

hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

- (i) The formulation of the food;
- (ii) The condition, function, and design of the facility and equipment;
- (iii) Raw materials and other ingredients;
- (iv) Transportation practices;
- (v) Manufacturing/processing procedures;
- (vi) Packaging activities and labeling activities;
- (vii) Storage and distribution;
- (viii) Intended or reasonably foreseeable use;
- (ix) Sanitation, including employee hygiene; and
- (x) Any other relevant factors, such as the temporal (*e.g.*, weather-related) nature of some hazards (*e.g.*, levels of some natural toxins).

§ 117.135 Preventive controls.

(a)(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(2) Preventive controls required by paragraph (a)(1) of this section include:

- (i) Controls at critical control points (CCPs), if there are any CCPs; and
 - (ii) Controls, other than those at CCPs, that are also appropriate for food safety.
- (b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and the food:

(1) *Process controls.* Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

(i) Parameters associated with the control of the hazard; and

(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

(2) *Food allergen controls.* Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(3) *Sanitation controls.* Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:

(i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;

(ii) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

(4) *Supply-chain controls.* Supply-chain controls include the supply-chain

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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