THE VOICE OF FOOD RETAIL
Feeding Families Enriching Lives

June 8, 2014

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

RE: Implementation of the FDA FSMA Amendments to the Reportable Food Registry Provisions

Docket No. FDA 2013-N-0590

On March 26, 2014, the Food and Drug Administration (FDA or the Agency) published in the *Federal Register* an advance notice of proposed rulemaking entitled "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" (the "ANPR"). Section 211 of the Food Safety Modernization Act (FSMA) directs FDA to improve the Reportable Food Registry (RFR) and requires grocery store notification of reportable food. In general, section 211 of FSMA provides that FDA may require a responsible party to submit to the Agency "consumer-oriented" information regarding a "reportable food", including information necessary to enable a consumer to accurately identify whether the consumer is in possession of a reportable food sold by grocery stores. Congress gave FDA the authority to determine acceptable locations for posting and "other such prominent and conspicuous locations and manners utilized by grocery stores."[1] The Food Marketing Institute (FMI) appreciates the opportunity to comment on this important matter.

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.

FMI supported the enactment of the Food Safety Modernization Act (FSMA). We believe the regulations issued to implement section 211 of FSMA, if crafted in a manner consistent with the

[1] P.L. 111-353 Section 211 (h)(2)(D)

following comments will facilitate communications, enhance public health and strengthen our nation's food safety regulatory system.

Recalls vs Reportable Foods

Any regulations or guidance issued by FDA to implement § 350f(H) should apply to Class I recalls only. Class I recalls by definition are those in which there is a reasonable probability that the use of or exposure to a product will cause serious adverse health consequences or death. Notifications about other less serious recalls and withdrawals should not be included within the scope of § 350f(H) regulations or guidance. The definition of "reportable food" in §350f(a) is consistent with foods covered by Class I recalls, but should be clarified in the regulation because recalls and the RFR are separate systems and processes at this time.

> **Reportable foods** are those in which there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Registered food facilities are required to report when they are aware of such products.
>
> **Recall** - The FDA defines a recall as a "firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers, and against which the Agency would initiate legal action (e.g., seizure)."[2]

Reportable foods are similar to but not the same as recalled foods. FDA has separate systems for the RFR and for recall notices. How will the FDA reconcile this with consumer notifications based on RFR reports and not recalls? Will all RFR reports lead to recalls? Will companies submitting a RFR report, in essence, be submitting a recall notification? How will the current recall classification system work in this case since recalls are typically classified after the RFR report is submitted?

FMI believes that two consumer notification systems under reportable and recalled foods create redundancies that could lead to consumer confusion between a recalled versus a reportable food. FMI suggests that FDA carefully consider a unified and coordinated approach regarding consumer RFR notices and consumer recall notices, with only recalled food notices being communicated when appropriate. FDA should also consider updating IT systems to be interoperable with other FDA systems (i.e. RFR and the current recall system) and other systems currently used by industry to share information about product information and recalls. Sharing and exchanging information electronically prior to consumer notification, could speed up availability of information and decision making in order to further protect public health.

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[2] FDA Investigations Operations Manual 2014
http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123513.pdf

Regulations or guidance issued under §350f (H) should provide retailers with the flexibility to choose from several effective approaches to communicate recall information to consumers. The regulations should afford the opportunity for new ideas and modes for notification and not be so prescriptive as to limit innovation.

Current Industry Practices

FMI believes regulations should not cause any delay in the notification procedures currently used by the industry. Recalls may not always be classified by FDA at the time of the notification, and depending on the reason for the recall, retailers will take action on their own prior to FDA classification based on their knowledge and experience. Retailers primarily receive product recall notification requests from their suppliers or manufacturers, usually before the information is provided by FDA or via the reportable food registry (RFR). In these situations, retailers take action within hours of initial notification to remove recalled product from store shelves, stop sales and hold product either at store level or at the distribution center or warehouse. Furthermore, retailers subsequently implement actions to notify consumers while preventing the sale of recalled product. Linking consumer notification to the RFR could result in a delay in this current system of recalls and notification. Although FMI has no objection to using the RFR as a database for capturing information, it should not be the basis for determining when a recall is needed and when product is removed from sale and consumers are notified.

