

any subsidiaries and affiliates) averaging less than \$10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (*e.g.*, held for a fee).

Vulnerability means the susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration.

You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

§ 121.4 Qualifications of individuals who perform activities under subpart C of this part.

(a) *Applicability.* You must ensure that each individual who performs activities required under subpart C of this part is a qualified individual as that term is defined in § 121.3.

(b) *Qualifications of individuals assigned to an actionable process step.* Each individual assigned to an actionable process step (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in § 121.3—*i.e.*, have the appropriate education, training, or experience (or a combination thereof) necessary to properly implement the mitigation strategy or combination of mitigation strategies at the actionable process step; and

(2) Receive training in food defense awareness.

(c) *Qualifications of individuals for certain activities described in paragraph (c)(3) of this section.* Each individual assigned to certain activities described in paragraph (c)(3) of this section must:

(1) Be a qualified individual as that term is defined in § 121.3—*i.e.*, have the appropriate education, training, or experience (or a combination thereof) necessary to properly perform the activities; and

(2) Have successfully completed training for the specific function at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to conduct the activities. Job experience may qualify an individual to perform

these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(3) One or more qualified individuals must do or oversee:

(i) The preparation of the food defense plan as required in § 121.126;

(ii) The conduct of a vulnerability assessment as required in § 121.130;

(iii) The identification and explanation of the mitigation strategies as required in § 121.135; and

(iv) Reanalysis as required in § 121.157.

(d) *Additional qualifications of supervisory personnel.* Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel with a combination of education, training, and experience necessary to supervise the activities under this subpart.

(e) *Records.* Training required by paragraphs (b)(2) and (c)(2) of this section must be documented in records, and must:

(1) Include the date of training, the type of training, and the persons trained; and

(2) Be established and maintained in accordance with the requirements of subpart D of this part.

§ 121.5 Exemptions.

(a) This part does not apply to a very small business, except that a very small business must, upon request, provide for official review documentation sufficient to show that the facility meets this exemption. Such documentation must be retained for 2 years.

(b) This part does not apply to the holding of food, except the holding of food in liquid storage tanks.

(c) This part does not apply to the packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact.

(d) This part does not apply to activities of a farm that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

§ 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.