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# **Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry**

## ***Draft Guidance***

**This guidance is being distributed for comment purposes only.**

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2016-D-2841 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document as it relates to our regulation entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,” contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2166.

For questions regarding this draft document as it relates to our regulation entitled “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,” contact the Center for Veterinary Medicine (CVM) at 240-402-6246.

For questions regarding this draft document as it relates to our regulation entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption,” contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1636.

For questions regarding this draft document as it relates to our regulation entitled “Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals,” contact the Office of Policy, Food and Drug Administration at 301-796-4576.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Center for Veterinary Medicine  
Office of Policy  
October, 2016**

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# **Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry<sup>1</sup>**

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 the form available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

## **I. Introduction**

This guidance concerns four of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111–353). Table 1 lists these four rules.

**Table 1. Four Foundational Rules Providing the Framework for Implementing FSMA**

| <b>Title</b>  | <b>Regulatory Codification</b> | <b>Abbreviation for the Purpose of This Guidance</b> | <b>Publication</b>              |
|---|--------------------------------|--|---------------------------------|
| Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food       | 21 CFR part 117                | Part 117   | 80 FR 55908, September 17, 2015 |
| Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals | 21 CFR part 507                | Part 507   | 80 FR 56170, September 17, 2015 |
| Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption                  | 21 CFR part 112                | Produce safety regulation                            | 80 FR 74354, November 27, 2015  |
| Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals                    | 21 CFR part 1, subpart L       | FSVP regulation                                      | 80 FR 74226, November 27, 2015  |

<sup>1</sup> This guidance has been jointly prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition, the Office of Surveillance and Compliance in the Center for Veterinary Medicine, and the Office of Policy in the Office of the Commissioner at the U.S. Food and Drug Administration.

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This guidance is intended for any entity that is subject to certain provisions (in part 117, part 507, the produce safety regulation, or the FSVP regulation) that require a disclosure statement, in documents accompanying food, that certain hazards have not been controlled by that entity. This guidance is not intended to address other requirements of part 117, part 507, the produce safety regulation, or the FSVP regulation.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

## **II. Background on the Four Foundational Rules**

### **A. Part 117**

#### **1. Framework of part 117**

In part 117, we have established our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.” Among other things, the rulemaking to establish part 117 amended our current good manufacturing practice (CGMP) regulation for manufacturing, packing, or holding human food to modernize it and establish it in new part 117, subparts A, B, and F. Part 117 also includes new requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350d)<sup>2</sup> in subparts A, C, D, E, F, and G to establish and implement hazard analysis and risk-based preventive controls for human food (the human food preventive controls requirements). The human food preventive controls requirements in part 117 implement the provisions of FSMA, established in section 418 of the FD&C Act (21 U.S.C. 350g), for human food.

Part 117 includes some exemptions from the CGMP requirements and the human food preventive controls requirements. See 21 CFR 117.5 for those exemptions.

Among other requirements, subpart C of part 117 requires a facility that manufactures/processes human food to conduct a hazard analysis to determine whether there are any hazards that require a preventive control (21 CFR 117.130) and identifies several types of possible preventive controls, including process controls (21 CFR 117.135(c)(1)), food allergen controls (21 CFR 117.135(c)(2)), sanitation controls (21 CFR 117.135(c)(3)), and supply-chain controls (21 CFR 117.135(c)(4)).

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<sup>2</sup> The requirements for domestic and foreign facilities to register under section 415 of the FD&C Act are established in 21 CFR part 1, subpart H. In this document, we refer to those requirements as “the section 415 registration regulation.”

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**2. “Disclosure statement” required in the “customer provisions” of part 117**

Subpart C of part 117 includes several provisions (referred to collectively as “customer provisions”) that apply when a manufacturer/processor of human food identifies a hazard requiring a preventive control (“identified hazard”), does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard (21 CFR 117.136(a)(2), (3), and (4)). A manufacturer/processor that complies with the customer provisions is not required to implement a preventive control for the identified hazard. (In these provisions, “customer” means a commercial customer, not a consumer.)

