CENTER FOR
Science IN THE
Public Interest
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June 25, 2019

Docket's Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Initiation of Voluntary Recalls Draft Guidance for Industry and Food and Drug Administration Staff; Docket No. FDA-2018-D-2074

To whom it may concern,

CSPI appreciates the opportunity to comment on the Food and Drug Administration (FDA)'s draft guidance titled *Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C; Guidance for Industry and FDA Staff.*[1] The draft guidance is an important step that will help facilitate prompt removal of recalled products from food supplied to restaurants, food service, and retail to protect consumer health.

We suggest that the draft guidance could be improved by clearly outlining the steps required for communication between the recalling firm and retail consignee.[2,3] In particular, we encourage the agency to advise industry on appropriate procedures for in-store notification about food recalls for consumer awareness.

To increase transparency and improve the efficiency of recalls, the guidance should adopt clear advice on specific measures for in-store notification of recalled food. Currently, the draft guidance states only that a firm's written recall procedures should include, "when appropriate, notifying the public about a product that presents a health hazard."[4] In February 2019, the agency also separately published guidance to industry regarding the use, content, and circumstances for issuance of public warnings and public notification of recalls under federal regulations.[5] However, while that guidance describes distribution of the public warnings to the press or via posting on a business or FDA webpage, there is no discussion of how consumer-targeted information will be conveyed through the supply chain to consumers.

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[1] U.S. Food and Drug Administration. *Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C; Guidance for Industry and FDA Staff* . Rockville, MD: FDA; April 2019. Accessed at <https://www.fda.gov/media/123664/download> [Hereinafter: The Draft Guidance]

[2] In the draft guidance, the agency uses the term "recalling firm" to refer to "the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled." The Draft Guidance, *see supra*, footnote 1.

[3] In the draft guidance, the agency uses the term "consignee" to refer to "anyone who received, purchased, or used the product being recalled." The Draft Guidance, *see supra*, footnote 1.

[4] U.S. Food and Drug Administration. *Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C; Guidance for Industry and FDA Staff.* Rockville, MD: FDA; February 2019. Accessed at <https://www.fda.gov/media/110457/download>

[5] *Ibid.*

Section 211 of the Food Safety Modernization Act (FSMA), which was signed into law on January 4, 2011, was intended to improve recall communication to consumers by requiring the FDA to create and post online one-page summaries of information related to product recalls.[6] Section 211 requires the grocery stores that have sold recalled products to promptly print and post these one-page summaries in a conspicuous location in the store, providing a clear means of communicating recall information directly to consumers likely to have been affected.

A survey of 32 major grocery store chains conducted by CSPI in 2016 found that all but one posted some form of in-store recall notification, but the method of posting varied, with many chains relying on posting at a central location rather than on the shelf where the product was sold.[7] The effectiveness of such programs has not been evaluated, leaving open the potential for variability in terms of the content, consistency, and informativeness of these messages.

Many grocery stores also maintain consumer contact and purchase information, gathered through store loyalty programs. This information can be used to provide recall information directly to the shoppers who may have purchased recalled products. The 2016 CSPI grocery store survey found that eight out of the nine stores that maintained customer loyalty programs made use of their programs to some extent to communicate recall information, including by telephone, email, a physical letter to the customer's address, and telephone text messages.[8]

We encourage the agency to incorporate discussion of these processes into its guidance, to help ensure that consumer-targeted communications are included in each firm's recall plan and clearly communicated throughout the supply chain.

Specifically, we ask that the guidance include the following:

Line 185:

- Providing instructions on consumer notification. The recall notification letter should include, where appropriate, instructions regarding methods for notifying consumers of the recall. This may include examples of consumer-targeted information, such a draft text for letters and emails, printable shelf tags, a copy of the recalling firm's public notice, or other forms of consumer-targeted messaging.

CSPI urges FDA to take this specific step to ensure that an efficient and effective food-recall process includes clear communications to consumers. Thank you for your consideration.

Sincerely,
Center for Science in the Public Interest

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[6] FDA Food Safety Modernization Act of 2010 ("FSMA"), Pub. L. No. 111–353, 124 Stat. 3885 (2011) (codified in sections of 21 U.S.C. § 301 *et seq*., as amended).
[7] Center for Science in the Public Interest (CSPI). Building a Food Recall System That Really Protects Consumers Implicated in Salmonella Outbreak, August 22, 2016. Accessed at: <https://cspinet.org/sites/default/files/attachment/Building%20a%20Food%20Recall%20System%202016.pdf>
[8] *Ibid.*