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# FDA Releases Two New FSMA-Related Documents

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Food, Drugs, and Devices

FDA has been active on the FSMA front, and released two new documents over the last few days. Last Friday, October 4, the Agency issued a draft guidance regarding establishing and implementing a recall plan under 21 CFR 117.139, the provision of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PC Human Food) rule that requires facilities to establish a written recall plan for food that requires a preventive control. This draft guidance is Chapter 14 of FDA's "Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food." Today, FDA released a list of records required by the Foreign Supplier Verification Program (FSVP) regulation. Both documents are summarized briefly below.

## FDA Draft Guidance on Developing a Recall Plan

FDA's draft guidance provides recommendations in the key subject areas described below that industry may choose to use when developing their recall plans. The draft guidance also lists a number of resources intended to assist firms in establishing and implementing recall plans, including other guidance documents, FDA's Regulatory Procedures Manual, and FDA's index of model press releases.

### Direct Notification to Direct Consignees

FDA recommends that recall plans describe a written recall communication for notifying direct consignees about the recall. This communication should provide direct consignees with the information that they need to conduct the recall, and it can be made through any effective means, including using letters, emails, or text messages. Where the recall plan provides for communication by phone, FDA recommends that the recalling firm document the phone communication in an appropriate manner.

The recall plan should proactively address questions that direct consignees are likely to have by describing the components of the written recall communication. For example, the recall plan should describe the following information to be included in the written recall communication:

- The identity of the food that is subject to the recall. This could include, for example, product name, size, lot number(s), code(s), and expiration dates. FDA also recommends that the recall plan specify that the communication will include a product label;
- The reason for the recall, including the health hazard(s) involved;

- The depth of the recall, including how the written communication will specify the depth to which the recall will extend (e.g., wholesale, retail, or consumer level);
- Instructions for what consignees should do with the recalled food. For example, the recall plan could explain how the written recall communication will instruct consignees to remove food from sale, cease distribution of food, or notify their customers about the recall, as appropriate. Where the recall plan calls for consignees to notify their customers, FDA recommends that the consignees send their customers a copy of the written recall communication; and
- Information about how consignees should communicate with the recalling firm.

FDA also emphasizes that recall plans should include model written communications that can be tailored to the circumstances relevant to a particular recall.

**Notification to the Public**

Recall plans should include procedures for notifying the public about any hazard presented by the food when appropriate to protect public health. Recall plans should describe the criteria for determining whether a public warning is appropriate, which should be informed by FDA's Public Warning and Notification of Recalls guidance. Furthermore, FDA recommends that recall plans describe the steps to be taken when a recalling firm determines that a public warning is appropriate. Lastly, FDA recommends that recall plans include one or more model press releases, which can include the model press releases provided on FDA's Industry Guidance for Recalls web page or model press releases prepared by the recalling firm.

**Effectiveness Checks**

FDA recommends that recall plans include procedures for conducting effectiveness checks to verify that all consignees at the specified recall depth have received notification and taken appropriate action. FDA recommends that the recall plan include model documents that can be used for conducting an effectiveness check, including a model effectiveness check letter.

**Disposition of Recalled Food**

FDA recommends that the recall plan describe the potential options for disposing of recalled food and the facts that should be considered in determining the appropriate disposition in a particular case.

**Assignment of Responsibilities**

Recall plans should assign responsibility for performing the relevant procedures. Particularly, recall plans should identify members (and alternate members) of a recall management team, headed by a recall coordinator. For each member, the recall plan should include the member's name and title, contact information, including an after-hours telephone number, and responsibilities. The recall plan should also identify the person who is responsible for deciding to initiate a recall.

**Procedures for Notifying FDA**

FDA recommends that recall plans include procedures for complying with the requirement to submit information about "reportable foods" to FDA's Reportable Food Registry (RFR). Consistent with prior industry guidance documents, recalling firms should also notify the

appropriate FDA Recall Coordinator as soon as a decision is made that a recall is appropriate and prior to the issuance of press releases or written notification to customers.

## FDA List of Records Required Under FSVP

The FSVP final rule requires covered importers to develop, implement, and maintain an FSVP to verify that the food they import into the U.S. has been produced in a manner compliant with applicable U.S. food safety requirements. FDA created the list of records released today to help importers more readily determine the records they should develop and maintain and which records an FDA investigator will review during an FSVP inspection. The list seems likely to be a handy reference tool for importers, as it is organized based on sections of the FSVP regulation to help importers readily determine the required records for the sections that apply to them, and is presented in checklist format.

Covington continues to monitor FDA developments regarding recalls and FSMA implementation, and will keep our clients and contacts updated. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food and Drug practice:


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|---|---|---|
| **Miriam Guggenheim** | +1 202 662 5235 | mguggenheim@cov.com |
| **Jessica O'Connell** | +1 202 662 5180 | jpoconnell@cov.com |
| **Jeannie Perron** | +1 202 662 5687 | jperron@cov.com |
| **Grant Dixon** | +1 202 662 5914 | gdixon@cov.com |