Dockets Management Branch (HFA-305)
Food and Drug Administration
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http://www.regulations.gov/

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; RIN 0910–AG97

The United Fresh Produce Association appreciates the opportunity to comment on the advance notice of proposed rulemaking regarding FSMA amendments to the Reportable Food Registry ("RFR ANPR").

United Fresh represents more than 1,200 companies at the forefront of the fresh and fresh-cut produce industry, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. United Fresh works to increase consumption of fresh produce for public health, shape legislative and regulatory policies that serve the public and provide for a sound business climate for its members, provide scientific and technical leadership in food safety, quality assurance, nutrition and health, and develop educational programs and business opportunities to assist member companies in growing successful businesses.

General Comments

While FSMA and Congress directed FDA to develop consumer-oriented messaging based on the Reportable Food Registry, we submit that doing so will only cause confusion among companies submitting such messaging, retailers required to display such messaging, and consumers, and incur unnecessary costs for all involved. The fundamental purpose of the Reportable Food Registry is for trending and tracking patterns of adulteration. Registered operations are required to submit reports even if the adulterated ingredient or product has never reached consumers. Intuitively, the only notifications of value to consumers will be those regarding product to which consumers have had access. Such product is subject to recall, and, while we agree that consumer-oriented messaging should be limited to the same scope as the Reportable Food Registry (i.e., Class I recalls) we submit that such messaging is much better tied to FDA's recall program than to the Reportable Food Registry. FDA requires operations that perform a recall – voluntary or mandatory – to issue a press release when a press release is able and necessary to provide consumers with information to identify Class I recalled food that reasonably may be in their possession. A recall press release typically has most or all of the information that consumer-oriented messaging should include. It would be far easier and far less costly and confusing to require operations to prepare consumer-oriented messaging at the same time as when preparing a press release. Therefore, unless otherwise described, our comments below are based on an approach that would link consumer-messaging by retail operations to FDA's recall program, not to the Reportable Food Registry.

Comments to Specific Questions Posed in the ANPR

Question 1a: What information should FDA require be included in consumer-oriented information submissions and consumer notifications for a reportable food to enable a consumer to accurately identify whether he or she is in possession of the reportable food?

A typical press release includes the information consumers need to identify the recalled product. FDA's *Guidance for Industry: Product Recalls, Including Removals and Corrections* provides examples of information recommended to be included in press releases that would also be appropriate for consumer-oriented messaging, as applicable to the specific product: "product name (include brand name and generic name); model, catalogue, or product order number(s); description of the product; include if product is powder, liquid, tablet, capsule, etc.; if the product is perishable, include the expected shelf life; include type of packaging (i.e. box, flexible plastic, glass);…product labeling (including all private labels)…". Press releases may include generic product information like Production Identification Numbers or UPC codes; these can be useful in consumer-oriented messaging if combined with lot-specific information like lot/unit numbers or, in the case of fresh produce, Produce Traceability Initiative (PTI) codes. Lot-specific information, if available, is important to avoid retailers and consumers shunning an entire category because of one lot. Some press releases include photographs of labels or the product itself; while useful in consumer-oriented messaging, photographs may not always be possible or practical and should be not required.

In addition to product information, consumer-oriented messaging should also include other information included in press releases; i.e., nature of the adulteration, company contact information and product disposition instructions. We suggest that FDA recommend or mandate the minimum that must be included in consumer-oriented messaging and allow operations the flexibility to include more as needed. However, we also suggest that too much information in the messaging can be counterproductive; overloading consumers with information can be a deterrent to attentiveness.

Question 1b: Should FDA require responsible parties to submit consumer-oriented information to FDA, as described in section 417(f) of the FD&C Act, for reportable foods that are not available, or will not be available, for sale to consumers in chain grocery stores or otherwise available for sale to consumers at the retail food market?

