

§ 117.136

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program as required by subpart G of this part.

(5) *Recall plan.* Recall plan as required by § 117.139.

(6) *Other controls.* Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

§ 117.136 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

(a) *Circumstances.* If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:

(1) You determine and document that the type of food (e.g., raw agricultural commodities such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate control.

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to ensure that the identified hazard will be significantly minimized or prevented and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 117.137, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard.

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food

is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements.

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 117.137, that your customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]”; and

(B) Will only sell to another entity that agrees, in writing, it will:

(1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart); or

(2) Obtain a similar written assurance from the entity’s customer, subject to the requirements of § 117.137, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document the implementation of that system.

(b) *Records.* You must document any circumstance, specified in paragraph (a) of this section, that applies to you, including:

(1) A determination, in accordance with paragraph (a) of this section, that

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the type of food could not be consumed without application of an appropriate control;

(2) The annual written assurance from your customer in accordance with paragraph (a)(2) of this section;

(3) The annual written assurance from your customer in accordance with paragraph (a)(3) of this section;

(4) The annual written assurance from your customer in accordance with paragraph (a)(4) of this section; and

(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the food you distribute.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3716, Jan. 22, 2016]

§ 117.137 Provision of assurances required under § 117.136(a)(2), (3), and (4).

A facility that provides a written assurance under § 117.136(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 117.139 Recall plan.

For food with a hazard requiring a preventive control:

(a) You must establish a written recall plan for the food.

(b) 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:

(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

(2) Notify the public about any hazard presented by the food when appropriate to protect public health;

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) 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.

§ 117.140 Preventive control management components.

(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 117.135 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:

(1) Monitoring in accordance with § 117.145;

(2) Corrective actions and corrections in accordance with § 117.150; and

(3) Verification in accordance with § 117.155.

(b) The supply-chain program established in subpart G of this part is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient:

(1) Corrective actions and corrections in accordance with § 117.150, taking into account the nature of any supplier non-conformance;

(2) Review of records in accordance with § 117.165(a)(4); and

(3) Reanalysis in accordance with § 117.170.

(c) The recall plan established in § 117.139 is not subject to the requirements of paragraph (a) of this section.

§ 117.145 Monitoring.

As appropriate to the nature of the preventive control and its role in the facility's food safety system:

(a) *Written procedures.* You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control; and

(b) *Monitoring.* You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.

(c) *Records.* (1) *Requirement to document monitoring.* You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 117.155(a)(2) and