June 9, 2014

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

Re: **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]**

To Whom It May Concern:

On behalf of our members, the Produce Marketing Association (PMA) respectfully submits the following comments as per the Food and Drug Administration's (FDA) Advance Notice of Public Rulemaking request for comments regarding the "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].

PMA is the largest produce trade association representing companies in the fresh fruit and vegetable industry globally. Our association represents more than 2,700 member companies located in 45 countries. In the U.S., our members operate at every level in the supply chain from growing to shipping, processing/manufacturing, distribution, wholesaling, retail and foodservice. Collectively, our members handle more than 90 percent of fresh produce sold to domestic consumers. Regardless of member size or scope of operations, our members are committed at every level in the supply chain to food safety.

An overarching objective for PMA is to increase the consumption of fresh fruits and vegetables on a global basis. PMA serves its members by providing a forum to make business connections and by providing them with the information they need to make informed decisions that will enhance their businesses and deliver fresh fruits and vegetables to consumers. It is in this role of educator that PMA's food safety and technology efforts are focused. During the initial discussions on the Food Safety Modernization Act (FSMA), PMA provided industry expertise to congressional staff and FDA to help inform them of current science and industry practices.

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In developing these comments in response to the FDA ANPR regarding, "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], PMA staff has relied on in-depth discussions with its members to gather feedback on issues of significance regarding this FSMA ANPR. We also engaged the PMA Science and Technology committee to get their input and guidance. This committee is composed of industry experts from around the industry: small producers to very large, technology vendors, growers, processors, retailers and foodservice representatives. Their insights have proven to be invaluable in sorting through this ANPR and developing comments based on their collective experience.

Comments

Assuring the safety of produce at all steps from farm to fork is a top priority for the global produce industry. Implications of this ANPR are important to PMA members' businesses and to the industry overall. PMA strongly supports advancing food safety in ways that are meaningful and that focus industry efforts to protect public health. PMA supports the implementation of science-based and risk-based regulations throughout the supply chain that use appropriate preventive controls to address hazards associated with the commodity, practices and procedures employed during the production, handling and holding of fresh produce.

Key issues from the perspective of PMA members regarding FDA's "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" ANPR are as follows:

- **FDA RFR Versus Recall Program:** PMA believes that the FSMA amendments to section 417 of the Federal Food Drug and Cosmetic Act creates two redundant FDA consumer notification systems regarding foods which may cause severe adverse health consequences or death. The redundancies in consumer notifications will likely lead to consumer confusion, in that, consumers will now have to understand and be able to differentiate a "recalled food" versus a "reportable food." The current FDA food recall program works well at gathering and communicating information about foods that if consumed may cause severe adverse health consequences or death and these communications effectively prevent consumption and inform consumers if they may have been exposed to adulterated foods. The FDA foods recall program has and should continue to be the primary channel of food product safety communication between FDA and consumers.

The FDA RFR is a separate program, whose purpose should remain to provide FDA with a reliable means to identify and track adulterated food and food ingredients in the supply and distribution chain. The FDA foods recall program and the FDA RFR have two very different purposes and these purposes should not be co-mingled. Food products which meet the definition of being a "reportable food" in almost all circumstance meet the FDA definition of a food requiring a Class I recall. Therefore, consumer notification of "reportable foods" which by definition may cause serve adverse health consequences or death, if consumed, is already being done by the FDA food recall program via coordinated recall notices and consumer communications. Additionally, food manufacturers and retailers need to be able to work with one office at FDA regarding a "reportable recalled food product" as dealing with multiple FDA offices during a potential public health emergency would be time consuming, inefficient and potentially place public health in jeopardy by slowed or uncoordinated response.

- **"Reportable Food" Versus a "Recalled Food Product"**
  However, not all "reportable food" products are recalled, because for example it may occur that a highly perishable food product could be a "reportable food," but it may be highly unlikely that the "reportable food" was still in commerce or available if purchased by consumers, hence a food product recall may not occur. This allows for effective use of the food recall system, in that consumers are not inundated with recall notices or reportable food notices that they cannot act on and it allows consumers to focus their attention and avoid potentially adulterated foods that are in commerce or in their homes. If RFR consumer notices are simply posted without consideration as to whether or not a food product is or is not likely to be available to consumers, it will likely lead to many consumers simply ignoring such notices. Hence it is suggested that FDA carefully consider a coordinated and unified approach regarding consumer RFR notices and consumer recall notices, with only recalled food notices being communicated to consumers when appropriate.