As described above, there is no value to consumers to learn about reportable or recalled foods that are not available, or will not be available, for sale to consumers. Worse, such notifications can lead to misunderstanding and fear among consumers who do not understand that those foods are not in the marketplace and foods that are available for sale do not pose a public health risk. Like recall press releases, consumer-oriented information should only be prepared when such notification enables consumers to determine if they are in possession of adulterated food. Consumer-oriented messaging for a product should only be required to be posted in points-of-sale that carried/sold the recalled product, and not in markets that only carry similar or the same product but did not carry the recalled lot(s).

Question 1c: For the one-page summaries of consumer-oriented information prepared by FDA and published on FDA's Web site, what structure and format would be the most useful to grocery stores and consumers? To what extent, if any, should the consumer-oriented information be provided in languages other than English?

We suggest that "one-page" may be too much information, depending on the product, and that focused brevity may be a better tool for communication. The information published on FDA's Web site should be in a downloadable, uniform format, ready for posting at retail, although points-of-sale should have the flexibility to post the information in other formats.

Information should be posted per event, not per product lot number. Where multiple lots are involved, tables or lists work well if kept simple and sorted by the feature most likely recognized by the consumer, e.g., product type or brand name. Pictures/photographs work well, when available, but should not be required. Generally, key information in such messaging should be at the top and readable in less than a minute, or likely will be missed by consumers. The consumer-oriented information should always be posted on FDA's Web site in English, and perhaps in additional language if FDA concludes that another language is a better approach to communicate with the primary consumer of the recalled food. Points-of-sale should have the flexibility to translate the information published on FDA's Web site into a language better understood by their customers.

Question 1d: Should FDA revise and republish a one-page summary of consumer-oriented information on FDA's Web site if the published information no longer provides the information necessary to enable a consumer to accurately identify whether such consumer is in possession of the reportable food? … If a one-page summary is revised and republished on FDA's Web site, should this trigger additional posting obligations for chain grocery stores?

Information provided to FDA and posted by FDA must be timely and accurate, or will be of no or misleading value. If a recall changes in scope (e.g., additional lot numbers) or if the consumer-oriented information requires correction because the information submitted to FDA was incorrect or because FDA made an error in transcription, then FDA should revise and republish the summary and restart the timeframe for posting as if it was a new recall. However, revised summaries should be so designated and the nature of the revision made obvious; e.g., a header that says "Revised on [date]; additional lot numbers included". FDA should also publish a revised summary, and notify through the same channels as the initial summary, if a recall is subsequently cancelled.

Question 1e: What mechanisms can be employed so that chain grocery stores are aware that a one-page summary of consumer-oriented information for a reportable food has been published on the Agency's Web site, or that a previously published one-page summary has been revised?

Large retail markets, and many smaller points-of-sale, already have effective means of being notified of recalls, either through FDA's notifications or through private list serves. Additionally, FDA can use information provided by operations in Reportable Food Registry reports to target notifications to consignees of reportable foods, since RFR reports must be submitted to FDA within 24 hr of the operation determining the food is reportable. Companies may be required to notify consignees in recall notification letters. However, reliance on RFR reports and recall notifications alone will not suffice, since there is no deadline for submitting secondary or revised reports, and a recalling operation may not be aware of all points-of-sale for the recalled product.

Question 2a: What types of retail establishments should FDA consider to be ''grocery stores'' within the meaning of section 417(h) of the FD&C Act?

We suggest that all points-of-sale that sell the affected food to consumers be included in scope and that there be no exclusions. Such atypical retail establishments could include drug stores, department stores, farmers markets, gas stations, newsstands and any other retail point-of-sale of the recalled food. It should not include restaurants, commissaries and other foodservice venues where the food is served in a manner that cannot be identified by consumers as being the recalled food.

Question 3a: How can a chain grocery store prominently display or provide a consumer notification via a conspicuous location or manner as described in section 417(h)(2) of the FD&C Act?

All points-of-sale should be required to prominently display the consumer-oriented information, but the method and location should be allowed to vary. For example, a single-register store that sold only a single recalled food may decide that posting at the register is the best means of communicating with customers. Another store may choose to post a notification on the shelf where the food was sold, notifying consumers of the recall and directing them to a location in the store for more information. Another store may notify affected customers by email using loyalty cards, either providing full information or directing them to the store's website for more information. We suggest that FDA publish a list of acceptable "conspicuous locations and manners", and allow stores the flexibility to choose how best to communicate with affected consumers.

