

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)?

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)]

YOU ARE COVERED BY THE RULE.

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.

FINAL REQUIREMENTS

Diagram 2

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]

* 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.