

1. **Date:** August 25, 2016
2. **Name of Applicant:** Henan Billions Chemical, Co., Billions Europe, Ltd., and Billions America Corporation
3. **Address:**

All communications on this matter are to be sent in care of Counsel for the Notifier:

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4. Description of the Proposed Action

A. Requested Action

The action identified in this Notification is to provide for the use of 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl) (CAS Reg. No. 77-99-6) as a dispersant for pigments: (1) at levels up to 0.6 percent by weight of the pigment when the pigment is used as a colorant for all types of polymers complying with 21 C.F.R. § 178.3297, and (2) at levels up to 1.0 percent by weight of the pigment when the pigment is used in inks that may come into contact with food. The finished polymers and inks may contact all food types under FDA's Conditions of Use A (High temperature heat-sterilized (e.g., over 212 deg. F)) through H (Frozen or refrigerated storage), as described in Table 2 of 21 C.F.R. § 176.170 (c). The FCS is not intended for use in contact with infant formula or human milk, as these uses were not specifically addressed in the FCN.

B. Need for Action

The FCS is used as a component of finished food-contact articles. The FCS aids in the milling or micronization step in the manufacture of pigments and facilitates the dispersibility of the pigments during the manufacture of materials to which the pigments are added.

C. Locations of Use/Disposal

The Notifier does not intend to produce finished food packaging materials from the subject FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with 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 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 from the subject FCS.

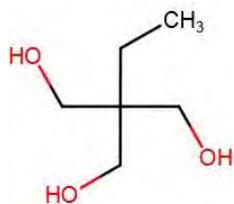
5. Identification of Chemical Substance that is the Subject of the Proposed Action

Chemical Identity

The subject of this notification is 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl) (CAS Reg. No. 77-99-6). The chemical structure is shown here:

1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)

CAS Reg. No. 77-99-6



MW: 134.174

¹ *Advancing Sustainable Materials Management: Facts and Figures 2013*, EPA-530-R-15-002, June 2015, available at http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013_advncng_smm_rpt.pdf. According to this report, of the total of 254.1 million tons of municipal solid waste (MSW) generated in 2013, 52.8% was land disposed, 12.9% was combusted, and 34.3% was recovered (a combination of waste recovered for recycling and for composting). As the FCS is expected to be disposed primarily by land-filling or combustion (*i.e.*, not recovered for recycling), we recalculate the disposal pattern based on only the quantities of MSW that are land disposed or combusted. On this basis, we estimate that 19.6% of food packaging materials containing the FCS will be combusted annually. This amount is calculated as follows:

$12.9\% \text{ combusted} \div (12.9\% \text{ combusted} + 52.8\% \text{ land disposed}) = 19.6\% \text{ combusted}$. The remaining 80.4% will be land-disposed.

6. Introduction of Substances into the Environment

a. As a Result of Manufacture

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, the Notifier is not aware of information to 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. Specifically, as set forth in FDA's guidance,² extraordinary circumstances include situations where: 1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); and 3) production associated with a proposed action 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. To the best of the Notifier's knowledge, no situations such as these apply to the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. As a Result of Use and Disposal

No environmental release is expected upon the use of the subject substance in the fabrication of food packaging materials. In these applications, the polymer 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 as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials containing the subject substance will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject polymer consists of carbon, hydrogen, and oxygen. These are elements that are commonly found in municipal solid waste. Based on confidential market volume information for the FCS (available in a confidential attachment to the EA, *Attachment 1*), we have calculated the carbon dioxide equivalent emissions associated with combustion of the FCS, as discussed in the confidential attachment to this document.

² *Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition*, Food and Drug Administration, May 2006, at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081049.htm>.

On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance³ to agencies regarding addressing greenhouse gas (GHG) emissions and climate change impacts in NEPA documents. This guidance is “intended to help Federal agencies ensure their analysis of potential GHG emissions and effect of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action”. The 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 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 refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines ‘significantly’ as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 1508.27(b)(10) states, that when evaluating intensity of an impact, one should consider “whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.” GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Based on the confidential market volume, 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 resulting from combustion of the FCS in MSW combustion facilities.

The FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and, therefore incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emission laws and regulations (40 C.F.R. Part 60 under/or relevant state and local laws).

In light of EPA’s regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of the food-contact articles containing the FCS. 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. Landfills are also required to have groundwater monitoring systems. (40 C.F.R. Part 258). Although owners and operators of existing 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 action as appropriate.

³ Council on Environmental Quality (CEQ) Final Guidance for Federal Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Review, dated August 1, 2016, *available at*: https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf.

