



February 4, 2020

Dockets Management Staff (HFA305)
Food and Drug Administration (FDA)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-D-2343

Thank you for the opportunity to provide comments on the guidance documents published to support regulations promulgated to carry out the Food Safety Modernization Act (FSMA). We are pleased to submit comments on the newly available draft chapter 14 – Recall Plan.

We appreciate the work of FDA on the FSMA regulations and subsequent guidance documents to provide needed information for the industry to appropriately implement all of the respective FSMA regulations.

About FMI

As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. www.FMI.org

Role of Recalls in Food Safety Management

Recalls are typically seen as the final step of a food safety management plan to effectively and efficiently remove potentially harmful products from commerce and are necessary to utilize when product is in the hands of consumers. No company wants to issue a recall, but for many in the food industry, recalls are occurring far too often.

While it may be rare for any individual company to initiate a recall, retailers and wholesalers execute recalls on a regular basis due to the large number of SKUs they carry. Consumers are also familiar with recalls and know how they typically hear about recalls and how they would like to receive that information. Regulatory requirements and best practices indicate that all companies should have recall plans in place to minimize the impact of a recall and should test their recall communication systems on a regular basis to ensure a recall plan works as intended.

Definitions

In the guidance, definitions were used that are not in 21 CFR 117.3. We encourage the agency to be precise and consistent with definitions. Clear and easily understood language helps to avoid confusion and misinterpretation of guidance.

Notifications

Businesses are very effective at recall communications particularly entities at the end of the supply chain due to the number of recalls based on the variety and volume of product. For some supply chain partners, and for consumers, recalls are less frequent, and communications need to be more targeted depending on the circumstance. There are many ways that consumers receive food and increasingly, consumers are purchasing food directly from the source who might be the direct consignee or direct account. We know that consumers prefer certain types of communication and tend to prefer electronic communication. We also know that consumers experience recall fatigue and we want to make sure we keep recall communications effective and want to prevent the overuse of communications so that consumers stop paying attention to the messages. Privacy of information is also a concern in that customer information should be kept private and the communication between the food manufacturer/processor/grower/seller and the consumer should not be shared as part of the recall investigation to protect that privacy.

Information collected from *FMI US Grocery Shopper Trends, 2019* and *Food Retailing Industry Speaks, 2019* is provided below and shows how consumers learn about recalls and how consumers prefer to receive information about recalls. Television remains the top source of information about food recalls. However, digital communications methods in the form of email and text messages leads the way in how consumers prefer to hear about food recalls. Communication preferences vary generationally and regionally; therefore, there is not a one size fits all and retailers utilize multiple methods of communication depending on the circumstances to communicate recalls to their customers.

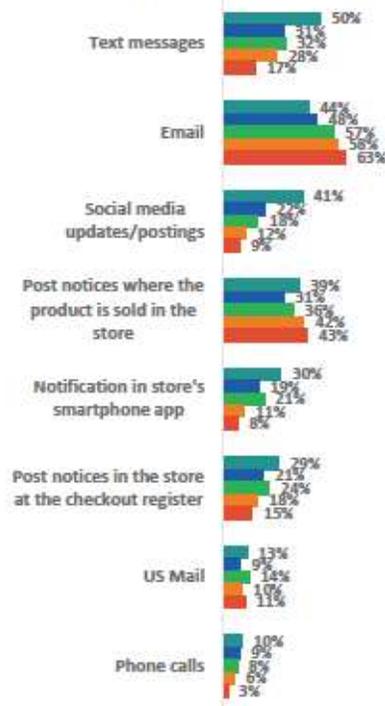
A multipronged approach to recall announcements is needed to reach across generations

Generational differences in media consumption dictate the need to share information about food safety recalls through both traditional and newer media as well as through official channels and word of mouth (see Chart 3.13). But even within a single generation, Gen Z, there is a desire for a multi-channel strategy: the average Gen Z shopper learns about recalls from 2.6 sources (vs. 2.2 for shoppers overall) and if given a choice would like to hear from 2.5 sources (vs. 2.0 overall). Even among Gen Z, nearly half still learn about recalls the old-fashioned way – from TV.

