United States Food and Drug Administration

Mitigation Strategies to Protect Food Against Intentional Adulteration

OMB Control No. 0910-0812

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), certain provisions 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 21 CFR part 121 and include requirements that an owner, operator, or agent in charge 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);

- 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);

- 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);

- 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 (§ 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);

- 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);

- 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);

- conduct a reanalysis of the food defense plan (§ 121.157);

- ensure that all individuals who perform required food defense activities are qualified to perform their assigned duties (§ 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).

We therefore request extension of OMB approval of the information collection provisions found in our regulations under 21 CFR part 121 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of the information collection is to ensure compliance with the provisions under 21 CFR part 121. The regulations are intended to protect food from intentional adulteration caused by acts of terrorism because 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.

In an effort to reduce burden and assist respondents, 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: Respondents to this information collection are manufacturers, processors, packers, and holders of retail food products marketed in the United States. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The information collection does not require the use of information technology, but we encourage this approach. We expect most respondents will fulfill the information collection in electronic format, as records must be made available upon FDA request (for inspection or to review a food defense incident).

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. This information collection involves requirements for food facilities regarding mitigation strategies to protect food against intentional adulteration not otherwise established elsewhere. The information compliments, but does not duplicate, other information collection provisions associated with FSMA.

5. Impact on Small Businesses or Other Small Entities

The regulations provide for exemptions to a "*very small business*," except that the facility would be required to provide for official review documentation that was relied upon to assert the exemption. To assist small businesses, we provided for a staggered effective date to minimize the impact of the new requirements.

We also assist small businesses in complying with our requirements through Regional Small Business Representatives and through scientific and administrative staffs within the agency. Assistance is also available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. Respondents must create and maintain records with appropriate frequency (e.g., hourly, weekly, monthly, quarterly or yearly basis) to demonstrate compliance.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of December 17, 2021 (86 FR 71646). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

Under § 121.325, records are protected from public disclosure to the extent allowable under 21 CFR part 20. Our general policies, procedures, and practices relating to the protection of confidential or otherwise protected information received from third parties would apply to information collected in accordance with the regulations.

Privacy Act

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted with the food defense plan is name. Recordkeeping is maintained by the facility to comply with the regulation. FDA determined that although PII is collected, it is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Act do not apply. Specifically, the facility or FDA do not use name or any other personal identifier to retrieve records from the information collected. Through appropriate instruction, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

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.

Certain facilities may qualify for an exemption under the regulations. Because these facilities must provide documentation upon request to verify their exempt status, we have characterized this as a reporting burden.

Table 2.--Estimated Annual Recordkeeping Burden[1]

Activity; 21 CFR Section	No. of Recordkeepers	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.

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.

12b. Annualized Cost Burden Estimate

The mean hourly wage of an operations manager in the food manufacturing industry is $54.02 (Bureau of Labor Statistics. May 2021 National Industry-Specific Occupational Employment and Wage Estimates. NAICS 311000 - Food Manufacturing, available at Occupation Code 11-1021, General and Operations Managers,

http://www.bls.gov/oes/current/naics3_311000.htm). We increase this cost by 50 percent to account for benefits and overhead, making the total cost per hour $81.03 ($54.02 × 1.5). The overall estimated cost incurred by respondents is $204,643,048 (2,525,522 burden hours × $81.03/hr).

Table 3.--Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Operations Manager	2,525,522	$81.03	$204,643,048

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information
collection.

14. Annualized Cost to the Federal Government

Our review of retained records generally occurs as part of routine or for-cause establishment inspection activities. We estimate that our review of the retained records takes approximately five hours per inspection. We estimate the hourly cost for review and evaluation is $19.59 to $66.54 per hour, the GS-5/Step 1 to the GS 13/Step 10 rates for the Washington-Baltimore locality pay area for the year 2022. To account for overhead, we increased our estimate by 50 percent, making the total cost $29.39 to $99.81 per hour. The midpoint of this range is $64.60 per hour. Thus, we estimate the cost to the Federal Government for the review of records to be $323 per review ($64.60/hour × 5 hours). We estimate that we will review records for an average of 500 inspections per year. Thus, we estimate that the total annual cost to the Federal Government for reviewing records during inspections would be $161,500 ($323 × 500 inspections).

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments other than to increase the burden estimate by 1,224 hours due to a corrected calculation for the estimate related to training (§ 121.4). Also, burden costs were inadvertently entered into OMB's ROCIS digital platform for this collection during the last approval. FDA requests OMB revise those costs from $24,097,974 to zero.

16. Plans for Tabulation and Publication and Project Time Schedule

These information collection requirements will not be published, tabulated or manipulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed as required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.