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(a)]

• 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(b)]

• 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(c)]

• Does your facility manufacture, process, pack, or hold food for animals? [21 CFR 121.3]

• 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

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

YES

You have four years to comply.

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.
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.