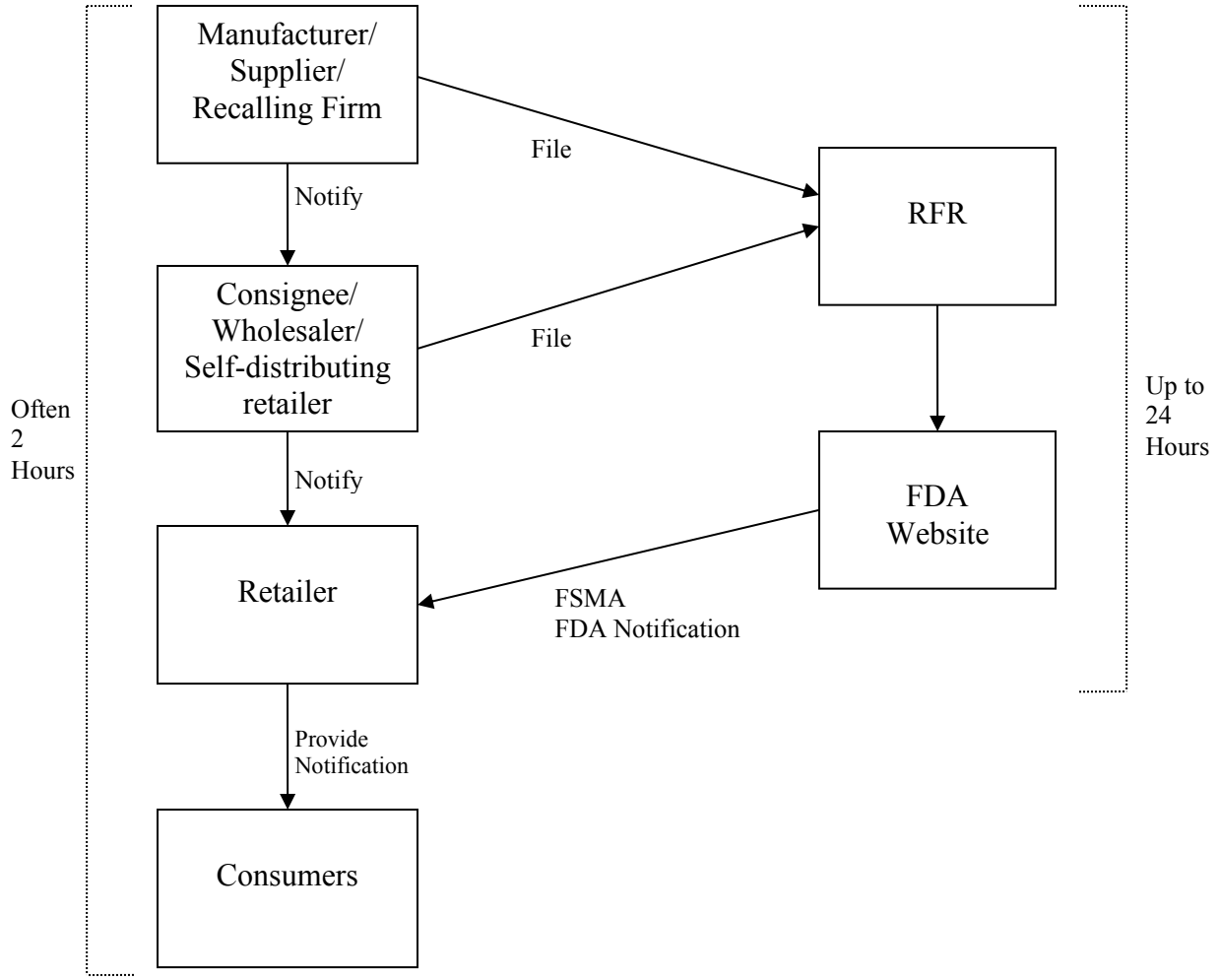
Retailers currently utilize the following modes of recall notifications for consumers: posting at or near register; posting at primary point of display; loyalty card or membership notifications via email, phone and mail; print-out at check-out; website posting; postings at kiosk(s) in store; and posting on a bulletin board or similarly informative area. As follows, FMI believes that the regulations should specify that a retailer shall "choose at least one" of the manners from the current list, although a retailer may utilize multiple manners or use a different manner of notification for different recalls, depending on the circumstances.

FMI members have used certain notification methods in circumstances where they were clearly advantageous over more traditional techniques such as posting a notice in a store. For instance, electronically contacting consumers who have purchased food via the Internet is often the best choice for purchases that occur over the Internet because the retailer knows exactly what the consumer purchased and has reliable information to contact them, and because those consumers may never see a posting in a store location. Loyalty card programs may also provide retailers with a highly effective tool in notifying consumers. A retailer reported to FMI that in one situation it sold only 19 packages of a recalled item, had loyalty card contact information

for 17 of the 19 purchasers and used the electronic method to achieve close to a 90% notification rate.