- **Consumer Notification:** FDA should strongly consider the array of consumer notifications available to food producers, distributors and retailers and allow for flexibility in notifying consumers regarding a "recalled food" or "reportable food." The practicality of posting and keeping up-to-date consumer notices at the consumer point of service is difficult, time consuming and likely less effective than other means available to retailers to communicate with their customers. Additionally, FDA needs to carefully consider the language that the FDA will use to communicate with consumers about reportable foods" versus "recalled foods." It is suggested that the FDA consider the use of the term "reportable-recalled food" to meet FSMA amendments in section 417 of the Federal Food Drug and Cosmetic Act and FDA should continue to use one program, that being the FDA foods recall program to coordinate consumer notifications regarding "reportable-recalled foods."

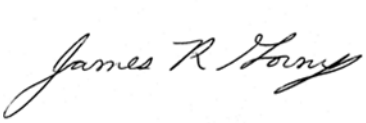
- **Consumer Notification Timeframe:** Section 350f(h) specifies that recall information be displayed for 14 days this does not seem to be science or risk-based on consumer behavior but arbitrary and capricious. Therefore, it is recommended that FDA carefully consider the notification period length, as for some products this prescribed 14 days of notification may be too short while for others this may be too long of period of time. In particular for highly perishable fresh-cut produce items, the 14 notification period may leave the RFR consumer notification posted well past the "best if used by date" or "expected shelf-life of the product" and deter consumers from eating healthy and nutritious fresh fruits and vegetable products. FDA must also carefully consider how the requisite timeframe would apply to various means of notification. For example, a consumer cannot be called on the phone about the same recall for 14 days; however, while a retailer could post information on a website for that period of time or longer. When a retailer has notified consumers prior to an FDA posting, should consider the 14 days beginning upon the first occurrence of retailer notifying consumers. Likewise, if a retailer uses more than one method of notification, the 14 days should be inclusive of all manners used and not apply to each one separately. For example, if a recalled product is already well past its shelf life, thereby inedible, it is unlikely any consumer would still have the product, so the retailer may choose to post a sign in the store for 2 days and then post the information about the recall on their website for the next 12 days.

- **FDA Question 4a Re: Raw Agricultural Commodities** "Section 417(f) of the FD&C Act, as amended by FSMA, provides that FDA may 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. Based on these exceptions and exclusions, responsible parties may not submit to FDA consumer-oriented information, under section 417(f) of the FD&C Act, for dietary supplements, infant formula, and fruits and vegetables that are raw agricultural commodities. There may be potential public health impacts if consumer notifications for reportable foods do not include information on dietary supplements, infant formula, and fruits and vegetables that are raw agricultural commodities, particularly if the public believes that such consumer notifications are meant to encompass all food products regulated by FDA. FDA seeks comments or other information on whether consumer notifications posted by chain grocery stores, as specified by section 417(h) of the FD&C Act, should include information advising consumers that such notifications do not cover certain foods, such as a statement asserting that the consumer notifications do not include reportable food or recall information for dietary supplements, infant formula, and fruits and vegetables that are raw agricultural commodities, and consumers should consult FDA's Web site for any relevant information for these products."

Question 4A as posed by FDA points out the potential adverse public health consequences of having two redundant and duplicative FDA programs to communicate with consumers about foods which may cause severe adverse health consequences or death, if consumed. The FDA “reportable food” and FDA “recalled food programs” must work seamlessly and in a unified manner. As per the PMA’s comments above, it is suggested that FDA develop a unified means of communicating with consumers about foods that may cause severe adverse health consequences or death, irrespective of if it is a “reportable food” or “not a reportable food” as per section 417 of the FD&C Act. It is suggested that FDA consider the use of the term “recalled food” for adulterated fruit and vegetable RACs that may cause severe adverse health consequences of death, if consumed and consumer notification should continue to use one the FDA foods recall program to coordinate consumer notifications regarding “recalled foods.” It is suggested that FDA foods recall program have two options to use either the term “reportable-recalled food” or “recalled foods” for items excluded as per section 417(h) of the FD&C Act. This unified FDA program consumer notification approach would provide consistency regarding consumer notification, alleviate redundant consumer notification efforts and target FSMA mandated RFR consumer notifications at retail to only those products subject to coverage as per the FSMA statute.

PMA has participated in the congressional debate about FSMA and has provided comment to FDA at every opportunity in the development of the proposed rules and policies. We greatly appreciate those earlier opportunities and the opportunity here to provide detailed comments on this FSMA ANPR.

Thank you for the opportunity.



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