FOOD MARKETING INSTITUTE

July 6, 2011

Submitted Electronically

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

RE: Food and Drug Administration Food Safety Modernization Act: Focus on Compliance and Inspections.

Docket No. FDA–2011–N–0366

The Food Marketing Institute (FMI) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) request for comments on the Food Safety Modernization Act (FSMA): Focus on Compliance and Inspections.[1] FMI looks forward to working with FDA on this matter.

FMI is the national trade association that conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's members in the United States operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of $680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms, and independent supermarkets. Our international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

I. Introduction

Food safety is the utmost priority for the supermarket industry and the exceptional record of grocers over the decades reflects this. First and foremost, the supermarket industry cares about the customers it serves and is committed to getting foods to consumers in the safest and freshest

[1] 76 Fed. Reg. 30727 (May 26, 2011).

manner. Secondly, competition in the industry is fierce and supermarkets know that if they fail to provide consumers with fresh and wholesome foods they will not succeed in the marketplace. Food safety issues influence consumer purchasing decisions. In a 2009 FMI sponsored survey of consumers, 31 percent of shoppers stopped purchasing a variety of items either short-term or permanently as a result of food safety concerns.[2] The industry's dedication to food safety extends beyond store shelves. FMI continues its commitment to the work of the non-profit Partnership for Food Safety Education, a government-industry effort to educate consumers about what they can do to reduce risk of foodborne illness.

Our commitment—and record on food safety—is reflected in the fact that consumers have confidence in the safety of food at their supermarkets. Nine in ten shoppers trust their grocery stores to sell safe produce, canned and boxed goods, meat, poultry and fish and to provide safe food in general.[3]

These comments will focus on FDA's implementation of the consumer notification requirements of the FSMA (21 U.S.C. § 350f(h)).

II. Class I Recalls

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.

Regulations or guidance issued under §350f (H) should provide retailers with the flexibility of being able 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.

[2] Food Marketing Institute, 2009 U.S. Grocery Shopper Trends.
[3] Food Marketing Institute, 2011 U.S. Grocery Shopper Trends.

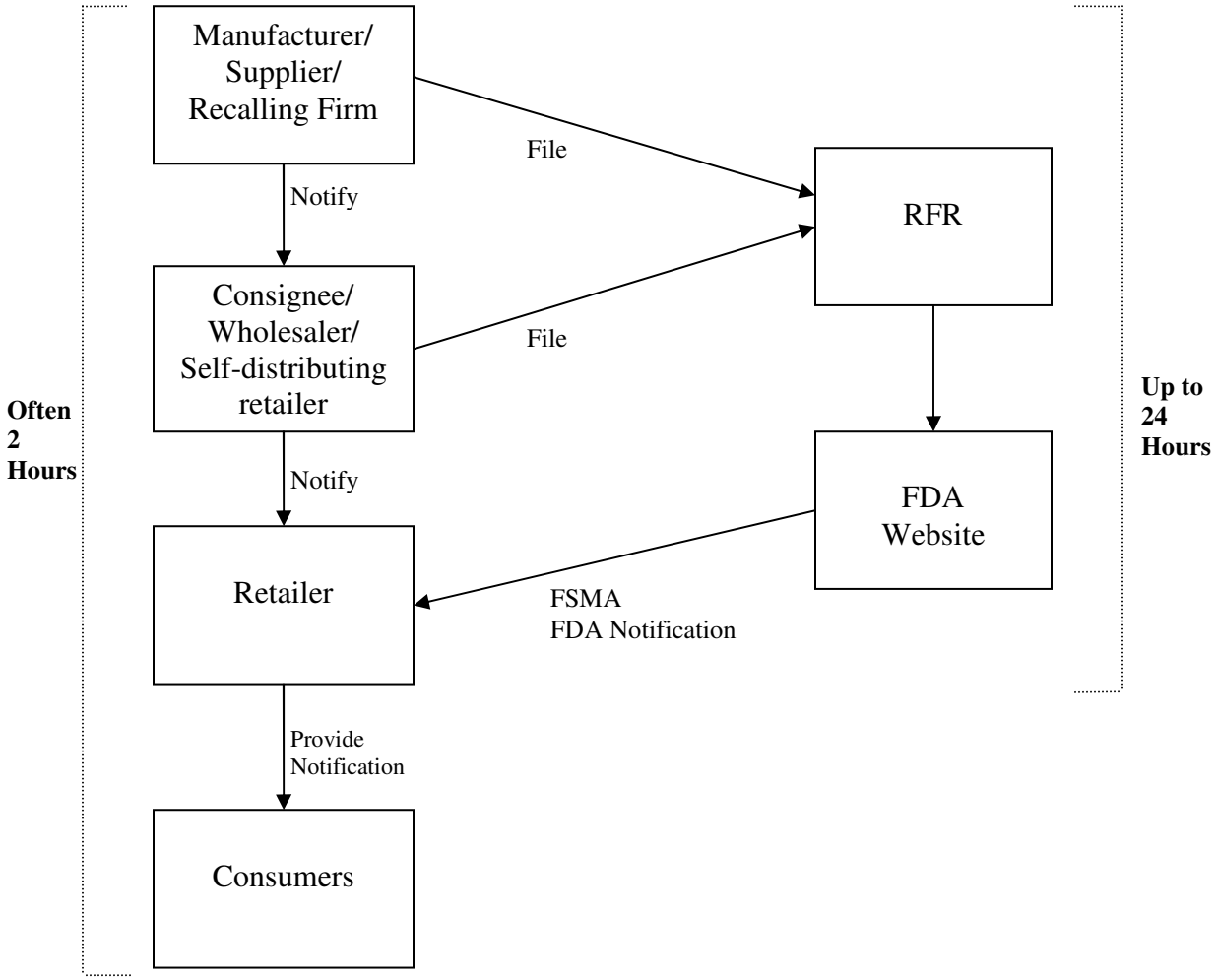
III. Current Industry Practices

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 simultaneously 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; Web site 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. Consideration should be given to several factors including the size of the recall, where the product was distributed (nationwide versus localized), the type of product, the target consumers, the shelf life of the product, the product's use as an ingredient in other foods, and other variables.

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.

Anatomy of a Recall



IV. Key Facts to Include

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 Web site, 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, 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.

V. Timing

Section 350f(h) specifies that recall information be displayed for 14 days. FDA must contemplate apply 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 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.

VI. 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; and,
- dollar stores.

The Agency may also wish to examine regulations implementing the recordkeeping provisions of the Bioterrorism Act[4] 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.[5]

FMI appreciates the opportunity to comment on these matters and looks forward to working with FDA on the implementation of § 350f(h) and other provisions of FSMA.

Sincerely,

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[4] P.L. 107-188.
[5] 21 C.F.R. § 1.327(e)(3).