There are also cases in which the product may be removed during distribution prior to reaching the retail store. When product is on store shelves, retailers are very efficient at removing the product from sale, with most FMI members reporting that in the case of class I recalls, product is removed from sale within 2 hours of notification from the supplier. In order to protect public health, FMI believes that any regulatory requirements should neither slow down the removal of product from sale, nor prevent consumer communication of recalls in advance of official FDA posting. For example, if a grocery store has information on a recall in advance of the FDA notification, the store should not have to wait to start the consumer notification process on a voluntary basis.

Figure 1.



Consumer Notification

Regulations or guidance issued under §350f (H) should provide retailers with the flexibility to choose from several effective approaches in communicating recall information to consumers. The regulations should afford the opportunity for new ideas and modes for notification and not be so prescriptive as to limit innovation.

Key Facts to Include in Notifications

Providing consumer notification without delay is imperative. Retailers often are able to alert consumers about a recalled product before FDA has posted the information on their website, thus any regulations or guidance issued to implement § 350f(h) should be compatible with what the industry currently does and not require duplicative notifications. The required information for Class I recall notifications for consumers should include: product description, identification code(s), responsible party contact information and reason for recall. The aforementioned key facts provide consumers with useful, practical information for identifying specific recalled products. Retailers should be permitted to provide additional information at their discretion. FDA should not be prescriptive regarding the font type or size, format, wording or template of the notice. It is essential that retailers who notify consumers before FDA information is available not be required to "re-issue" their notice or change the content and format of the notification, unless information about the recall has changed.

Locations for posting

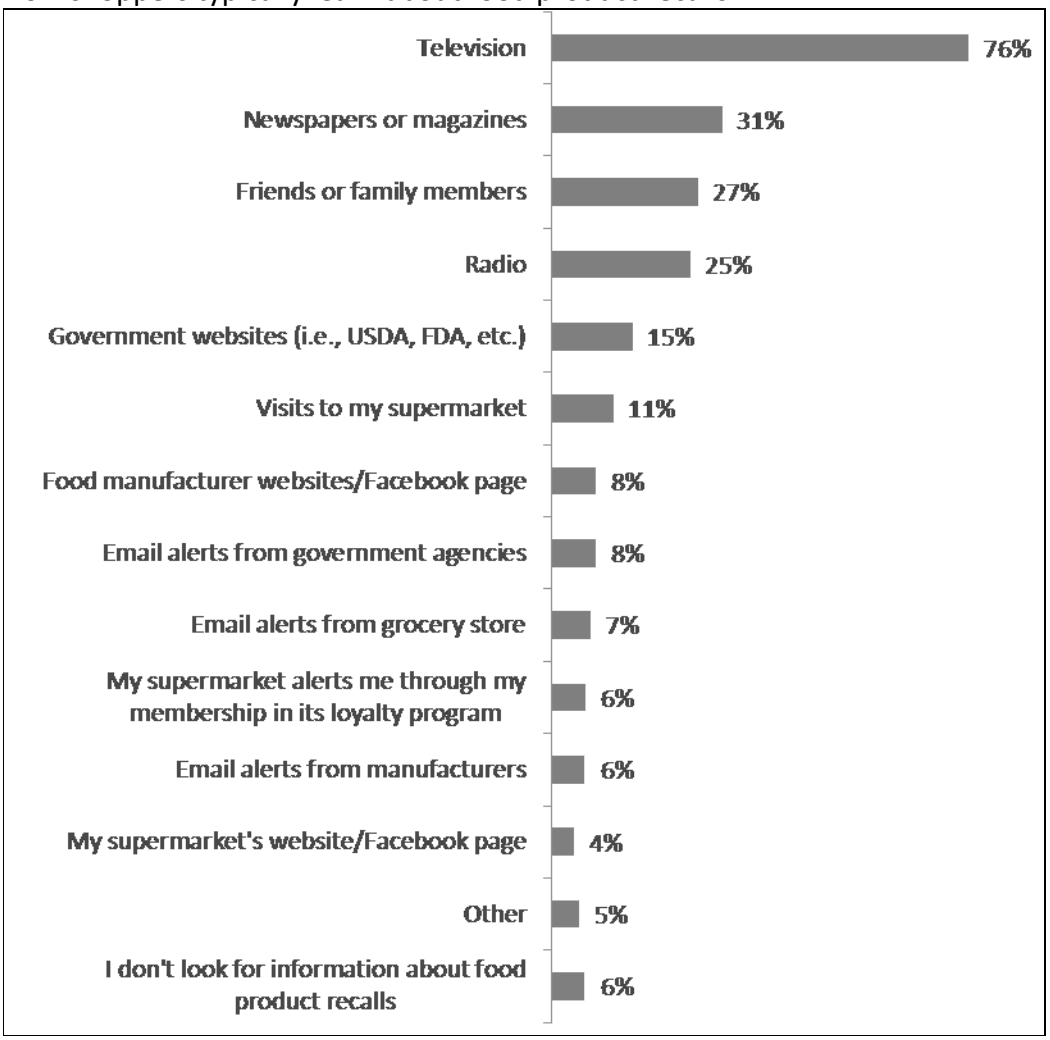
Locations and manners currently used by retailers to notify consumers about recalled product. Retailers should be able choose any one or a combination of manners/methods and locations. Since technology is rapidly advancing, FDA should provide flexibility in the regulation to allow for technology advances in the future.

