Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 14: Recall Plan

Table of Contents

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

14.1 Purpose of This Chapter

The purpose of this chapter is to help you establish and implement a written recall plan as required by 21 CFR 117.139. Although the written recall plan is a type of preventive control (see 21 CFR 117.135(c)(5)), the PCHF requirements specify that the written recall plan is not subject to the preventive control management components specified in 21 CFR 117.140 (i.e., monitoring, corrective actions and corrections, and verification.) (See 21 CFR 117.140(c).) Therefore, this chapter does not discuss the application of preventive control management components to your written recall plan.

14.2 Terms Used in This Chapter

14.2.1 Definitions Established in 21 CFR 117.3

See section III.A in the Introduction of this guidance for a glossary of terms that are used in this guidance and are defined in 21 CFR 117.3.

14.2.2 Other Terms That FDA Uses in This Chapter

Section III.B in the Introduction of this guidance includes a glossary of terms that are used in this guidance but are not defined in 21 CFR 117.3. At this time, that glossary does not include all terms that are used in this chapter. See Table 14-1 for additional terms that we use in this chapter. We intend to include these terms in the glossary in the Introduction of this guidance when we update the Introduction. When we do so, we will delete Table 14-1 from this chapter.

Table 14-1 Terms Used in this Chapter

Term	What the Term Means
Consignee	The term defined in 21 CFR part 7 to mean anyone who received, purchased, or used the product being recalled. (See 21 CFR 7.3(m).)
Direct account	The term used in FDA's recall policy in 21 CFR part 7, subpart C to mean the first consignee in a recalling firm's distribution chain.
Direct consignee	The term used in 21 CFR 117.139 to mean the first consignee in a recalling firm's distribution chain. Part 117 uses the term "direct consignee" to have the same meaning as "direct account" in 21 CFR part 7, subpart C.
Recall	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. Recall does not include a market withdrawal or a stock recovery. (See 21 CFR 7.3(g).)
Recall classification	The numerical designation (i.e., I, II, or III) assigned by FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. (1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (21 CFR 7.3(m)(1)); (2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote (21 CFR 7.3(m)(2)); and (3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause illness or injury (21 CFR 7.3(m)(3)). (See 21 CFR 7.3(m).)

14.3 Overview of the Requirements for a Recall Plan

The PCHF requirements specify that you must establish a written recall plan for food that requires a preventive control (21 CFR 117.139(a)). The PCHF requirements also specify that the written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility (21 CFR 117.139(b)):

- Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food (21 CFR 117.139(b)(1));
- Notify the public about any hazard presented by the food when appropriate to protect public health (21 CFR 117.139(b)(2));
- Conduct effectiveness checks to verify that the recall is carried out (21 CFR 117.139(b)(3)); and
- Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food (21 CFR 117.139(b)(4)).

14.4 Resources That Can Help You Prepare a Recall Plan

The following resources are available to help you prepare a recall plan:

- Our general guidance on policy, procedures, and industry responsibilities regarding recalls in subpart C of 21 CFR part 7 (21 CFR 7.40 through 7.59; FDA's recall guidance);

- Our guidances for industry, available from our Web site entitled "Industry Guidance for Recalls: Information on Recalls of FDA Regulated Products" (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls):

    - "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C. Guidance for Industry and FDA Staff. Draft Guidance" (FDA, 2019a; the draft initiation of voluntary recalls guidance)

    - "Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C. Guidance for Industry and FDA Staff" (FDA, 2019c; FDA's public warning and notification guidance);

    - "Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls Guidance for Industry and FDA Staff. Draft Guidance" (FDA, 2018b);

    - "Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff" (FDA, 2018c);

    - "Guidance for Industry: Product Recalls, Including Removals and Corrections" (FDA, 2014; the industry recall guidance); and

- Index of Model Press Releases (available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls); and

- Chapter 7 of FDA's Regulatory Procedures Manual (FDA, 2019d), including:

    - Exhibit 7-1 – Model Effectiveness Check Letter (Industry) (FDA, 2019e);

    - Exhibit 7-2 – Model Effectiveness Check Response Format (Industry) (FDA, 2019f);

    - Exhibit 7-3 – Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry) (FDA, 2019g);

    - Exhibit 7-4 - Model Recall Letter (Generic, All Centers) (FDA, 2019h); and

    - Exhibit 7-5 - Model Recall Response Form (FDA, 2019i).

Throughout this chapter we refer you to specific recommendations in these guidances and our Regulatory Procedures Manual.

14.5 Procedures That Describe the Steps to be Taken to Perform Recall Actions

The goal of procedures that describe the steps to be taken to perform recall actions is to help you to act promptly when you determine that a recall is warranted by following your plan.

