



Terry Troxell
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January 23, 2009

Dear Mr. Troxell:

This responds to your inquiry dated November 19, 2008, submitting a food-contact substance prenotification consultation (PNC 757) regarding the use of decabromodiphenyl ether to be used as flame retardant in plastic pallets at levels ranging from 6 to 24 percent by weight. The plastic pallets will be used to hold uncovered produce in storage containers. These will go through a production line, where a pre-cooling solution will be sprayed or applied to the produce. The plastic pallets with the storage containers with the dripping pre-cooled produce will be vertically racked together. You also mention that the pre-cooling fluids are captured and recirculated. In particular, you are interested in knowing whether decabromodiphenyl ether would become a food contact substance by incorporation of it into the pre-cooling solution.

I have addressed your questions in order asked.

1. *Does the FDA consider BDE congener 209 used in HDPE pallets for precooling a food additive scenario?*

A food additive is defined by the Federal Food, Drug, and Cosmetic Act as "any substance the intended use of which results or may reasonably be expected to result- either directly or indirect- in its becoming a component or otherwise affecting the characteristics of any food."

According to the scenario described above, if you were not recycling the pre-cooling solution and/or vertically racking the dripping pre-cooled pallets, then, the components of the plastic pallet would not be considered a food additive situation. However, because you are recycling the pre-cooling solution and/or vertically racking the dripping pre-cooled pallets; the decabromodiphenyl ether may become a component in the pre-cooling solution. This would also be the case if you were racking the pallets with uncovered produce in storage containers, and then running a pre-cooling solution from top to bottom, even without recycling.

It is important to determine if this component is intended to or will have any technical effect on the produce. If yes, then the component may be a direct food additive. If no, then the component may be an indirect food additive, also known as a food contact substance. Unfortunately, based on the information submitted, we are unable to determine whether decabromodiphenyl ether will have an intentional technical effect on the produce.

2. Is BDE congener 209 already cleared for food contact use that would cover the use for precooling?

No.

If the substance is not intended to have any technical effect on the produce, then the food contact substance notification (FCN) is the preferred method of providing for the safe use. However, under 21 CFR 170.100(c)(2), the FDA has the authority to require a food additive petition for the use of food contact substance when there exists a bioassay on the food contact substance (FCS). In this case, FDA found a 2-year bioassay on decabromodiphenyl ether that we have not reviewed, and the bioassay is not clearly negative for carcinogenic effects. Based on the data, we cannot at this time agree to evaluate your submission as an FCN. We believe that you should provide us your submission as another PNC under which we may continue to review the data.

Or, a substance used in a food contact article may be exempted from the need of an FCN or a petition (regulation) as a food additive if the use in question has been shown to result in a very low concentration (<0.5 ppb). For further details see, "Submitting Requests Under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Articles." available at our following website: <http://www.cfsan.fda.gov/~dms/torguid.html>. Please be aware that 21 CFR 170.39(c)(5) states that a request for the FDA to exempt a use of a substance from regulation as a food additive shall include the results of an analysis of existing toxicological information on the substance and its impurities. This information on the substance is needed to show whether an animal carcinogen bioassay has been carried out, or whether there is some other basis for suspecting that the substance is a carcinogen or potent toxin. This type of information on the impurities is needed to show whether any of them are carcinogenic, and, if carcinogenic, whether their TD50 values are greater than 6.25 milligrams per kilogram bodyweight per day in accordance with paragraph (a)(1) of this section.

3. If precooling is considered a food additive situation for BDE congener 209 in HDPE pellets and BDE congener 209 is not currently cleared for this type food contact, does this mean that BDE congener 209 cannot be used in HDPE pallets that may be used in precooling?

Again, if you do not recycle the pre-cooling solution and/or vertically rack the dripping pre-cooled pallets, the issue with decabromodiphenyl ether used on the plastic pallets to hold the uncovered produce storage containers becomes moot. However, if pre-cooling

solution is recycled and/or there is vertical racking of the dripping pre-cooled pallets, there is the possibility that decabromodiphenyl ether may become a component of the produce and premarket approval is required.

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

Sincerely,

Elizabeth Sánchez Furukawa
Consumer Safety Officer
Division of Food Contact Notifications
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration