
21 U.S. Code § 350g

Hazard analysis and risk-based preventive controls

(a) In general

The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 342 of this title or misbranded under section 343(w) of this title, monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

(b) Hazard analysis

The owner, operator, or agent in charge of a facility shall—

- (1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including—
 - (A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and
 - (B) hazards that occur naturally, or may be unintentionally introduced; and
- (2) identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and
- (3) develop a written analysis of the hazards.

(c) Preventive controls

The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

- (1) hazards identified in the hazard analysis conducted under subsection (b)(1) will be significantly minimized or prevented;
- (2) any hazards identified in the hazard analysis conducted under subsection (b)(2) will be significantly minimized or prevented and addressed, consistent with section 350i of this title, as applicable; and
- (3) the food manufactured, processed, packed, or held by such facility will not be adulterated under section 342 of this title or misbranded under section 343(w) of this title.

(d) Monitoring of effectiveness

The owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under subsection (c) to provide assurances that the outcomes described in subsection (c) shall be achieved.

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