One aspect of the customer provisions is a requirement for the manufacturer/processor to disclose, in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]” ((21 CFR 117.136(a)(2)(i), (3)(i), and (4)(i)). In this guidance, we refer to this required disclosure as the “part 117 disclosure statement.”

**B. Part 507**

**1. Framework of part 507**

In part 507, we have established our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.” Among other things, the rulemaking to establish part 507 established new requirements for CGMPs in subparts A, B, and F (CGMP requirements) and also established requirements for hazard analysis and risk-based preventive controls for food for animals in subparts A, C, D, E, and F (the animal food preventive controls requirements). The part 507 requirements apply to domestic and foreign facilities that are required to register under the section 415 registration regulation. The animal food preventive controls requirements in part 507 implement the provisions of FSMA, established in section 418 of the FD&C Act (21 U.S.C. 350g), for animal food.

Part 507 includes some exemptions from the CGMP requirements and the animal food preventive controls requirements. See 21 CFR 507.5 for those exemptions.

Among other requirements, subpart C of part 507 requires a facility that manufactures/processes food for animals to conduct a hazard analysis to determine whether there are any hazards that require a preventive control (21 CFR 507.33) and identifies several types of possible preventive controls, including process controls (21 CFR 507.34(c)(1)), sanitation controls (21 CFR 507.34(c)(2)), and supply-chain controls (21 CFR 507.34(c)(3)).

**2. “Disclosure statement” required in the “customer provisions” of part 507**

As with part 117, subpart C of part 507 includes “customer provisions” that apply when a manufacturer/processor of food for animals identifies a hazard requiring a preventive control (“identified hazard”), does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard (21 CFR 507.36(a)(2), (3), and (4)). A manufacturer/processor that complies with the customer provisions is not required to implement a preventive control for the identified hazard.

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As with part 117, one aspect of the customer provisions applicable to manufacturing/processing food for animals is a requirement for the manufacturer/processor to disclose, in documents accompanying the animal food, in accordance with the practice of the trade, that the animal food is “not processed to control [identified hazard]” ((21 CFR 507.36(a)(2)(i), (3)(i), and (4)(i)). In this guidance, we refer to this required disclosure as the “part 507 disclosure statement.”

## **C. Produce Safety Regulation**

### **1. Framework of the produce safety regulation**

In part 112 (21 CFR part 112), we have established our regulation entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”. Among other things, the rulemaking to establish the produce safety regulation set forth in a new part 112 procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. The produce safety regulation applies to certain produce farms, and does not apply to activities of facilities that are subject to part 117 (as established in part 117). The produce safety regulation established in part 112 implements the provisions of FSMA established in section 419 of the FD&C Act (21 U.S.C. 350h).

### **2. “Disclosure statement” required in the “commercial processing exemption” of the produce safety regulation**

The produce safety regulation applies to “covered produce” as set forth in 21 CFR 112.1 and 112.2. Produce that would otherwise be covered is eligible for an exemption from the requirements of the produce safety regulation if it receives commercial processing that adequately reduces the presence of microorganisms of public health significance and certain other conditions are met, including the disclosure statement that is the subject of this guidance document (21 CFR 112.2(b)). Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of 21 CFR part 113, 114, or 120; treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes); and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products. In this document, we refer to this exemption as the “commercial processing exemption” from the produce safety regulation.

For the commercial processing exemption to be satisfied, the farm that produces the produce must, among other things, disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.” In this guidance, we refer to this required disclosure as the “produce safety regulation disclosure statement.”