1. Posting (physical, electronic) at or near register
2. Posting (physical, electronic) at primary point of display
3. Loyalty card/membership notification (email, phone, mail, other)
4. Print out at check-out (example: cash register receipt)
5. Website and social media
6. Kiosk in store
7. Posting on a bulletin board or similar information center
8. Service desk sign, notice, other
9. Other methods, locations and manners as agreed to by FDA

Consumer Preferences

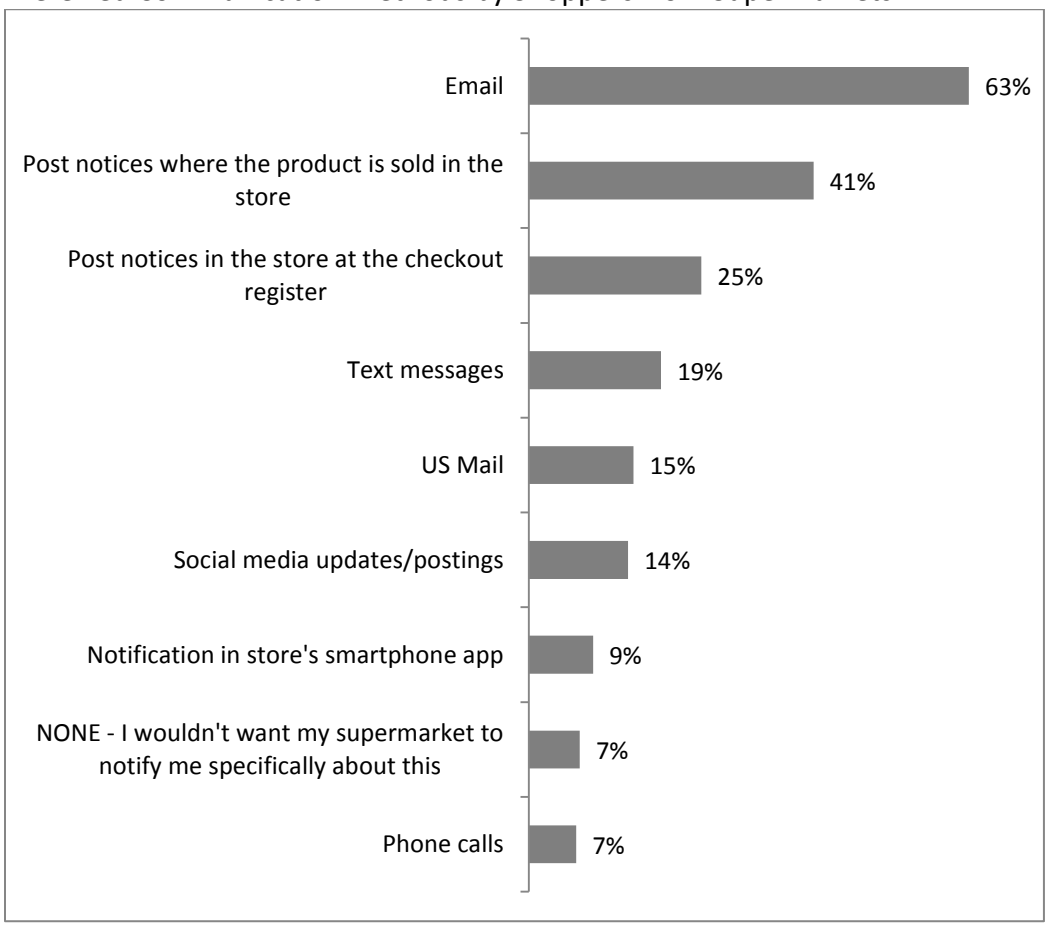
Each year, FMI surveys consumers about many different issues applicable to the retail industry. In this year's survey (2014), we included questions about recall notifications to obtain information regarding consumer preferences on how they currently receive information about recalls and would like to receive information about recalls from retailers.