14.5.1 Notify Direct Consignees

We recommend that your recall plan describe a written recall communication that you will use to notify your direct consignees about the recall. (See 21 CFR 7.49.) A written recall communication should provide direct consignees with the specific information that they need to conduct the recall and be a reference for direct consignees to consult on an ongoing basis throughout the recall procedure.

A written recall communication can be through any effective means (e.g., through letters, email, telefax, or text messaging). If your recall plan specifies that you will contact your direct consignees by phone, we recommend that your recall plan also specify that you will confirm that phone communication in writing (e.g., follow up the phone call with a written communication such as a letter, email, telefax, or text message) and/or document your phone communication in an appropriate manner. (See 21 CFR 7.49(b)).

As discussed in sections 14.5.1.1 through 14.5.1.6, we recommend that your recall plan:

- Proactively address the questions that direct consignees are likely to have by describing in detail the components to be included in your written recall communication (e.g., identify the food, explain the reason for the recall, specify the depth of the recall, provide instructions for what direct consignees should do with the food, and make it easy for recipients to communicate with you); and

- Include model letters that you would modify based on the specific situation that warranted the recall. See our recommendation in section 14.5.1.6 for you to include a model recall letter(s) in your recall plan.

14.5.1.1 Identify the food

We recommend that your recall plan describe how your written recall communication will clearly provide pertinent, descriptive information to enable accurate and immediate identification of the food being recalled (e.g., identify the product name, size, lot number(s), code(s), expiration dates, and any other pertinent descriptive information (such as UPC codes and shipping dates)). (See the Model Recall Letter (FDA, 2019h) and 21 CFR 7.49(c)(1)(ii)). To help direct consignees identify the recalled product, we recommend that your plan specify that the written recall communication will include a product label. (See the Model Recall Letter (FDA, 2019h).)

14.5.1.2 Explain the reason for the recall

We recommend that your recall plan describe the information that your written recall communication will use to concisely explain the reason for the recall and the health hazard(s) involved. (See the Model Recall Letter (FDA, 2019h) and 21 CFR 7.49(c)(1)(iii)).

14.5.1.3 Specify the depth of the recall

We recommend that your recall plan describe how your written recall communication will specify the depth to which the recall will extend (e.g., wholesale, retail, or consumer level). (See the Model Recall Letter (FDA, 2019h) and 21 CFR 7.42(b)(1)). If you have reason to believe that your direct consignees have further distributed the food (e.g., if your direct consignees include distributors who would in turn sell to retail food establishments), then your recall plan should specify that the written recall communication will instruct your direct consignees to in turn notify their customers about the recall. (See the Model Recall Letter (FDA, 2019h), 21 CFR 7.49(a)(3), and section 14.5.1.4 of this chapter).

14.5.1.4 Provide instructions for what consignees should do with respect to the recalled food

We recommend that your recall plan describe how your written recall communication will provide specific instructions on what consignees who receive the recall communication should do with respect to the recalled food. (See the Model Recall Letter (FDA, 2019h) and 21 CFR 7.49(c)(1)(iv)). For example, your recall plan could describe how your written recall communication will instruct consignees to:

- Remove food from sale;
- Cease distribution of food;
- Notify their customers (e.g., to the wholesale or retail level as appropriate) about the recall;
- Return food to you or to another location specified in the recall communication; and/or
- Explain what to do with any food that is not returned (e.g., whether and how to destroy the food).

If your recall plan will describe how your written recall communication will ask direct consignees to notify their customers, we recommend that it specify that recipients of the written recall communication do so by sending a copy of the written recall communication to their customers. Alternatively, your recall plan could specify that you give your direct consignees a modified recall communication to use for this purpose, provided that the modified recall communication includes all pertinent information (e.g., accurate and complete information about the food, the reason for the recall, the depth of the recall, instructions for what to do with the food, and an easy way for recipients to communicate with you).

14.5.1.5 Make it easy for recipients to communicate with you

We recommend that your recall plan describe how your written recall communication will inform recipients (i.e., any consignees that receive a recall communication) about any information that they should send you (e.g., whether the recipient has any of the applicable food), explain how recipients will do so, and make it easy for recipients to do so. For example, your recall plan could specify that your written communication will provide recipients with a toll-free phone number where they can call you, or a response form that they can send you (e.g., using a

postage-paid, self-addressed postcard or envelope, an email, or an online submission). (See the Model Recall Letter (FDA, 2019h) and 21 CFR 7.49(c)(1)(v)). If your recall plan will specify that you will use a response form, we recommend that the form include all instructions from your recall letter to make it easy for recipients to indicate that they followed each instruction. See our Web site entitled "Industry Guidance for Recalls: Information on Recalls of FDA Regulated Products" (available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls) for access to an example of a model recall response form (FDA, 2019i). Your plan should also include procedures to follow up with consignees who do not respond to your written recall communication.

