxygen are either typical elements in MSW (i.e., C, H, and O) or are mitigated *via*

² Prior to FDA editing, this EA referenced 40 C.F.R. Parts 1500-1508. For the reason provided below this reference was deleted and the text revised to reflect the appropriate context.

40 C.F.R. Parts 1500-1508 have been rescinded pursuant to a February 25, 2025 interim final rule issued by Council on Environmental Quality (CEQ). 90 Fed. Reg. 10,610 (Feb. 25, 2025) available at <https://www.federalregister.gov/documents/2025/02/25/2025-03014/removal-of-national-environmental-policy-act-implementing-regulations>. This EA referenced these rescinded regulations pursuant to FDA’s existing NEPA implementing procedures provided in 21 C.F.R. § 25 and related guidance. See U.S. Food and Drug Admin., *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN*, May 2006 (current as of Sept. 20, 2018), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan#III>. CEQ has advised that “agencies should apply their current NEPA implementing procedures with any adjustments needed to be consistent with the NEPA statute as amended by the [Fiscal Responsibility Act].” Exec. Office of the President, CEQ, Chief of Staff, Katherine R. Scarlett, *Memorandum for Heads of Federal Departments and Agencies*, February 19, 2025, available at <https://ceq.doe.gov/docs/ceq-regulations-and-guidance/CEQ-Memo-Implementation-of-NEPA-02.19.2025.pdf>.

these Clean Air Act regulations, and MSW incineration units reduce the emissions of these harmful pollutants).

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 articles, 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, and to have ground-water monitoring systems (40 C.F.R. Part 258). 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 collection systems, they are required to monitor groundwater and to take corrective actions as appropriate.

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 FCS does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact films manufactured with these pigments.

The FCS will make up a very small portion of the total municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 C.F.R. Part 60-compliant operating municipal solid waste combustors, and incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations. See Confidential Attachment for additional details.

B. Water

No significant effects on exposures to any substances from the FCS in freshwater, estuarine, or marine ecosystems are anticipated due to its proposed use. The fate of 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 concentration of and exposure to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, the inorganic pigment nature of the FCS is expected to result in virtually no leaching of FCS components under normal environmental conditions when the food packaging articles in which they are contained are disposed of. Furthermore, the very low production of the polymer for use in food-contact applications precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to 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 polymers. Therefore, the environmental fate of substances does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Item 6.

8. Environmental Effects of Released Substances

As discussed above, the only substances that may be expected to be released into the environment upon the use and disposal of food packaging materials fabricated with the FCS consist of very small quantities of combustion products and extractables, if any. None of these potential releases presents any toxicological concern at the low levels at which they could occur upon use and disposal of food-contact materials containing the FCS. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of food-contact materials containing the FCS. In addition, the use and disposal of the polymers containing the FCS is not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Part 60 ("Standards of performance for new stationary sources") that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products, coal, and the like. The manufacturer of the FCS will consume comparable amounts of energy and resources as similar products already being marketed, as the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of applications. Therefore, the use of this alternative product will have no impact on the use of resources and energy.

Plastics containing the FCS are expected to be disposed of according to the same patterns when they are used in place of the currently used plastic articles containing OTES-modified titanium dioxide. Because the FCS is used in a manner consistent with other colorants for polymers in the manufacture of pigmented plastics, 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 articles fabricated within the subject FCS. This is primarily due to the minute levels, if any, of leaching of components of the FCS from finished food-contact materials, and the insignificant impact on environment concentrations of combustion products of the FCS. Thus, no significant adverse environmental impacts were identified that require mitigation procedures.

11. Alternatives to the Proposed Action

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

12. List of Preparers

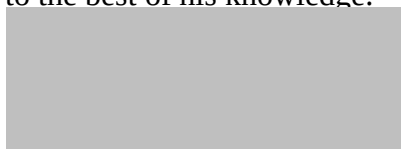
Devon Wm. Hill, J.D., Partner, Keller and Heckman LLP, 1001 G Street NW, Suite 500 West, Washington, D.C. 20001. Mr. Hill has more than 25 years of experience counseling and representing corporate entities on Food Contact Notifications, including their Environmental Assessments.

Adam W. Freeman, Ph.D. (Chemistry), Scientist, Keller and Heckman LLP, 1001 G Street NW, Suite 500W, Washington, DC 20001. Dr. Freeman has 4 years of experience with Environmental Assessments for FDA submissions.

13. Certification

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

Signature:



Devon Wm. Hill, Partner
Counsel for Billions Europe Ltd
Date: March 27, 2026

14. References

1. United States Food and Drug Administration, *Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations*, Appendix V, Table 2, available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparation-premarket-submissions-food-contact-substances-chemistry>.
2. See United States Environmental Protection Agency, *Advancing Sustainable Materials Management: 2018 Tables and Figures* (December 2020), Table 1 (Generation, Recycling, Composting, Other Food Management Pathways, Combustion with Energy Recovery and Landfilling of Materials in MSW, 2018), page 4, available at: https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf.

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15. Attachment

1. Confidential Environmental Assessment