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By FedEx

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Presence and Labeling of Allergens in Foods, Docket No. 00P-1322

Dear Sir or Madam:

In the FEDERAL REGISTER of July 25, 2001, 66 FED. REG. 28591, the Food and Drug Administration (FDA) announced a public meeting on the labeling of food products containing allergens. In addition to the public meeting, held on August 13, 2001, FDA invited the submission of written comments by October 29, 2001.

The issue of allergenic substances in foods has attracted increasing attention, both from the food industry and from FDA. As part of the agency's response, FDA has issued a compliance policy guide (CPG) concerning the labeling of allergens in food.[1] The CPG identifies the following foods as accounting for more than 90% of all food allergies: peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat. The CPG further states that products which contain allergenic ingredients "by design" must list those ingredients in the ingredient statement, unless exempt. In the July 25 FEDERAL REGISTER notice, FDFA explained that:

> Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food have been exempted by regulation from labeling on an ingredient statement (Sec. 101.100(a)(3)). Incidental additives include substances that have no technical or functional effect in the finished product, processing aids, and substances that may migrate to the food from equipment or packaging. FDA has stated that because very small amounts of some allergenic substances can cause serious allergic responses, allergens that cause serious allergic reactions cannot be considered to be present at an "insignificant" level in the food. The agency has stated that all allergenic substances introduced as ingredients or as the result of manufacturing processes do not

00P-1322 C465

[1] Compliance Policy Guide Sec. 555.250, *Statement of Policy for Labeling and Preventing Cross- contact of Common Food Allergens.*

qualify as incidental additives and must be declared in the ingredient statement on the label of a food product.

66 Fed. Reg. at 38593.

These comments are submitted by CP Kelco, an international manufacturer of functional food ingredients such as whey protein concentrate, xanthan gum, pectin, gellan gum, and carageenan. CP Kelco fully supports labeling the presence of allergens in foods. Nonetheless, for the reasons set forth below, CP Kelco believes that FDA's position that there is no level of an allergen which does not require label disclosure will cause unnecessary and confusing declaration of allergens which are in fact not present and could serve as a disincentive to proper testing for the presence of allergens.

A number of the biopolymers which CP Kelco manufactures are produced by the fermentation of a nutrient source by an appropriate organism. Since no fermentation process is 100% efficient, some form of the nutrient source may be present in the finished biopolymer, despite post-fermentation treatments, including pasteurization and alcohol precipitation, to assure product purity. Where identifiable levels of an allergenic substance are present in the finished biopolymer, CP Kelco agrees that it should be labeled as an ingredient.

However, whether or not an allergen is actually present in the finished biopolymer is not a simple issue. For example, some biopolymers CP Kelco produces use soy protein as the nutrient source. When the fermentation process is complete and the biopolymer has undergone post-fermentation treatment,, there is no level of soy that can be detected using the ELISA method, a standard test procedure. If, however, the finished product is tested using PCR amplification, a positive result may be obtained. What does that positive result show? PCR amplification can produce positive results for soy when only fragments of soy DNA are present in the finished product. Should this trigger a labeling obligation? Surely the obligation to label the presence of an allergenic ingredient should not depend solely on the sophistication of the test method a company chooses to employ, for otherwise there would be a real incentive to use technology that is unlikely to produce a positive result.

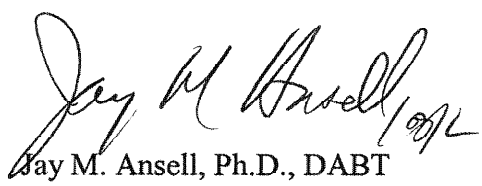
The difficulty of this issue is accentuated by the fact that the typical biopolymer is used in a finished food at levels of less than one percent. Thus, an allergen which is only detectable (but not quantifiable) using the most sophisticated technology is then diluted by a factor of 100 or more, probably rendering it undetectable by any method. But if the allergen is declared on the label of the biopolymer, the manufacturer of the finished food is likely to believe that it is necessary to declare the "presence" of the allergenic ingredient in the finished food.

CP Kelco believes, accordingly, that it is important for FDA to standardize the test method or methods that will be used to determine the "presence" of an allergenic ingredient for labeling purposes. Failing to do so will cause the needless labeling as allergenic of many food products which contain no measurable amount of an allergen. Alternatively, customers may purchase food ingredients from manufacturers which do not use the most advanced detection technology.

CP Kelco recognizes that this is a difficult issue. The failure to address it, however, will carry with it its own consequences which may not be in the best interest of the public.

CP Kelco appreciates the opportunity to submit these comments and would welcome the opportunity to work with FDA to resolve the issues we have raised.

Respectfully submitted,



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