Question 3b: How can a chain grocery store prominently display or provide a consumer notification ''at or near the register'' as described in section 417(h)(2)(A) of the FD&C Act?

While some may choose to post consumer-oriented messaging at the register, for large, multi-register stores, especially those that sold multiple recalled foods, posting the consumer-oriented information at or near the register may be burdensome and of questionable value to consumers. At the register, consumers are usually involved with checking out and may not notice a recall message.

Based upon FDA recall numbers for the last three years, there is an average of 1000 Class I recalls of food products per year, or about 3 per day, that would have to be posted for 14 days. While not every store will carry every recalled product, we estimate that there could be 42 pages of recalls posted at or near the register. Recall fatigue is a likely consequence, eventually resulting in both the consumer and the market ignoring the documents.

However, if locating information at or near the register is important, it may be better to either post a notice at the register notifying consumers of a location in the store where information on recalled foods can be obtained, or post a list of the brand names for which recall information is current, again directing consumers to a location in the store where more information can be obtained.

Question 3c: How can a chain grocery store prominently display or provide a consumer notification in a way that provides ''the location of the reportable food,'' as described in section 417(h)(2)(B) of the FD&C Act?

Points-of-sale should remove recalled foods from being available to consumers as soon as they know the food is recalled, even before posting consumer-oriented information. Therefore, there should be no "location" that a point-of-sale would post, so we are unclear of Congress' intent in this provision, even if intended to post the location of a reportable food.

Question 3d: How can a chain grocery store prominently display or provide a consumer notification in a way that provides ''targeted recall information given to customers upon purchase of a food,'' as described in section 417(h)(2)(C) of the FD&C Act?

Aside from paper notifications posted or available in-store as already described, stores have used:

- Loyalty cards with robo-calls or emails to customers who purchased the specific product. While exquisitely targeted, this approach only works when customers have approved receiving such notifications and have provided up-to-date, accurate contact information.
- The store's company website. While easily accessible, it is unknown to us how effective this is as a means of communication.
- Notifications on store receipts when a customer buys the same SKU

Question 3e: …What methods, manners, and/or locations, if any, have grocery stores or other retail food establishments used to effectively notify consumers about food recalls?

We have described such in answers to previous questions. Whatever methods, manners, and/or locations FDA should eventually decide are acceptable, we suggest that FDA allow for additional future methods and technologies.

Question 3f: What factors could influence a chain grocery store's decision about whether to display a one-page summary of consumer-oriented information regarding a reportable food as published on FDA's Web site, or instead to display the information from the FDA summary?

Points-of-sale that rarely post such notices, or do not have the expertise or desire to reformat the information, may decide that posting the FDA summary is most convenient. Others may decide that reformatting the information provides a customer service in terms of clarity or convenience. Stores should be allowed the flexibility to decide which approach to use, provided required information is posted in an approved location or manner.

Question 3g: Could compliance with the consumer notification requirements of section 417(h) of the FD&C Act by chain grocery stores affect the voluntary or mandatory display of other information regarding a food recall by retail establishments?

As we noted previously, it is important that markets not be required to post messaging for recalled lots that were not carried or sold at that point-of-sale. Otherwise, we are not aware of any negative effect on the voluntary or mandatory display of other information regarding a food recall, provided FDA allows reasonable flexibility in what, how and when to display the recall information.

Question 3h: What, if any, impact will the consumer notification requirements in section 417(h) have on grocery store operations? For example, how might the requirements affect resources if resources are spent monitoring FDA's Web site for new consumer notifications to be posted, or resources are spent posting such notifications or the information from such notifications?

Inevitably, such requirements will expend company/store resources – monitoring for or receiving recall reports, preparing and posting notifications, removing old posts, and supervisory verification that notification procedures have been followed appropriately. Some of these actions will be concurrent but in addition to identifying and removing the recalled product from consumer access.

Question 3i: What are the estimated costs to chain grocery stores, per store and per reportable food, associated with displaying consumer notifications as required by section 417(h)?