CHART 3.13: HOW CONSUMERS DO LEARN ABOUT PRODUCT RECALLS



CHART 3.14: HOW CONSUMERS PREFER TO LEARN ABOUT PRODUCT RECALLS



Source: FMI U.S. Grocery Shopper Trends, 2019. Q: "From which of the following sources do you typically hear about food product recalls or government advisory messages about products? [Select all that apply]" Q: "Food recalls and government advisory messages regarding food safety are often publicized through notices in food stores near the shelf where the unsafe product was sold. Imagine that in addition to that, you could sign up for food safety alerts from your supermarket about food recalls and government advisory messages about food safety that affect products you specifically may have purchased recently. If you had your choice, how would you prefer to receive these food safety alerts? [Select all that apply]" Both charts: Gen Z n=106, Millennials n=323, Gen X n=473, Boomers n=568, Mature n=113.

Recalls

SEEKING MAXIMUM REACH FOR URGENT MESSAGES

Food recalls and government advisory messages regarding food safety require highly effective communication strategies. The vast majority of food retailers (94%) communicate these important messages to their shoppers, and they often utilize a variety of methods to gain maximum exposure. See Detailed Table 17.

- **Shelf Notices:** The most common method to communicate these messages is posting notices where the product is sold in store (83%).
- **Front-End Notices:** Another in-store approach that some food retailers employ is posting notices at the checkout counter (26%).
- **Electronic Alerts:** Many food retailers use technology-driven forms of communication such as email (46%), social media (40%), text messages (4%) or notification in a store's smartphone app (4%).
- **Other Communications:** Some retailers also utilize more traditional methods of communication for urgent messages, such as phone calls (24%) or even U.S. mail (2%).

TABLE 17 COMMUNICATION OF FOOD SAFETY MESSAGES

Q8A: HOW DOES YOUR ORGANIZATION COMMUNICATE FOOD RECALL AND GOVERNMENT ADVISORY MESSAGES REGARDING FOOD SAFETY FOR UNSAFE PRODUCTS TO YOUR SHOPPERS? CHECK ALL THAT APPLY.

	ALL (n=94)	Number of stores operated		
		1-10 (n=51)	11-100 (n=23)	>100 (n=20)
POST NOTICES WHERE THE PRODUCT IS SOLD IN THE STORE	83%	88%	70%	85
EMAIL	46%	39%	52%	55
SOCIAL MEDIA	40%	47%	17%	50
POST NOTICES IN THE STORE AT THE CHECKOUT REGISTER	26%	27%	26%	20
PHONE CALLS	24%	24%	13%	40
TEXT MESSAGES	4%	4%	--	10
NOTIFICATION IN STORE'S SMARTPHONE APP	4%	4%	4%	5
US MAIL	2%	--	--	10
NONE OF THE ABOVE	6%	6%	13%	--

Source: Food Retailing Industry Speaks, 2019

Disposition of Food

For most recalls, the disposition of the product is unknown at the time of the initial recall notification and the jurisdiction has significant input over the disposition instructions of the recalled product. There is some planning that can take place, but flexibility is needed because plans often change quickly, and product disposition may vary depending on the food and the hazard. More importantly, a system is needed to separate segregated product that is on hold from recalled product so that it is not mistaken with acceptable lots and accidentally sold.

Procedures for Notifying FDA

We appreciate the clarification from the FDA on the RFR and the FDA Recall coordinator and agree that that information should be identified in advance of a recall.

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.

Industry Solutions

The food industry developed Rapid Recall Express which is a downloadable fillable form to standardize recall notifications from suppliers to retailers and wholesalers. This is free and the information aligns with RFR requirements to allow for complete information sharing.

https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=689&language=en-US&PortalId=0&TabId=134

We appreciate the opportunity to comment on this guidance document. Please feel free to contact me should you have questions about our comments.

Sincerely,



Hilary Thesmar, PhD, RD, CFS
Chief Food and Product Safety Officer and SVP Food Safety