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May 13, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds; Establishment of Docket

Docket No. FDA-2012-N-0711

Dear Sir or Madam:

On December 14, 2012, the Food and Drug Administration announced in the Federal Register the establishment of a docket to obtain comments relevant to conducting a risk assessment to establish regulatory thresholds for major food allergens as defined in the Food Allergen Labeling and Consumer Protection Act of 2004 ("FALCPA") (the "Notice"). The Food Marketing Institute (FMI) appreciates the opportunity to comment on this important matter.

FMI conducts programs in public affairs, food safety, research, education and industry relations on behalf of its nearly 1,250 food retail and wholesale member companies in the United States and around the world. FMI's U.S. members operate more than 25,000 retail food stores and almost 22,000 pharmacies with a combined annual sales volume of nearly $650 billion. FMI's retail membership is composed of large multi-store chains, regional firms and independent operators. Its international membership includes 126 companies from more than 65 countries. FMI's nearly 330 associate members include the supplier partners of its retail and wholesale members.

FMI Supports Risk-Based Regulatory Thresholds

FMI supports the establishment of risk-based regulatory thresholds to help the agency determine whether, or what type of, enforcement action is appropriate when specific problems are identified. Such thresholds would also help FDA establish a clear standard for evaluating claims in FALCPA petitions that an ingredient "does not cause an allergic response that poses a risk to human health" or "does not contain allergenic protein." FMI agrees with FDA that regulatory thresholds would help industry to conduct allergen hazard analyses and develop standards for evaluating the effectiveness of allergen preventive controls.

Quantitative Risk Assessment-Based Approach is the Strongest for Establishing Allergen Thresholds

FMI agrees with the FDA Threshold Working Group that a quantitative risk assessment-based approach is the strongest approach for purposes of establishing these thresholds. We concur that it provides the most transparent scientific analyses to establish such thresholds.

Thresholds Should be Applied to Reduce the Number of Class I Recalls and RFR Incidents Without Increasing Public Health Risk

FDA should examine how the application of allergen thresholds could reduce the number of Class I recalls and Reportable Food Registry incidents without increasing public health risk as part of the rulemaking process in this docket. Thresholds should be established and applied with the aim of effectuating this outcome. Unnecessary recalls pertaining to allergens impose very significant costs on the supply chain every year. Although retailers shoulder much of the burden, in an industry where profit margins are well under one percent, consumers bear many of these costs. FDA should establish thresholds with the goal in mind of minimizing unnecessary recalls that do not serve to protect public health. Consistent with a risk-based approach, FDA should craft thresholds that focus regulatory and industry resources to guard against incidents that pose the greatest threat to human health in order to maximize the benefits of FALCPA.

Necessity of Guidance on Enforcement and Application

Clear guidance from FDA will be needed on how thresholds will be used by the agency for enforcement and how the agency should apply such thresholds. The agency should also contemplate applying the allergen regulatory threshold for the notification exemption process by defining “does not contain allergenic protein.”

Application of Food Allergen Thresholds and FSMA

On January 15, 2013, FDA issued a proposed regulation entitled Preventive Controls for Human Food: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (“Preventive Controls Rule”) pursuant to the Food Safety Modernization Act (FSMA). The Preventive Controls Rule applies to food facilities required to be registered with FDA pursuant to Section 415 of the Federal Food, Drug and Cosmetic Act. While FMI members operate a variety of types of food facilities required to be registered with FDA, the bulk of these facilities are distribution centers. There are 1,903 grocery distribution centers operating in the U.S. according to the latest industry statistics. The vast majority of product held in these facilities is in packaging and not exposed to environment. As FDA has stated in the Preventive Controls Rule, the outcome of a hazard analysis for the holding of non-TCS packaged foods not exposed to the environment is that no hazards are reasonably likely to occur.