For recalled foods, we estimate that stores will expend an average cumulative equivalent of 1–1½ hr per store per recall in the tasks identified in Question 3h. We anticipate the potential for additional costs for some notification methods (e.g., robo-calls) and for responding to consumer inquiries about the recalled food. The robo-calls bring a secondary follow up from consumers seeking further information as to lot codes and where and when sold, so this becomes an added cost to support. We anticipate that such costs related to customer inquiries would escalate dramatically if the intent is actually to post notifications of "reportable foods", because the meaning, concern, identification, distribution, handling and disposition of "reportable foods" are virtually unknown by consumers.

Question 3j: How much time (hours per reportable food) is currently used by grocery store and other retail food establishment employees (including managers) to notify consumers about reportable foods? What is the estimated change, if any, in the time spent on notifying consumers about reportable foods as a result of the consumer notification requirements in section 417(h) of the FD&C Act?

We estimate that costs and time now used by points-of-sale to notify customers of recalled foods range from about the same as answered to Question 3i, diminishing to zero for those that are not currently notifying customers.

Question 3k: Should chain grocery stores be permitted to use multiple manners and locations, as identified by FDA, to post consumer notifications consecutively for a total of 14 days?

We believe that points-of-sale should be permitted to use multiple methods at their own discretion and in a concurrent and/or consecutive manner to notify customers of a recalled food for a minimum length of 14 days, beginning the day the recall is announced by the recalling company. For example, posting on a shelf or at a register for 14 days may be appropriate for a long shelf life, low turnover product (i.e., one that customers may not shop for frequently) but be unnecessary for perishable, high turnover products. For the latter, prominent posting (e.g., robo-calls, receipt notifications, posting on shelf) may be useful for a few days, but then less prominent notifications (e.g., central store location or store website) may suffice beyond the reasonable shelf life of the product for the remainder of the 14 days. Whatever methods are used, they should be consistent for similar recall notifications at the particular point-of-sale, so as to avoid customer confusion. Also, the method of posting should consider customer readability.

Question 4a: …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.

The types of products not covered by the Reportable Food Registry go well beyond dietary supplements, infant formula, and fruits and vegetables that are raw agricultural commodities, e.g., pharmaceuticals, non-food consumables, electronics, toys and other consumer goods. Listing all of the items not covered would only cause confusion. On the other hand, we believe that recall notifications should be posted for any Class I recalled food sold at a point-of-sale, whether a reportable food or exempt from the RFR, which re-emphasizes our conclusion that notifications should not be linked to the Reportable Food Registry.

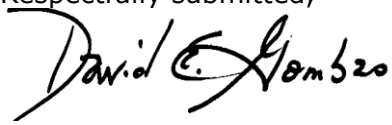
Notwithstanding consumer-oriented messaging prompted by recall of an FDA-regulated food, markets should retain the flexibility to post any customer-relevant recall information, regardless of the oversight regulatory agency, and to refer consumers to other locations for additional information, such as to the multi-agency supported website www.recalls.gov.

Question 4b: There may be a situation where FDA is aware of a class 1 recall for a reportable food for which a responsible party would be required to submit to FDA consumer-oriented information for such reportable food under section 417(f) of the FD&C Act, but the responsible party failed to submit such information to FDA. In such situations, should FDA prepare and publish a one-page summary of consumer-oriented information, if known, for such reportable food, and require chain grocery stores that sold the reportable food to post such summary or the information from such summary, as specified in section 417(h) of the FD&C Act?

If a company agrees to a voluntary or mandatory recall that FDA classifies as Class I of a food that was sold or otherwise provided to consumers at retail points-of-sale, the company should be required to provide consumer-oriented information under the same conditions that they are currently required to provide a press release; i.e., when such notification provides consumers with information reasonably useful to determine whether they are in possession of adulterated food. If the company fails to provide such information, FDA's recourse should be the same as for companies that fail to provide a press release; i.e., FDA should prepare and post their own version for posting by points-of-sale.

The members of United Fresh hope that FDA finds value in these considered comments.

Respectfully submitted,



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