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)]

YES The rule does not apply to these activities in your facility.

NO

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]

YES You have four years to comply.

NO

You have three 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.

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**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]