Figure 2.
How shoppers typically learn about food product recalls



Source: FMI U.S. Shopper Trends, 2014. n=1059-2014.

Figure 3.
Preferred Communication Methods by Shoppers from Supermarkets



Source: FMI U.S. Shopper Trends, 2014. n=1059-2014.

As visible in figure 3, the preferred communication method is email. However, with rapidly changing technology, email may not be the preferred communication method in five or ten years. Only retail operations with shopper loyalty card programs currently have email addresses for customers. Approximately 50-60% of FMI member companies report having shopper loyalty card programs. Loyalty card programs can be a great way to contact customers in the case of a food product recall; however, having accurate contact information is necessary. Consumers do not always update their contact information with loyalty card programs after an email address or phone number change.

Also visible in figure 3, a variety of methods are preferred by consumers. Flexibility in posting is needed to reach consumers depending on the type of recall, the scope, the type of store and the customers. Consumer retail fatigue is another factor that is not fully understood.

Timing and Duration of Posting

Section 350f(h) specifies that recall information be displayed within 24 hours for 14 days. FDA must contemplate this timeframe in light of the various means of notification. For example, a consumer cannot be called on the phone about the same recall for 14 days; however, a retailer could post information on a website for that period of time or longer. When the retailer has notified consumers prior to an FDA posting, the 14 days should begin upon the first occurrence of a 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.

Recalls are frequently modified, expanded or clarified. How will a change to the product information impact the timing of the notification? When would the clock start? What about a product with a short shelf life?

The volume of recalls at any time in a grocery store for a 14 day period can be quite high. As specified in FSMA, displaying a one page notice on every reportable food for a two week period could be overwhelming and lead to consumer fatigue of notifications after a very short period of time.

FMI proposes that retailers have flexibility in communicating recalls to their customers and that the 14 day clock start with the first notification and be flexible depending on the communication method and the shelf life of the product.

FMI also suggests that FDA integrate an email alert system for all retail stores required to post notices.

Definition of "Grocery Store"

In today's marketplace a wide variety of retailers sell food items. Retail formats recognized by FMI where the sale of groceries is a primary business activity include:

- supermarkets;
- fresh formats, which are stores emphasizing perishables and generally market ethnic, natural or organic foods;
- superstores, which are supermarkets with extra services and specialty departments;

- warehouse stores, where the concentration is price appeal and items are often displayed in their original shipping cartons;
- wholesale club stores;
- supercenters, which offer almost equally wide varieties of both food and non-food merchandise;
- convenience stores and
- dollar stores.

Retailers are notified by their suppliers if they received affected product in the case of recalls. Within several hours of notification, retailers have either removed affected product from the shelves or have confirmed that the product they have is not part of the recall.

The Agency may also wish to examine regulations implementing the recordkeeping provisions of the Bioterrorism Act in crafting a definition of "grocery store" for purposes of § 350f(h). These regulations cover establishments with the primary function of selling food directly to consumers where the monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

Products not covered by the RFR

Some products sold by food retailers are not reported through the RFR. These include USDA inspected products, infant formula, dietary supplements and drugs and medical products. Retailers communicate these recalls with the same communication methods they currently use for FDA regulated food items.

FMI proposes that FDA allow flexibility in recall communications to permit retailers to use the same communication tools to communicate recalls in non-RFR products in order to maintain consistent consumer communications. For example, if a form is developed for point of sale notification recalls, FMI requests that the same form be made available (voluntarily) for use by retailers in the case of recalls with non-RFR products.

Summary

Food safety is the utmost priority for the supermarket industry and the exceptional record of grocers over the decades reflects this. Our commitment—and record on food safety—is reflected in the fact that consumers have confidence in the safety of food at their supermarkets. FMI supported the enactment of FSMA and has provided comments to FDA in the development of the proposed rules and policies. Regulations or guidance issued under §350f should provide retailers with the flexibility to choose from several effective approaches to communicate recall information as quickly and effectively as possible to consumers.

We greatly appreciate your consideration of these comments. Please do not hesitate to contact Stephanie Barnes at sbarnes@fmi.org or (202) 220-0614 if you have any questions.

Sincerely,

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