June 19, 2014

Docket Room Manager
U.S. Department of Agriculture
Food Safety and Inspection Service
Patriots Plaza 3
1400 Independence Avenue SW.
Mailstop 3782, Room 8–163B

RE:   FSIS Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention, and Control, and Declaration through Labeling

Docket No. FSIS-2013-0029

On April 21, 2014, the U.S. Department of Agriculture’s Food Safety and Inspection Service (“FSIS” or “the Agency”) published in the Federal Register a Notice announcing the availability of the “FSIS Compliance Guidelines – Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling,”\(^2\) (“Guidelines”) and requested that comments on the Guidelines be submitted on or before June 20, 2014. The Food Marketing Institute (“FMI”) appreciates the opportunity to comment on the Guidelines.

FMI proudly advocates on behalf of the food retail industry. FMI’s U.S. members operate nearly 40,000 retail food stores and 25,000 pharmacies, representing a combined annual sales volume of almost $770 billion. Through programs in public affairs, food safety, research, education and industry relations, FMI offers resources and provides valuable benefits to more than 1,225 food retail and wholesale member companies in the United States and around the world. FMI membership covers the spectrum of diverse venues where food is sold, including single owner grocery stores, large multi-store supermarket chains and mixed retail stores. For more information, visit www.fmi.org and for information regarding the FMI foundation, visit www.fmifoundation.org.

Introduction

\(^2\) Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling
The Guidelines are intended to assist FSIS-regulated establishments in identifying, preventing and controlling hazards associated with allergens and ingredients of public health concern. Based on the principles of “identify, prevent and control, and declare,” the Guidelines include best practices that these FSIS inspected establishments can adopt as part of their food safety systems to ensure that product labels declare all ingredients and products do not contain undeclared allergens and other ingredients of public health concern.

Eight of the most common allergenic foods account for 90 percent of all food allergies. The “Big Eight” allergens include wheat, crustacean shellfish (e.g., shrimp, crab, lobster), eggs, fish, peanuts, milk, tree nuts (e.g., almonds, pecans, walnuts), and soybeans. In addition to these allergens, some other ingredients cause adverse reactions in susceptible individuals. These ingredients of public health concern include sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten and monosodium glutamate (MSG).

Over the last several years, FSIS has noted a sustained increase in recalls of meat and poultry products due to undeclared allergens and other ingredients of public health concern. For example, the number of recalls attributed to undeclared ingredients increased from 7 in 2008 to 29 in 2012. FSIS believes that these recalls were preventable as they were caused by ingredient changes, new suppliers, product changes, products in the wrong package and products with misprinted labels. FSIS is issuing the Guidelines to assist in preventing these recalls in the future.

FMI fully supports and commends FSIS on the issuance of the Guidelines to provide assistance to FSIS inspected establishments in identifying and controlling allergens and ingredients of public health concern. All members of FMI are very concerned with the increase in the number of allergen-related recalls, and support the Agency’s actions in providing information that establishments can use to ensure they are preventing the introduction of product containing unidentified allergens or ingredients of public health concern to consumers.

**Substantial Increase in Recalls Affects All FMI Members**

Because it is FMI members who execute the recalls that result when establishments fail to identify an allergen or ingredient of public health concern; FMI has a strong interest in promoting any information that can assist in their reduction. In fact, our members have been vocal in expressing their concerns over the increase in these types of recalls – both in products produced in FSIS-regulated facilities as well as those regulated by the Food and Drug Administration (FDA). FMI members all bear increased costs that are never fully recovered when a recall for allergens or an ingredient of public health concern occurs – even if no adverse consumer events are associated with the product subject to the recall.

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3 The Guidelines note that some foreign countries, such as Canada and the European Union, recognize more than the “Big Eight” allergens identified herein.
Suggestions for Additional Actions to Take

While the information in the draft Guidelines is excellent, FMI believes that for it to be effectively implemented, FSIS should more proactively reach out to the meat and poultry industry with this information. As an example, FSIS hosted a number of webinars on the changes made to the generic labeling regulations earlier this year with great success. FMI recommends that FSIS conduct similar webinars for the industry on best practices related to allergen control. Another suggestion is to do joint webinars with FDA for not only FSIS inspected establishments, but those regulated by the FDA as well. This would then reach the suppliers of the ingredients brought into FSIS-regulated facilities which, many times, are the cause of the recalls due to an unknown change in formulation. Moreover, if FSIS and FDA reached out to the many trade associations and/or State extension offices with the information on the webinars, it could be promoted to those very small facilities that could benefit the most.

Conclusion

Again, we applaud FSIS in putting together these Guidelines. We believe these Guidelines provide information to establishments on best practices they can use in preventing future recalls for allergens or ingredients of public health concern. Our members strongly support actions FSIS can take to proactively provide these best practices to FSIS inspected establishments.

Sincerely,

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Vice President, Food Safety Programs