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Via electronic submission

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

Re: Food and Drug Administration, Implementation of the Food and Drug Administration Food Safety Modernization Act Amendments to the Reportable Food Registry Provisions of the Federal Food, Drug, and Cosmetic Act; Docket No. FDA–2013–N–0590; 79 *Federal Register 16698* (March 26, 2014)

Dear Sir or Madam:

The American Spice Trade Association (ASTA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) advance notice of proposed rulemaking related to the implementation of the FDA Food Safety Modernization Act Amendments (FSMA) to the Reportable Food Registry (RFR) provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Introduction

American Spice Trade Association

ASTA was established in 1907 to provide representation for the American spice trade. Its members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the wholesale and retail levels. On behalf of its members, ASTA works with federal and state regulators and legislators and assists its members in addressing a variety of technical issues to help members provide an adequate supply of safe and wholesome spices for their industrial, food service and consumer customers.

Joint Role to Protect Public Health and the Food Supply

Passage of FSMA, signed into law on January 4, 2011, underscores FDA's role to protect human health and the critical mission it plays in ensuring that our nation's food supply is safe. ASTA shares FDA's commitment to food safety. The highest priority to ASTA and its members is providing clean, safe spices to customers: food manufacturers and consumers. ASTA continues to engage actively in the regulatory process by providing comments to FDA as it implements FSMA. ASTA also continues to provide needed resources

to members to share with the entire supply chain as appropriate, including tools to assist in the manufacturing, handling, and processing of clean safe spices.

ASTA supports efforts that strengthen and modernize our nation's food safety system. ASTA supports both the general requirements of FSMA as well as the critical role FDA plays to ensure the safety of our nation's food supply. ASTA also generally supports the Reportable Food Registry, which has a general purpose to provide a "reliable mechanism to track patterns of adulteration in food... [to] support efforts by the [FDA] to target limited inspection resources to protect the public health."[1] As a general matter, although the RFR plays an integral role in tracking adulterated foods, it was not intended as a notification mechanism to communicate product recalls directly to consumers. Therefore, to develop the consumer-oriented one-pagers required by FSMA, FDA should consider relying on existing information in its control rather than adding obligations for responsible parties reporting to the RFR. Increasing the RFR reporting requirements could create confusion and slow down currently effective consumer outreach strategies employed by industry and the FDA during food recall events. FDA already has all necessary consumer-oriented information in its control through recall press releases provided for review to the District Offices. Furthermore, Congress provided flexibility in FSMA to determine whether or not to require responsible parties to submit consumer oriented information to FDA. ASTA maintains that there are more appropriate tools to assist FDA in providing this information to consumers than adding submission fields to the RFR.

Background

FSMA amended section 417 of the FD&C Act which governs the RFR. Newly added Section 417(f) provides that FDA *may* (emphasis added) require a responsible party to submit to FDA "consumer-oriented information" regarding a reportable food with the exception of fruits and vegetables that are raw agricultural commodities. The consumer-oriented information would include: 1) a description of the article of food; 2) affected product identification codes; 3) contact information for the responsible party; and, 4) any other information the FDA determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food.[2]

General Comments

Our comments offer a general perspective on this matter. For the specific questions that we do not address, we urge that FDA give thoughtful consideration into the comments provided by subject matters experts, such as our colleagues at the Food Marketing Institute and Grocery Manufacturers Association, who work specifically with the industries that will likely be most impacted by these changes: the consumer product companies and retail grocery stores.

ASTA generally believes that requiring responsible parties, who submit a report to FDA through the RFR regarding a reportable food, to also submit a separate consumer-oriented notification through the RFR will not be effective at protecting public health. Mandating that additional information be submitted to the RFR is not necessary because FDA already has all of the information that it needs to prepare one-page consumer-oriented summaries for consumers. Responsible parties already are required to submit to FDA 1) a description of the article of food and 2) affected product identification codes.[3] Further, they routinely submit contact information for the responsible party on a voluntary basis. Any additional consumer-oriented

[1] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-085, sec.1005(a)(4), §417, 121 Stat. 823, 964-969 (2007).
[2] FSMA § 211; FD&C Act § 417(f)(1)-(4).
[3] FD&C Act § 417(e).

information, such as information about how to identify recalled foods, is included in recall press releases that FDA typically reviews and posts on its website.

We also are concerned that requiring responsible parties to submit additional information could cause confusion and delay. The FD&C Act requires responsible parties to submit reports on reportable foods to the FDA through the RFR within 24 hours after determining that there is a reasonable probability that the use of, exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.[4] In addition to reporting to the FDA through the RFR, responsible parties must efficiently evaluate and communicate the issues addressed in RFR reports to downstream users of their products. Additional requirements for industry to simultaneously submit additional consumer-oriented information will divert limited resources that should be spent on otherwise minimizing food safety risks and effectuating recalls.

Additionally, requiring submission of RFR documentation for items that will never reach consumers does not make sense. For example, some RFR reports are tied to foods that are not recalled. Relatedly, there may be instances where a food reported to the FDA through the RFR is an ingredient used in a finished food and as such the food ingredient initially reported is not sold directly to consumers. In such an instance, while the responsible party reporting that food ingredient is positioned to notify and identify the downstream users of that reported food ingredient, the responsible party may not be best positioned to know the consumer-oriented finished product information such as the SKU or UPC. Therefore, requiring the responsible party in this example to supply additional information, such as identifying the resulting finished product, would not provide any public health benefits given that the finished product manufacturer also is required to file an RFR report. Responsible parties are many times not the manufacturers of finished foods sold to consumers.

Furthermore, it is imperative that FDA keep in mind the critical importance of maintaining fast, accurate communications during recalls. FDA should take caution that its implementation of this provision of FSMA does not in fact slow the speed of current consumer notification practices. Other recall resources are being used by industry that could be of assistance to notify consumers quickly about recalled foods. ASTA urges FDA to be thoughtful when promulgating these regulations and to ensure the new requirements do not detrimentally affect the current, effective practices used to notify consumers of recalls.

Conclusion

ASTA and its members are committed to ensuring the safety of spices. We thank you for the opportunity to comment on this important subject and respectfully request your consideration.

Sincerely,

Cheryl Deem
Executive Director

[4] FD&C Act § 201(ff) and 417(a)(2).