## **D. Foreign Supplier Verification Regulation**

### **1. Framework of the FSVP regulation**

In part 1, subpart L (21 CFR part 1, subpart L), we have established our regulation entitled “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals”. The FSVP regulation requires importers to establish foreign supplier verification programs to verify that their foreign suppliers are using processes and procedures that provide the same level of public health protection as those required under the provisions on hazard analysis and risk-based preventive controls and standards for produce safety in the FD&C Act, that the imported food is not adulterated, and that food is not misbranded with respect to food allergen labeling. The FSVP regulation established in part 1, subpart L implements the provisions of FSMA established in section 805 of the FD&C Act (21 U.S.C. 384a.).

### **2. “Disclosure statement” required in the “customer provisions” of the FSVP regulation**

The FSVP regulation includes “customer provisions” that apply when an importer imports a food that cannot be consumed without the hazards being controlled or for which the hazards are controlled after importation (21 CFR 1.507). One aspect of these provisions is a requirement for the importer to disclose to customers that the food is “not processed to control [identified hazard]” (21 CFR 1.507(a)(2)(i), (a)(3)(i), and (a)(4)(i)). In this guidance, we refer to this required disclosure as the “FSVP regulation disclosure statement.”

## **III. Discussion**

### **A. FDA’s Recommendations Regarding the Part 117 Disclosure Statement**

#### **1. How to describe the identified hazard**

We believe that, in practice, the part 117 disclosure statement will be required mostly for biological hazards, because the part 117 disclosure statement only applies when a manufacturing/processing facility has identified a hazard requiring a preventive control, but has not applied that preventive control. In the case of most chemical and physical hazards, a chemical or physical hazard that a manufacturing/processing facility identifies as requiring a preventive control would most likely be controlled by the first manufacturing/processing facility in the supply/distribution chain. For example, a corn miller that is the first manufacturer/processor could identify the chemical hazard aflatoxin in corn that it receives from a supplier and use physical sorting techniques to remove aflatoxin-contaminated corn (or moldy, damaged corn that could potentially be contaminated) during processing. Therefore, the miller controls the aflatoxin hazard and would not pass the chemical hazard on to a subsequent manufacturer/processor for control. Likewise, a manufacturing/processing facility that receives produce RACs likely would establish and implement a control for physical hazards such as stones that get into the RACs as a result of harvesting.

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For biological hazards, we will consider a manufacturing/processing facility that describes the “identified hazard” using a general term (e.g., “microbial pathogens,” “microorganisms of public health significance”) rather than a specific biological hazard (e.g., *Salmonella* or *Listeria monocytogenes*) to be in compliance with the requirements for the part 117 disclosure statement. Such a statement adequately communicates the key safety information. Regardless of whether the establishment that receives food accompanied by such a disclosure statement is subject to the CGMP requirements, the human food preventive controls requirements, or both the CGMP and human food preventive controls requirements in part 117, that establishment is responsible for taking appropriate steps to ensure that biological hazards applicable to that food are controlled before the food reaches the consumer.

For chemical and physical hazards, a manufacturing/processing facility that chooses to not control chemical and physical hazards and to rely on its customers to do so, would be subject to the requirements of the part 117 disclosure statement. We expect such a facility to describe the identified chemical or physical hazard using a specific term (e.g., “mycotoxins,” “aflatoxin,” “stones”) that adequately communicates the key safety information regarding the chemical or physical hazard that needs to be controlled. Referring to physical or chemical hazards using a general term only does not provide a customer with sufficient information to address the hazard.

## **2. Documents of the trade**

The requirements for the part 117 disclosure statement specify that the disclosure must be made in “documents accompanying the food, in accordance with the practice of the trade.” See 21 CFR 117.136(a)(2)(i), (a)(3)(i), and (a)(4)(i). This allows for the disclosure statement to be provided using a wide variety of types of documents that accompany the food, such as labels, labeling, bill of lading, shipment-specific certificates of analysis, and other documents or papers associated with the shipment that a food safety manager for the customer is likely to read.

However, it is not sufficient to reference a website in a document of the trade without including the disclosure statement, itself, in the document of the trade. It is permissible, for the purposes of the requirements of the part 117 disclosure statement, to use labeling that includes a disclosure statement such as “not processed to control microbial pathogens” and then directs the recipient to a website for additional information about those microbial pathogens.

