Center for Foodborne Illness Research & Prevention
Consumer Federation of America – Food & Water Watch
National Consumers League – STOP Foodborne Illness
Trust for America's Health

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

RE: Docket No. 2013-N-0590

The undersigned members of the Safe Food Coalition and the Make Our Food Safe Coalition appreciate the opportunity to comment on the Food and Drug Administration's advance notice of proposed rulemaking on FSMA Amendments to the Reportable Food Registry Provisions of the Food Drug and Cosmetic Act [Docket No. FDA 2013-N-0590]. This rule is important to provide consumers with specific information about reportable foods.

Introduction
Under the Food Safety Modernization Act, new provisions were added to the Reportable Food Registry requirements of the Federal Food, Drug, and Cosmetics Act (FD&C Act) to provide consumers with information to identify whether they are in possession of a reportable food. The provision requires FDA to develop a summary document with information about the reportable food. Grocery store chains must then post the summary notification in specific manners or locations in the store.

While FDA already communicates recall information to the media and the public, this provision will provide consumers with additional notification about potentially contaminated food that may be in their possession. Importantly, this information will be posted in grocery stores where consumers purchase food. This notification at the point of purchase could serve as an important additional cue for consumers to ensure that they are not in possession of potentially contaminated food. Notifications should also help reinforce recall information already being communicated to the public.

In communicating with consumers, FDA should use the term "recall" instead of the regulatory term "reportable food." Even though there is a technical difference between the two terms, most consumers are unlikely to be familiar with the Reportable Food Registry and the use of the term "reportable food." Consumers are familiar with recalls and understand that food is recalled because of a possible risk to human (or animal) health. In consumer-oriented notifications, FDA should use the more consumer-oriented term "recall."

The following are answers to selected questions posed in the ANPRM.

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

In addition to the requirements under Section 417(f) of the FD&C Act, FDA should also require a picture of the product or product label which would facilitate consumer identification of the reportable food. Pictures of the product or product label are more likely to trigger consumer recognition than the written name of the product, especially if the name is not the common name consumers typically associate with the product. The required product identification codes (UPC, SKU or lot or batch numbers) would then provide more precise information for consumers to identify whether the specific product was in their possession.

FDA should also require information in the notification about the reason that the product has been reported. This is commonly provided in recall notices now, and provides consumers with specific information about the particular hazard. Consumers are familiar with certain hazards such as *E. coli*, *Salmonella* and *Listeria,* and know to take those hazards seriously. Providing this information in the notification would further highlight the importance of consumer action in responding to the notification.

FDA should include in the notification directions for what consumers should do with the reportable food, such as whether consumers should discard the product or return it to the grocery store for a refund. In certain cases, special handling instructions for the food product may be necessary. For example, FDA issued specific instructions in a 2007 recall notice for handling canned food products that were contaminated with botulism.[1] These instructions emphasized that particular care must be used when handling or disposing of cans that show signs of swelling or leakage. Consumers would need similar handling information in a notification required under this provision.

It would also be helpful to provide information in the notification about the states in which the product was sold. This could facilitate consumers informing each other about the notification if they know a family member or friend may have purchased the product in another state.

> **Question 1b: Should FDA require responsible parties to submit consumer-oriented information to FDA 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?**

No, if a reportable food is not available for sale to consumers at the retail food market, it would not be necessary for responsible parties to submit consumer-oriented information to FDA. This is consistent with provisions in Section 417 that indicate that only grocery stores that sold a reportable food must post a notification.

> **Question 1c: 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?**

FDA should conduct research into how best to present the information in the notification to elicit the appropriate response from consumers. Effective risk communication strategies are necessary to accurately and adequately inform consumers about the reportable food and what action should be taken. FDA should share any best practices with stakeholders, particularly the retail food industry, so

[1] Food and Drug Administration, "Chili Products (Botulism) Recall," September 4, 2007 via: http://www.fda.gov/newsevents/publichealthfocus/ucm179201.htm

that notifications are as effective as possible. Notifications should be provided in all languages commonly spoken in the geographic area served by a particular grocery store.

Question 1d: Should FDA revise and republish a one-page summary of consumer-oriented information if the published information no longer provides the information necessary to enable a consumer to accurately indentify whether such consumer is in possession of the reportable food?

Yes, if the notification is still relevant (i.e., if the product could still be in consumers' possession) but the information has changed, then FDA should revise and republish the notification. This is particularly important in the case of a recall that has been expanded to include additional lots of product or UPC/SKU codes. This would be similar to a revised recall notice published by FDA or USDA's Food Safety and Inspection Service (FSIS) when an investigation reveals that additional product should be recalled. FDA should clearly indicate that the new notice is a revised version, so that consumers are adequately notified that additional product has been made subject to the recall. If FDA revises and republishes a notification, grocery stores should be obligated to post a revised notice as well.

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?

FDA should consider section 417 to apply to all retail food establishments that sell food products directly to consumers. This should include supermarkets, grocery stores, co-ops, warehouse stores, wholesale club stores, convenience stores and other chain stores. It would also include stores that sell food in addition to other household products. FDA should also include online retailers and grocery store chains in the definition for the purposes of these requirements, since consumers purchasing food online should also be notified of recalled food. However, a grocery store should only be required to post notifications for reportable foods that it has actually sold rather than all reportable foods.

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

Section 417(h)(2) requires FDA to develop and publish a list of locations and manners for posting notifications in grocery stores. Locations and manners should include: signage at the register; signage at the location/aisle where the food would normally be available for purchase; signage where other recall information is typically posted; notification to loyalty card holders or club members via email, phone call and/or mail; notification via instant printout information at the register (though such information would have to be designed differently from coupons so as to catch the consumer's attention); and electronic notification, particularly from online retailers. Posting on the grocery store's website alone would not be sufficient notification, as consumers may not ever visit the website and so would not see the notification. However, posting on the website could be done in combination with one of the other locations or manners.

If FDA wishes to consider other manners in which grocery chains can provide notifications, which may not be currently available but could be future innovations, the FDA should consider guidance that provides a set of essential parameters for other types of notifications through which grocery chains might comply with the rule.

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

Grocery stores should be permitted and encouraged to post notifications in multiple manners and locations – e.g., grocery stores could post a sign at the register, directly contact consumers via email, AND post a notification on the store's website. However, once a notification is posted in a particular manner and location, the notification should remain posted in that manner and location for the full total of 14 consecutive days. If grocery stores use loyalty card programs or memberships or are online retailers, FDA should strongly encourage the stores to directly notify consumers who have purchased the reportable food, in addition to posting notifications in the store.

Grocery stores should not be permitted to mix and match the manners and locations so that any manner and location occurs for less than 14 days. The example highlighted in the ANPRM is that a grocery store could post a notification for 2 days in the store and then post the information for the next 12 days on the store's website. In our view, this would not adequately inform consumers, since consumers may not frequent the store every 2 days, and so many of them would not see the notification. However, consumers are more likely to visit the store at some point over the course of 14 days, and so would more likely see a notification that is posted for the full time period.

Question 4b: Should FDA prepare and publish a one-page summary when FDA is aware of a class I recall for a reportable food but the responsible party failed to submit the information to FDA?

Yes, particularly for a class I recall, FDA should prepare and publish a one-page summary and require grocery chains to post the notification, even if the responsible party has failed to submit the information to FDA. This is important for ensuring that consumers receive adequate notice that the product is being recalled, and FDA has an obligation to provide this information if the agency is aware of it.

We appreciate the opportunity to provide comments on this provision of FSMA.

Sincerely,

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