



July 29, 2020

William Lillis
President
AGC Chemicals Americas, Inc.
Business and Technical Center
55 E. Uwchlan Ave., Suite 201
Exton, PA 19341

Dear Mr. Lillis:

The purpose of this letter is to acknowledge the receipt of the voluntary commitment made by AGC Chemicals Americas, Inc. (hereinafter “AGC”),¹ for the following three food contact substances (FCSs): “Copolymer of perfluorohexylethyl methacrylate, 2-N,N-diethylaminoethyl methacrylate, 2-hydroxyethyl methacrylate, and 2,2'-ethylenedioxydiethyl dimethacrylate, acetic acid salt (CAS Reg. No. 863408-20-2) or malic acid salt (CAS Reg. No. 1225273-44-8),” which are the subject of effective food contact notifications (FCNs) 599 and 604; “Butanedioic acid, 2-methylene-, polymer with 2-hydroxyethyl, 2-methyl-2-propenoate, 2-methyl-2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, sodium salt (CAS Reg. No. 1345817-52-8),” which is the subject of FCN 1186; and “2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester, polymer with 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, sodium salt (CAS Reg. No. 1878204-24-0),” which is the subject of FCN 1676.

This commitment, as stated in your correspondence² of July 17, 2020, states that AGC will, by December 31, 2023, voluntarily cease introduction into interstate commerce and delivery for introduction into interstate commerce these FCSs for any use in food-contact applications that are subject to the jurisdiction of the U. S. Food and Drug Administration (FDA). This commitment also states that AGC will, as of January 1, 2021, begin to phase-out the introduction into interstate commerce and delivery for introduction into interstate commerce products containing the FCSs authorized by the above-listed FCNs for use in food-contact applications in the United States.

AGC also committed to provide FDA with annual updates for 2021, 2022, and 2023 by January 31st of the following year, on progress towards the phase-out plan, as well as an interim update in 2023, to be provided by July 31st of 2023. Information to be provided will include the annual market volume of these products sold for use in food-contact applications in the United States. AGC will also provide similar information from 2019 for comparison purposes. AGC also agreed to provide analytical samples for the food contact substances authorized by the above-referenced FCNs to the extent that they are still commercialized so that FDA may monitor the prevalence of these materials in the marketplace. Analytical samples will include the product as sold by AGC to their downstream customers, and when

¹ AGC Chemicals Americas, Inc. is a subsidiary of AGC, Inc., formerly known as Asahi Glass Company, Ltd.

² Letter from William Lillis (AGC Chemicals Americas, Inc.) to Dennis Keefe (FDA), dated July 17, 2020.

available, samples of the product applied to paper and/or paperboard, and the food contact substances as applied in a finished food contact article used for food packaging.

Under Section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act, “the term ‘food contact substance’ means the substance that is the subject of a notification . . . and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.” The original notifier for FCNs 599, 604, 1186, and 1676 was AGC Chemicals Americas, Incorporated, which is also listed as the manufacturer/supplier along with Asahi Glass Company, Ltd. for these FCNs on the Inventory of Effective Food-Contact Notifications on FDA’s website as of the date of this letter.

The FCSs subject to FCNs 599, 604, 1186, and 1676, belong to a class of compounds termed short-chain per- and poly-fluoroalkyl substances (PFAS) (compounds with extended perfluorinated chains typically 6 carbon atoms in length). Based on information available to FDA after the above-listed FCNs became effective, FDA conducted an updated comprehensive review of current information on the safety of certain short-chain PFAS compounds. FDA’s assessment of the available data on these types of compounds has indicated the need to consider factors in addition to those traditionally considered by the Agency at similar exposure levels. These include additional possible toxic endpoints including, but not limited to, effects on pre- and post-natal development, reproductive health and function, and carcinogenicity.³

Based on this assessment, FDA informed AGC that additional testing would be needed to address these safety questions.⁴ FDA also informed AGC that the additional testing would need to be of an extended nature to account for the expected body burden levels resulting from chronic exposure to these biopersistent FCSs. In response, AGC discussed with FDA possible plans to voluntarily cease introduction into interstate commerce the FCSs from the related FCNs for use in food-contact applications sold in the United States, and agreed to a voluntary commitment to cease the introduction and delivery for introduction of the FCSs covered by FCNs 599, 604, 1186, and 1676 into interstate commerce for use in any food-contact applications subject to the jurisdiction of the FDA pursuant to the phase-out plan and reporting obligations described above.¹

AGC has stated that, based upon its prior experience with the usage of such products by companies further down the supply chain, the large majority of existing stocks of the neat FCSs, paper and paperboard coated with these FCSs, and food packaged in paper coated with these FCSs will be exhausted within 18 months of the cessation of initial introduction into interstate commerce. Therefore, it is expected that consumer exposure to these FCSs will rapidly decrease, and that little to no additional exposure will occur 18 months after the voluntary phase-out ends.

FDA maintains an Inventory of Effective Food-Contact Notifications on FDA’s website.⁵ FDA intends to update this inventory to reflect the commitment by AGC with respect to these FCNs.

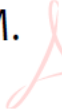
³ P. Rice, J. Aungst, J. Cooper, O. Bandele, S. Kabadi, Food and Chemical Toxicology, 2020, 138, 111210.

⁴ Letter from Dennis Keefe (FDA) to Warren Lehrenbaum (Legal Representative for AGC), dated October 1, 2019.

⁵ “Inventory of Effective Food Contact Substance (FCS) Notifications.” This document can be accessed in the Food Ingredients and Packaging section under the Food topic on the Agency’s internet site at <http://www.fda.gov>.

Sincerely,

Dennis M.
Keefe -S



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Dennis M. Keefe, Ph.D.
Director
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