We do not recommend documents such as contractual agreements, letters of guarantee, specifications, or terms and conditions be used to communicate the information required in the part 117 disclosure statement. Such documents generally are not specific to a particular shipment, and some of these documents may not be available to the customer’s food safety manager.

## **B. FDA’s Recommendations Regarding the Part 507 Disclosure Statement**

See the discussion in section III.A of our recommendations regarding the part 117 disclosure statement. The same discussion and recommendations apply to the part 507 disclosure statement.



## **C. FDA’s Recommendations Regarding the Produce Safety Regulation Disclosure Statement**

### **1. How to describe the identified hazard**

Because both part 117 and part 507 define the term “pathogen” to mean “microorganism of public health significance,” and because some disclosure statements in accordance with the requirements of part 117 or the requirements of part 507 likely will use terms such as “microbial pathogens,” we will consider a farm that discloses “not processed to adequately reduce the presence of microbial pathogens,” or similar phrases, to be in compliance with the requirements for the produce safety regulation disclosure statement.

### **2. Documents of the trade**

See the discussion in section III.A of our recommendations regarding the part 117 disclosure statement. The same discussion and recommendations apply to the produce safety regulation disclosure statement.

## **D. FDA’s Recommendations Regarding the FSVP Regulation Disclosure Statement**

### **1. How to describe the identified hazard**

We believe that, in practice, the FSVP regulation disclosure statement will be required mostly for biological hazards, because the FSVP regulation disclosure statement only applies when an importer has identified a hazard requiring a control, but that control has not been applied prior to importation, or by the importer if the importer is a manufacturer or processor. In the case of most chemical and physical hazards, a chemical or physical hazard that an importer identifies as requiring a control would most likely be controlled by the first manufacturing/processing facility in the supply/distribution chain. For example, an animal food vitamin pre-mix manufacturer that is a foreign supplier could identify the chemical hazard “nutrient toxicity” in the vitamin ingredients it receives from its supplier. The pre-mix manufacturer would evaluate the potency of the individual vitamin ingredients prior to manufacturing the pre-mix, controlling the nutrient toxicity hazard by combining the vitamin ingredients at an appropriate ratio. In this scenario, the pre-mix manufacturer would not pass the chemical hazard on to a future customer for control. Likewise, an importer that is a manufacturing/processing facility that receives produce RACs from a foreign supplier likely would establish and implement a control for physical hazards such as stones that get into the RACs as a result of harvesting.

For biological hazards, we will consider an importer that describes the “identified hazard” using a general term (e.g., “microbial pathogens,” “microorganisms of public health significance”) rather than a specific biological hazard (e.g., *Salmonella* or *Listeria monocytogenes*) to be in compliance with the requirements for the FSVP regulation disclosure statement. Such a statement adequately communicates the key safety information. Regardless of whether the establishment that receives food from the importer accompanied by such a disclosure statement is subject to the CGMP requirements, the preventive controls requirements, or both the CGMP

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and preventive controls requirements in part 117 or part 507, that establishment is responsible for taking appropriate steps to ensure that biological hazards applicable to that food are controlled before the food reaches the consumer.

For chemical and physical hazards, an importer that chooses to rely on its customers to control chemical and physical hazards (instead of controlling the hazards itself or verifying that the hazards have been controlled prior to importation) would be subject to the requirements of the FSVP regulation disclosure statement. We expect such an importer to describe the identified chemical or physical hazard using a specific term (e.g., “mycotoxins,” “aflatoxin,” “stones”) that adequately communicates the key safety information regarding the chemical or physical hazard that needs to be controlled. Referring to physical or chemical hazards using a general term only does not provide a customer with sufficient information to address the hazard.

**2. Documents of the trade**

See the discussion in section III.A of our recommendations regarding the part 117 disclosure statement. The same discussion and recommendations apply to the FSVP regulation disclosure statement.