DOES THE FINAL RULE ON INTENTIONAL ADULTERATION APPLY TO ME?

Diagram 1

Are you the owner, operator or agent in charge of a domestic or foreign facility that manufactures/processes, packs or holds food for consumption in the United States and is required to register with FDA?

[21 CFR 121.1]

NO The rule does not apply to you.

YES Do any of the following apply to you?

• Does your facility hold food, except the holding of food in liquid storage tanks?
  [21 CFR 121.5(b)]

• Does your facility pack, re-pack, label, or re-label food where the container that directly contacts the food remains intact?
  [21 CFR 121.5(c)]

• Is your facility a farm mixed-type facility* that conducts activities that fall within FDA’s “farm” definition?
  [21 CFR 121.5(d)]

• Does your facility produce alcoholic beverages?** [21 CFR 121.5(e)]

• Does your facility manufacture, process, pack, or hold food for animals?
  [21 CFR 121.5(f)]

• Is your facility a farm mixed-type facility whose only activities that would be subject to section 418 of the Federal Food, Drug, and Cosmetic Act are on-farm manufacturing, processing, packing, or holding of eggs [in-shell, other than raw agricultural commodities] and certain game meats? (Note this is limited to small and very small businesses.) [21 CFR 121.5(g)]

NO The rule does not apply to these activities in your facility.

YES You are exempt, except that you are required to provide for official review, upon request, documents sufficient to show your status as a very small business. Such documentation must be retained for two years. You have five years to comply. [21 CFR 121.5(a)]

Is your facility part of a very small business?
I.e. a business [including 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)?

NO

YES You are exempt, except that you are required to provide for official review, upon request, documents sufficient to show your status as a very small business. Such documentation must be retained for two years. You have five years to comply. [21 CFR 121.5(a)]

Is your facility part of a “small business”? I.e., a business [including any subsidiaries and affiliates] employing fewer than 500 full-time equivalent employees? [21 CFR 121.3]

NO You have three years to comply.

YES You have four years to comply.

* A farm mixed-type facility is a farm that also conducts activities outside of the farm definition and is required to register.

** Certain conditions apply.
A

**Written food defense plan that includes:** [21 CFR 121.126]

1. **Vulnerability assessment, including required explanations,** to identify significant vulnerabilities and actionable process steps* [21 CFR 121.130(c)]
2. **Mitigation strategies, including required explanations** [21 CFR 121.135(b)]
3. **Food defense monitoring procedures** [21 CFR 121.140(a)]
4. **Food defense corrective actions procedures** [21 CFR 121.145(a)(1)]
5. **Food defense verification procedures** [21 CFR 121.150(b)]

B

**Training and qualifications of supervisors and personnel working at actionable process steps** [21 CFR 121.4]

C

**Records to be prepared and kept:**

1. **Vulnerability assessment to identify significant vulnerabilities and actionable process steps**
   
   For each point, step, or procedure in the facility’s operation, you must evaluate:
   - The severity and scale of the potential impact on public health, if a contaminant were added
   - The degree of physical access to the product
   - The ability of an attacker to successfully contaminate the product [21 CFR 121.130]

2. **Mitigation strategies for actionable process steps**
   
   Identify and implement mitigation strategies at each actionable process step to significantly minimize vulnerabilities, and include a written explanation of how the strategy minimizes the vulnerability. [21 CFR 121.135]

3. **Food defense monitoring**
   
   Monitor the mitigation strategies with adequate frequency to provide assurances that they are consistently performed. [21 CFR 121.140]

4. **Food defense corrective actions**
   
   Establish and implement procedures for corrective actions if mitigation strategies are not properly implemented. [21 CFR 121.145]

5. **Food defense verification**
   
   Verify that monitoring is conducted.
   Verify that appropriate decisions about corrective actions are being made.
   Verify that mitigation strategies are properly implemented.
   Verify that a reanalysis of the food defense plan has been conducted, as appropriate, according to 21 CFR 121.157. [21 CFR 121.150]

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* An actionable process step is a point, step or procedure in a food process where a significant vulnerability exists and at which mitigation strategies can be applied and are essential to significantly minimize or prevent the significant vulnerability.

** The vulnerability assessment must consider the possibility of an inside attacker.