

§ 121.126

(e)(1) This part does not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 *et seq.*) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(2) This part does not apply with respect to food that is not an alcoholic beverage at a facility described in paragraph (e)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(f) This part does not apply to the manufacturing, processing, packing, or holding of food for animals other than man.

(g) This part does not apply to on-farm manufacturing, processing, packing, or holding of the following foods on a farm mixed-type facility, when conducted by a small or very small business if such activities are the only activities conducted by the business subject to section 418 of the Federal Food, Drug, and Cosmetic Act.

(1) Eggs (in-shell, other than raw agricultural commodities, *e.g.*, pasteurized); and

(2) Game meats (whole or cut, not ground or shredded, without secondary ingredients).

Subpart B—Reserved

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Subpart C—Food Defense Measures

§ 121.126 Food defense plan.

(a) *Requirement for a food defense plan.* You must prepare, or have prepared, and implement a written food defense plan.

(b) *Contents of a food defense plan.* The written food defense plan must include:

(1) The written vulnerability assessment, including required explanations, to identify significant vulnerabilities and actionable process steps as required by §121.130(c);

(2) The written mitigation strategies, including required explanations, as required by §121.135(b);

(3) The written procedures for the food defense monitoring of the implementation of the mitigation strategies as required by §121.140(a);

(4) The written procedures for food defense corrective actions as required by §121.145(a)(1); and

(5) The written procedures for food defense verification as required by §121.150(b).

(c) *Records.* The food defense plan required by this section is a record that is subject to the requirements of subpart D of this part.

§ 121.130 Vulnerability assessment to identify significant vulnerabilities and actionable process steps.

(a) *Requirement for a vulnerability assessment.* You must conduct or have conducted a vulnerability assessment for each type of food manufactured, processed, packed, or held at your facility using appropriate methods to evaluate each point, step, or procedure in your food operation to identify significant vulnerabilities and actionable process steps. Appropriate methods must include, at a minimum, an evaluation of:

(1) The potential public health impact (*e.g.*, severity and scale) if a contaminant were added;

(2) The degree of physical access to the product; and

(3) The ability of an attacker to successfully contaminate the product.

(b) *Inside attacker.* The assessment must consider the possibility of an inside attacker.