FDA stated in the Preventive Controls Rule that for the holding of TCS packaged foods, the principal hazard that would be identified in any hazard analysis is the potential for the growth of, or toxin formation by, microorganisms of public health significance. It follows that in the outcome of a hazard analysis for the storage of packaged foods, cross-contact is not a hazard reasonably likely to occur. Regulatory activities related to allergens should thus not be focused on holding facilities—such as grocery distribution centers—that are primarily engaged in the distribution and storage of packaged foods.

The Preventive Controls Rule extensively addresses the issue of food allergens. Food allergens are contemplated under the Rule in two key ways:

1. Allergens must be addressed as a potential chemical hazard under the subpart C Preventive Controls Requirements.

2. The Current Good Manufacturing Practice regulations are revised to address cross-contact.

Subpart C Preventive Controls Requirements

Regarding the first point, FMI notes that the allergen thresholds FDA seeks to establish are likely to have implications for proposed § 117.135 (c)(2) of the Preventive Controls Rule: "Preventive controls must include . . . The maximum or minimum value, or combination of values, to which any . . . chemical . . . parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur." Allergens are considered chemical hazards.

The allergen thresholds will also have clear implications for proposed § 117.135(d)(2) which states:

> (2) *Food allergen controls.* Food allergen controls must include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed for:
>
> (i) Ensuring protection of food from cross-contact, including during storage and use; and
>
> (ii) Labeling the finished food, ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.

FMI asks that FDA contemplate the implications of the allergen thresholds it seeks to establish for compliance with applicable FSMA regulations and create a science-based standard that minimizes public health risk from major allergens while not imposing unnecessary burdens that do not serve to enhance public health.

In the context of the Preventive Controls Rule, the thresholds should be applied in a risk-based manner, consistent with the risk-based principles on which FSMA was enacted. For example, FMI is not aware of a single allergen-related illness incident

arising from contamination occurring within a grocery distribution center and as discussed above, no allergen hazards are reasonably likely to occur. FDA should thus not focus the application of allergen thresholds on warehouses and distribution centers. Doing so could impose very significant—and costly—burdens, while not serving to enhance protection of public health. Any application of allergen thresholds should contemplate the difference in risk between the mere holding/storage of product and the processing/manufacturing of it.

CGMPs

The Preventive Controls Rule establishes new CGMP requirements whereby "Storage and transportation of food must be under conditions that will protect against cross-contact . . ."

FDA notes in the Preventive Controls Rule that:

> There are limited routes of contamination for unexposed packaged food in a facility that solely stores unexposed packaged food (e.g. packaged food in containers in a warehouse). Contamination can occur, for example, if rodents gnaw through packages or it human waste from an improperly maintained toilet facility spills and seeps into paper-based packaging. However, with one exception, the CGMP requirements in proposed part 117, subpart B…..would apply to the storage of unexposed packaged food and be adequate to prevent such contamination so that it would not be necessary for the owner, operator or agent in charge of a facility to address these routes of contamination by applying the hazard analysis and risk-based preventive controls that would be established in proposed subpart C.[1]

The revised CGMPs obviate the need for the subpart C requirements to apply to grocery distribution centers in the judgment of FMI. Distribution centers are extremely low risk environments for cross-contact. As stated earlier, FMI is not aware of a single allergen-related illness incident attributable to contamination occurring at a grocery distribution center.

FMI believes the thresholds FDA seeks to establish in any rulemaking initiated pursuant to this notice should be focused on manufacturing/processing facilities and not warehousing/holding facilities. Application of such thresholds should similarly be directed to manufacturing and processing facilities rather than holding facilities. Grocery distribution centers handle little product that is not in a package and the chances of cross-contact with allergens are very remote.

[1] 78 Fed. Reg. 3713. The exception is for facilities solely engaged in the storage of raw agricultural commodities and is not applicable to supermarket distribution centers.

We appreciate your consideration of these comments. Please do not hesitate to contact me at elieberman@fmi.org or (202) 452-8444 if you have any questions.

Sincerely,

Erik R. Lieberman
Regulatory Counsel