14.5.1.6 Include model letters in your recall plan

We recommend that your recall plan include one or more model recall letters that you would modify based on the specific situation that warranted the recall and use as your written recall communication. Including model recall letters in your recall plan will facilitate the rapid preparation of such letters when needed and can prompt you to include all the information described in your recall plan (e.g., identify the food, explain the reason for the recall, specify the depth of the recall, provide instructions for what consignees should do with the food, and make it easy for recipients to communicate with you). See the Model Recall Letter (FDA, 2019h).

14.5.2 Notify the Public When Appropriate

Your recall plan must include procedures to notify the public about any hazard presented by the food when appropriate to protect public health (See 21 CFR 117.139(b)(2).) For example, public warnings are used to alert the public that a food being recalled presents a serious hazard to health. A public warning is reserved for urgent situations where other means of preventing use of the recalled product appear inadequate. Depending on the circumstances, a public warning is issued through the general news media or through specialized news media (such as professional or trade press, or communications to medical professionals). (See 21 CFR 7.42(b)(2).)

FDA provides public access to information on recalls by posting a listing of recalls according to their classification in the FDA Enforcement Report, whether they were requested by FDA or firm-initiated, and the specific action taken by the recalling firm. (See 21 CFR 7.50.) The FDA Enforcement Report is designed to provide a public listing of products in the marketplace that are being recalled. Unlike with public warnings, the recalls listed in the FDA Enforcement Report are not limited to urgent situations that present serious hazards to health and are not necessarily used to alert the public about the risk or hazard of a product under recall.

Currently, FDA also provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products on its Web page entitled "Recalls, Market Withdrawals, & Safety Alerts" (available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts). When FDA posts removal or correction information that has been publicized by a firm, we do so as a public service and it does not necessarily mean that the situation is urgent or that the product presents a serious hazard to health, such that it would be considered a "public warning" as the term is used in this chapter.

Your recall plan should describe your criteria for determining whether a public warning is appropriate. See the public warning and notification guidance (FDA, 2019c) for

recommendations regarding the circumstances for issuance of public warnings, including a discussion of the parties responsible for issuing a public warning.

Your recall plan also should describe the steps you will take when you determine that a public warning is appropriate. See the public warning and notification guidance for recommendations regarding the use, content, and distribution of public warnings, including a discussion of what information should be included in a public warning. (See 21 CFR 7.42(b)(2) and the public warning and notification guidance (FDA, 2019c).)

See model press releases for recalls related to food allergens and some pathogens (e.g., *Listeria monocytogenes*, *Clostridium botulinum*, *Salmonella*, and *E. coli* O157:H7), which are available from the Index of Model Press Releases on our Web site entitled "Industry Guidance for Recalls: Information on Recalls of FDA Regulated Products" (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls). We recommend that your recall plan include one or more of these model press releases (or other model press releases that you prepare), which you would modify based on the specific situation that warranted the recall. Including model recall press releases in your recall plan will facilitate the rapid preparation of such press releases when needed.

14.5.3 Conduct an Effectiveness Check

The purpose of an effectiveness check is to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action. (See 21 CFR 7.42(b)(3).) See the Index of Generic Model Letter Exhibits, in the FDA Regulatory Procedures Manual available from our Web site entitled "Industry Guidance for Recalls: Information on Recalls of FDA Regulated Products" (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls), for model documents (i.e., an Effectiveness Check Letter (FDA, 2019e), an Effectiveness Check Response Format (FDA, 2019f), and an Effectiveness Check Questionnaire for Telephone or Personal Visits (FDA, 2019g)) that you can use to conduct an effectiveness check. We recommend that your recall plan include one or more of these model documents, which you would modify based on the specific situation that warranted the recall. Including such model documents in your recall plan will facilitate the rapid preparation of such documents when needed.

14.5.4 Decide What to Do with the Recalled Food

We recommend that your recall plan describe the options that you will consider to appropriately dispose of recalled food (e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food) and the factors that you will use to determine the appropriate disposition of recalled food.

14.6 Procedures in Which You Assign Responsibility to Perform Recall Actions

In the procedures in your recall plan, you must assign responsibility for taking the steps to notify the direct consignees, notify the public, conduct effectiveness checks, and appropriately dispose of recalled food. (See 21 CFR 117.139(b).) The goal of such procedures is to save time during a

recall and help you to clearly communicate responsibilities to applicable managers and staff so that they can act as soon as the decision to conduct a recall is made.

We recommend that the procedures in your recall plan:

- Identify members (and alternate members[2]) of a recall management team, headed by a recall coordinator. The members (and alternate members) assigned to the recall management team could include, as applicable to your facility, those with responsibilities for distribution, production and quality assurance, consumer affairs, accounting, legal counsel, public relations, technical, marketing, and regional sales managers and staffs as shown in Table 14-2 (New Zealand Ministry of Agriculture and Forestry, 2012).