FDA requests that this EA address the potential source of environmental introductions of the FCS could occur from the consumption and subsequent elimination of the minute amounts of the FCS that may migrate to food and subsequently be consumed by the consumer. The total concentration of the FCS in the diet is estimated to be 0.137 ppm.⁴ Assuming as a worst-case that the FCS is eliminated unchanged, this concentration will be diluted significantly when: 1) combined with other waters used in the household and 2) again when these household waters are disposed of by sanitary sewer and subsequently combined with other municipal waters received at a publicly owned wastewater treatment works (POTW), and then 3) again when the POTW discharges to surface waters. Nevertheless, further refinement of this value is unnecessary because, even if undiluted, the resulting expected environmental concentration (EEC) of 0.137 ppm is 100 fold lower than the lowest acute ecotoxicity (5 ppm 24hr LC50 for sea lamprey) as described in the Organization for Economic Cooperation and Development – Screening Information Dataset (OECD-SID) for Trimethylpropane (CAS No. 77-99-6).⁵

7. Fate of Emitted Substances in the Environment

a. Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. The FCS has a boiling point of approximately 285°C and, thus, does not readily volatilize. Thus, no significant quantities of the FCS will be released during the use and disposal of the FCS.

As indicated above, the FCS will make up a very small portion of the total municipal solid waste currently combusted, and 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.

b. Water

No significant effect on the concentrations of and exposures to the FCS in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the FCS or the disposal of food-contact articles containing the FCS. No significant quantities of the FCS will be added to these systems upon the proper incineration of such food-contact articles, nor upon their disposal in landfills equipped with composite liners and leachate monitoring protocols.

As noted under Section 6 above, even if small amounts of the FCS was to transfer from food-contact articles disposed into landfill leachate, EPA's regulations governing landfills (40 C.F.R. Part 258) will minimize migration of the leachate into the natural environment. MSW landfills must comply with the federal regulations in 40 CFR Part 258 or equivalent state regulations. The federal standards include composite liner requirements, leachate collection and

⁴ See Attachment 2 containing copies of FDA's Chemistry Memorandum for FCN No. 527 and Attachment 3 to FCN No. 527, "Migration and Dietary Exposure Calculations," obtained pursuant to the Freedom of Information Act (FOIA).

⁵ Available at: <http://www.inchem.org/documents/sids/sids/77996.pdf>.

removal systems, groundwater monitoring requirements, and closure and post closure care requirements.

The environmental fate of substances does not need to be addressed because no significant introduction of substances into the environment as a result of the proposed use of the FCS is identified.

c. Land

Considering the factors discussed above, no significant effects on the concentrations of, or exposures to, any substances in terrestrial ecosystems are anticipated as a result of the proposed uses of the FCS and its proper disposal. Only very small amounts of leaching of the FCS may be expected to occur under normal environmental conditions when finished food contact materials are disposed of. Furthermore, as noted above, if the FCS were to migrate from the food-contact articles, the leachate will be prohibited from entering adjacent ecosystems by proper environmental controls in place at landfill sites. Thus, there is little expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the FCS.

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 subject FCS consist of extremely small quantities of combustion products and leachables, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the FCS because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of articles containing the FCS. Therefore, the use and disposal of the FCS 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

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 No. 527. 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.

The partial replacement of these materials by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS will consume

energy and resources in amounts comparable to the manufacture of other similar materials. Furthermore, the use of the subject FCS proposed in this Notification is as a replacement for similar pigment dispersants.

The raw materials that are used in the manufacture of the FCS are commercially manufactured chemicals that are produced for the use in various chemical reactions and used for production purposes. Thus, the energy used for the production of the FCS is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS. This is primarily due to: (1) the minute levels, if any, of leaching of components of the FCS from finished food-contact articles, (2) the insignificant impact on environmental concentrations of combustion products of the FCS, and (3) the similarity of the subject FCS to the materials it is intended to replace. Therefore, the FCS is not reasonably expected to result in any new environmental issues that require mitigation measures of any kind.

11. Alternatives to the Proposed Action

No 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 environmental impact. In view of the fact that the FCS constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of the FCS and articles containing it, and the absence of any significant environmental impact which would result from its use, the establishment of an effective FCN to permit the use of the subject FCS as described herein is environmentally safe in every respect.

12. List of Preparers

Joan Sylvain Baughan, Counsel for Notifier, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. J.D. with 25 years of experience with FCN submissions and environmental assessments.

Lester Borodinsky, Ph.D., Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001. Ph.D. in Chemistry, with more than 30 years of experience with FCN submissions and environmental assessments.

13. Certification

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



Joan Sylvain Baughan
Counsel for Notifier

14. References

The following footnotes are found within the Environmental Assessment document:

1. Advancing Sustainable Materials Management: Facts and Figures 2013, EPA-530-R-15-002, June 2015, *available at* http://www.epa.gov/solidwaste/nonhaz/municipal/pubs/2013_advncng_smm_rpt.pdf.
2. Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition, Food and Drug Administration, May 2006, *at* <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081049.htm>.
3. Council on Environmental Quality (CEQ) Final Guidance for Federal Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Review, dated August 1, 2016, *available at:* https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf.
4. The Organization for Economic Cooperation and Development – Screening Information Dataset (OECD-SID) for Trimethylpropane (CAS No. 77-99-6), *available at:* <http://www.inchem.org/documents/sids/sids/77996.pdf>.

15. Attachments

1. Confidential Environmental Information
2. FDA's Chemistry Memorandum for FCN No. 527
3. FCN 527: Migration and Dietary Exposure Calculations