§ 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-labelling 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 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.