February 14, 2019

Mr. Gary McDowell, Director
Michigan Department of Agriculture
and Rural Development
P.O. Box 30017
Lansing, Michigan 48909

Dear Director McDowell,

I write in response to a letter from your predecessor, former Director Gordon Wenk, and the former director of the Michigan PFAS Action Response Team (MPART), Carol Isaacs, to the U.S. Food and Drug Administration (FDA or the Agency) and the U.S. Department of Agriculture (USDA) describing Michigan's approach to per- and polyfluoroalkyl substances (PFAS) contamination in your state, including the establishment of MPART. In their correspondence, Mr. Wenk and Ms. Isaacs requested that FDA share current guidance on PFAS in food, as well as develop additional guidance. They also requested a nationally-supported approach that protects human health but does not raise unnecessary concern over the safety of the food supply.

FDA has been working to address the issue of PFAS in food through the development of analytical methods and the collection and analysis of foods to provide occurrence data in order to estimate PFAS exposure from food. In addition, the Agency has been working with other federal, state and local agencies to address this issue, including participating at the Federal Information Exchange on PFAS, the PFAS National Leadership Summit, and through regularly occurring Environmental Council of the States PFAS Coordinating Committee meetings.

FDA is reviewing the currently available information on PFAS authorized for use in food packaging to ensure that these uses continue to be safe. Specifically, we have been monitoring the available scientific information regarding PFAS used in packaging materials and have worked with industry to voluntarily discontinue the use of certain long-chain PFAS that were authorized for use through effective food contact notifications (FCNs).[1] In 2015 and 2016, FDA amended the indirect food additive regulations to no longer permit the use of other long-chain PFAS that have been approved for food-contact use due to the food packaging industry's abandonment of these uses in food packaging.[2] This means that any food additive use of these substances is no longer allowed.

[1] https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/ucm308462.htm
[2] https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm528911.htm

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

We have recently established a workgroup of food safety experts from across the Agency to address the issue of PFAS in human and animal food. At this time, FDA's approach to PFAS in food is to handle instances of contamination on a case-by-case basis. When PFAS has been detected in a food, FDA reviews the relevant information, such as the levels of PFAS found in that food, the type of food, the consumption of that food, and the most currently available toxicological information for PFAS to help develop an informal screening level which we use to evaluate whether the levels of PFAS found in that food may pose a health hazard such that the food is considered to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act.

We note that the U.S. Environmental Protection Agency (EPA) has established health advisories (HA) for perfluorooctanoic and perfluorooctanesulfonic acid in drinking water to provide public water system operators and state, local, and tribal officials with information on the health risks of these chemicals, so they can take appropriate actions to protect their residents. EPA's HAs only apply to public drinking water.

The USDA Food Safety and Inspection Service regulates the safety of traditional (non-game) meats, poultry, and certain egg products; therefore, we would defer to USDA on PFAS issues related to these products. Jordan Bonfitto, Associate Director of USDA's Office of External and Intergovernmental Affairs, may be reached at jordan.bonfitto@osec.usda.gov.

We appreciate the opportunity to collaborate with Michigan on these important matters. As the workgroup advances its efforts to address this issue, we plan to explore ways for extensive engagement with stakeholders, including states.

If you would, please share a copy of this letter with your colleagues at MPART, and if you have further questions or need assistance with any other FDA-related issue, please contact the FDA Intergovernmental Affairs team at IGA@fda.hhs.gov.

Sincerely,

Susan Mayne, Ph.D.
Director
Center for Food Safety
and Applied Nutrition

Clearance Legend

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