



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0339]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mitigation Strategies to Protect Food Against Intentional Adulteration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0812. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

This information collection supports FDA regulations. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA), certain provisions have been established to protect against the intentional adulteration of food. Section 418 of the FD&C Act (21 U.S.C. 350g) addresses intentional adulteration in the context of facilities that manufacture, process, pack, or hold food and are required to register under section 415 of the FD&C Act (21 U.S.C. 350d). Section 419 of the FD&C Act (21 U.S.C. 350h) addresses intentional adulteration in the context of fruits and vegetables that are raw agricultural commodities. Section 420 of the FD&C Act (21 U.S.C. 350i) addresses intentional adulteration in the context of high-risk foods and exempts farms except for farms that produce milk. These provisions are codified at part 121 (21 CFR part 121) and include requirements that an owner, operator, or agent in charge of a facility must:

- Prepare and implement a written food defense plan that includes a vulnerability assessment to identify significant vulnerabilities and actionable process steps, mitigation strategies, and procedures for food defense monitoring, corrective actions, and verification (§ 121.126 (21 CFR 121.126));
- identify any significant vulnerabilities and actionable process steps by conducting a vulnerability assessment for each type of food manufactured, processed, packed, or held at the facility using appropriate methods to evaluate each point, step, or procedure in a food operation (§ 121.130 (21 CFR 121.130));
- identify and implement mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated. For each mitigation strategy implemented at each actionable process step, include a written explanation of how the mitigation strategy

- sufficiently minimizes or prevents the significant vulnerability associated with the actionable process step (§ 121.135 (21 CFR 121.135));
- establish and implement mitigation strategies management components, as appropriate to ensure the proper implementation of each such mitigation strategy, taking into account the nature of the mitigation strategy and its role in the facility's food defense system (21 CFR 121.138);
 - establish and implement food defense monitoring procedures, for monitoring the mitigation strategies, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system (§ 121.140 (21 CFR 121.140));
 - establish and implement food defense corrective action procedures that must be taken if mitigation strategies are not properly implemented, as appropriate to the nature of the actionable process step and the nature of the mitigation strategy (§ 121.145 (21 CFR 121.145));
 - establish and implement specified food defense verification activities, as appropriate to the nature of the mitigation strategy and its role in the facility's food defense system (§ 121.150 (21 CFR 121.150));
 - conduct a reanalysis of the food defense plan (21 CFR 121.157);
 - ensure that all individuals who perform required food defense activities are qualified to perform their assigned duties (§ 121.4 (21 CFR 121.4)); and
 - establish and maintain certain records, including the written food defense plan (vulnerability assessment, mitigation strategies and procedures for food defense monitoring, corrective actions, and verification) and documentation related to training of personnel. All records are subject to certain general recordkeeping and record retention requirements (§§ 121.301 through 121.330 (21 CFR 121.301 through 121.330)).

Under the regulations, an owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food defense plan, including written identification of actionable process steps, written mitigation strategies, written procedures for defense monitoring, written food defense corrective actions, and written food defense verification procedures.

The purpose of the information collection is to ensure compliance with the provisions under part 121 related to protecting food from intentional adulteration. The regulations are intended to address hazards that may be intentionally introduced to foods, including by acts of terrorism, with the intent to cause widespread harm to public health. Under the regulations, domestic and foreign food facilities that are required to register under the FD&C Act are required to identify and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation.

To facilitate the collection of information, FDA offers tools and educational materials related to protecting food from intentional adulteration, including the FDA Food Defense Plan Builder, a user-friendly tool designed to help owners and operators of food facilities develop a personalized food defense plan, and the Mitigation Strategies Database, a database for the food industry providing a range of preventative measures that firms may choose to implement. These and other informational resources are available at <https://www.fda.gov/food/food-defense/food-defense-tools-educational-materials>. FDA also offers a small entity compliance guide titled “Mitigation Strategies to Protect Food Against Intentional Adulteration” (August 2017) to inform domestic and foreign food facilities about compliance with regulations to protect against intentional adulteration. Further, FDA developed two draft guidance documents titled “Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry” (March 2019) and “Supplemental Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration”(February 2020). Once finalized, the draft guidance documents would assist the food industry in developing and implementing the elements of a food defense plan. These guidance documents are available at

<https://www.fda.gov/food/food-defense>. All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Description of Respondents: The respondents to this information collection are manufacturers, processors, packers, and holders of retail food products marketed in the United States.

In the *Federal Register* of July 2, 2025, 90 FR 29025, we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. We retain, therefore, our estimate of burden for the information collection, which is as follows:

Table 1.--Estimated Annual Reporting Burden¹

| Activity; 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|--|-----------------------|---------------------------------------|------------------------------|-----------------------------------|----------------|
| Exemption for food from very small businesses; § 121.5 | 18,080 | 1 | 18,080 | 0.5 (30 minutes) | 9,040 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden¹

| Activity; 21 CFR 121 | No. of Recordkeeper s | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|-----------------------------|---------------------------------------|----------------------------|--|----------------|
| Food Defense Plan; § 121.126 | 3,247 | 1 | 3,247 | 23 | 74,681 |
| Actionable Process Steps; § 121.130 | 9,759 | 1 | 9,759 | 20 | 195,180 |
| Mitigation Strategies; § 121.135(b) | 9,759 | 1 | 9,759 | 20 | 195,180 |
| Monitoring, Corrective Actions, Verification; §§ 121.140(a), 121.145(a)(1), 121.150(b) | 9,759 | 1 | 9,759 | 175 | 1,707,825 |
| Training; § 121.4 | 367,203 | 1 | 367,203 | 0.67 (40 minutes) | 246,026 |
| Records; §§ 121.305, 121.310 | 9,759 | 1 | 9,759 | 10 | 97,590 |
| Total | | | | | 2,516,482 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