- Provide the following information about each member (and alternate member) of your recall management team:

    - Name and job position/title;

    - Business phone number (including cell phone number when applicable) and email address;

    - After-hours phone number (e.g., home or cell phone number); and

    - Responsibilities; and

- Specify who is responsible for the decision to conduct a recall.

Table 14-2 Examples of Some Roles and Responsibilities for Members of a Recall Management Team*

Role	Responsibility
Recall coordinator	Coordinate and document all recall activities
Distribution	Stop distribution and arrange for return of recalled food; prepare inventory and distribution status of affected food
Production and quality assurance	Prepare batch identification; stop production of food if related to the problem; investigate the cause of the problem and check records to determine whether other product lots should also be recalled
Consumer affairs	Prepare response to consumers; answer consumer inquiries

[2] The alternate members would replace team members who are not available when the facility is considering or implementing a recall.

Role	Responsibility
Public relations	Handle press release; manage media contacts
Marketing	Notify sales managers and brokers; arrange for pick-up at retail levels
Regional sales manager	Help contact customers; assist in product pick-up as needed

*Adapted from Recall Guidance Material available from the New Zealand Ministry of Agriculture and Forestry (New Zealand Ministry of Agriculture and Forestry, 2012).

14.7 Procedures for Notifying FDA

14.7.1 Procedures for Notifying FDA About a Reportable Food

Section 417 of the FD&C Act (21 U.S.C. 350f) requires FDA to establish a Reportable Food Registry (RFR). A ''reportable food'' is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals (Section 417(a)(2) of the FD&C Act). Under section 417(d)(1) of the FD&C Act, food firms that are ''responsible parties'' as defined in the statute are required to notify FDA electronically with certain information within 24 hours of determining that a food they manufactured, processed, packed, or held is a reportable food. We have issued guidance regarding the RFR (FDA, 2009 and FDA, 2010). That guidance includes examples of circumstances under which food might be reportable.

We recommend that your recall plan include any procedures you have to comply with the RFR, or a cross-reference to such procedures, so that the procedures will be readily available to your recall management team. Doing so may save time, which is critical during a recall.

14.7.2 Procedures for Notifying the Appropriate FDA Recall Coordinator

The industry recall guidance recommends that you 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 or written notification to customers (FDA, 2014). The industry recall guidance also provides our recommendations for what to send to the appropriate FDA Recall Coordinator about your recall. In addition, the draft initiation of voluntary recalls guidance encourages firms to consult with FDA while its own investigation is ongoing if the firm has questions about its examination of a product problem (FDA, 2019a). See "ORA Recall Coordinators" for a current list of FDA Recall Coordinators (FDA, 2019b).

We recommend that your recall plan include the guidances and exhibits listed in section 14.4 so that they will be readily available to your recall management team.

14.8 References

FDA, 2009. "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry As Established by the Food and Drug Administration Amendments Act of 2007," (https://www.fda.gov/FoodGuidances)

FDA, 2010. "Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry As Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2)," (https://www.fda.gov/FoodGuidances)

FDA, 2014. "Guidance for Industry: Product Recalls, Including Removals and Corrections," (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2018a. Index of Model Press Releases," (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2018b. "Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls Guidance for Industry and FDA Staff. Draft Guidance," (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2018c. "Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff," (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2019a. "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C. Guidance for Industry and FDA Staff. Draft Guidance," (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2019b. Office of Regulatory Affairs (ORA) Recall Coordinators, (https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators)

FDA, 2019c, "Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C. Guidance for Industry and FDA Staff," (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2019d, Regulatory Procedures Manual, Chapter 7, (https://www.fda.gov/media/71814/download)

FDA, 2019e, Regulatory Procedures Manual, Chapter 7, Exhibit 7-1, "Model Effectiveness Check Letter (Industry)," (https://www.fda.gov/media/71814/download)

FDA, 2019f, Regulatory Procedures Manual, Chapter 7, Exhibit 7-2, "Model Effectiveness Check Response Format (Industry)," (https://www.fda.gov/media/71814/download)

FDA, 2019g, Regulatory Procedures Manual, Chapter 7, Exhibit 7-3, "Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry)," (https://www.fda.gov/media/71814/download)

FDA, 2019h, Regulatory Procedures Manual, Chapter 7, Exhibit 7-4, "Model Recall Letter (Generic, All Centers)," (https://www.fda.gov/media/71814/download)

FDA, 2019i Regulatory Procedures Manual, Chapter 7, Exhibit 7-5, "Model Recall Response Form," (https://www.fda.gov/media/71814/download)

Ministry of Agriculture and Forestry (New Zealand), 2012. Recall Guidance Material, (https://www.mpi.govt.nz/food-safety/food-recalls/developing-your-food-recall-plan/)