DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

November 16, 2005

Mr. Stephen Korzenowski
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RE: PFOA (Perfluorooctanoic Acid) and other perfluorinated migrants in perfluorocarbon resins and telomer-based food contact products.

Dear Mr. Korzenowski,

This correspondence is in response to your request for clarification of FDA's view on perfluorocarbon resins and telomer-based paper coatings intended for use in contact with food. Your request was to clarify whether the recent publication of an article in the journal *Food Additives and Contaminants*, describing analytical work done in the Food and Drug Administration's (FDA) Office of Food Additive Safety (OFAS)[1], has caused FDA to change its position on the safe use of these materials.

Because of recent initiatives at the U.S. Environmental Protection Agency (EPA) related to the safety of certain perfluorocarbons, OFAS is investigating the potential for consumer exposure to PFOA and other perfluorinated compounds via FDA regulated food-contact products. We recognize that the vast majority of perfluorocarbon and telomer-based products are used in a wide variety of non-food contact applications such as carpet, textiles, wire insulation, and industrial parts. However, PFOA is used as a surfactant in the manufacture of perfluorocarbon resins used on non-stick cookware, and telomer-based paper coatings used in contact with food have been reported to contain residual PFOA. While FDA has previously reviewed these compounds and found them to be safe for their food-contact use provided they comply with applicable regulations, we also routinely monitor new developments in scientific knowledge to ensure that our current information is complete and understood within the context of total human exposure.

In response to recent interest in consumer exposure to PFOA and other structurally related perfluorinated compounds, OFAS is currently working towards characterizing the potential for exposure to these compounds from regulated food-contact substances. OFAS is presently (1) analyzing perfluorocarbon and telomer-based products to better quantify consumer exposure to PFOA and perfluorinated compounds via food-contact applications and (2) continuing to assess the toxicity of PFOA and other relevant perfluorinated compounds. This work is being done in conjunction with industry (including DuPont) and other federal agencies such as EPA and the Consumer Product Safety Commission.

[1] Begley, T., et. al. *Food Additives and Contaminants* 22(10) **2005**, 1023-1031.

Conventional analytical techniques are limited in their ability to detect perfluorochemical migration. As such, information on the potential for PFOA migration specifically, and on the types of perfluorochemicals that have the potential to migrate from telomer-based coatings in general, is limited. The purpose of the above mentioned journal article was to highlight a recently developed analytical technique which is applicable towards characterizing such migration. FDA used this journal article as an opportunity to disseminate preliminary analytical information that could potentially be useful to guide industry in their own research efforts on this issue. This information demonstrated that the potential for PFOA migration from perfluorocarbon resins used on cookware is negligible. In addition, this preliminary work detected PFOA migration from microwave popcorn bags coated with telomer-based products only at a level below the standard of quantitation for the analytical technique (< 1 part per billion in food).

The amount of total fluorotelomer migration from telomer-based coatings as detected in this preliminary work (11,000 ng/dm^2) is far larger than the amount of residual fluorochemical that could possibly migrate from perfluorocarbon resins used on cookware. However, it should be noted that this fluorotelomer migration from coated paper, as reported in this article, occurs in the form of the telomer-based compounds themselves and should not be equated to PFOA exposure.

At this time, we have no reason to change our position that the use of both perfluorocarbon resin and telomer-based coatings are safe for use in contact with food as described in the applicable regulations or notifications. However, we are still investigating the quantification of potential cumulative exposure to PFOA from all food contact materials. For this reason, OFAS is continuing to work with all sectors of the industry to improve our understanding regarding consumer exposure to PFOA and other perfluorinated compounds through the use of food-contact materials.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

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