UNITED STATES FOOD & 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. The Federal Food, Drug, and Cosmetic (FD&C) Act, as amended by the FDA Food Safety Modernization Act (FSMA), establishes certain provisions that serve 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. To implement these provisions, regulations are codified at 21 CFR part 121: *Mitigation Strategies to Protect Food Against Intentional Adulteration*.

Specifically, the regulations require that an owner, operator, or agent in charge:

- 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 to 121.330).

Accordingly we are seeking OMB approval of the information collection provisions found in our regulations under 21 CFR part 121 and 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 public health requirements covered by agency regulations. 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.

Description of Respondents: Respondents to the collection are food production facilities with more than $10 million in annual sales. We estimate there are 9,759 such facilities owned by 3,247 firms. We estimate there are 18,080 facilities with less than $10 million in annual sales that will need to show documentation of their exemption status as prescribed by the regulations.

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 safety incident).

4. Efforts to Identify Duplication and Use of Similar Information

This information collection implements new 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 implementation.

5. Impact on Small Businesses or Other Small Entities

The regulations provide for exemptions to a "*qualified facility*," 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.

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 the Federal Register of February 25, 2019 (84 FR 6009), we published a 60-day notice soliciting public comment of the proposed collections of information. Several comments were received in response to the notice and are summarized here. Minor comments included general support for efforts at protecting food against intentional adulteration. Other comments, however, questioned the estimates we ascribed to meeting the requirements found in subpart C of the applicable regulations; food defense measures (21 CFR parts 121.126 through 121.157). The comments offered alternative estimates ranging from few to several hours, and most correlated this time to aspects of developing plans, conducting vulnerability assessments, and documenting procedures, activities which we attribute to the initial review and implementation of new regulations.

We responded to the comments, noting that alternative compliance dates were established for the covered entities and some have yet to be realized. In addition, to assist respondents in complying with the requirements, we offer both agency guidance as well as an FDA Food Defense Plan Builder, a user-friendly tool designed to help owners and operators of food facilities develop a personalized food defense plan, which is currently under development with stakeholder input. These and other resources are available from our website at www.fda.gov. Finally, none of the comments appeared to question the applicability of the recordkeeping or the associated retention requirements found in subpart D of the regulations.

While we continue to invite comment regarding our burden estimates, we note that they reflect what we believe is representative of the industry average. This information collection covers numerous respondents with varying facility sizes and with differing product inventories. As compliance with the regulatory requirements continues to take effect, we will continue to evaluate the associated information collection burden accordingly. Although we always appreciate feedback regarding ways to improve efficiencies associated with our information collection activities, we decline to adopt alternative burden estimates for the information collection at this time. Rather, we retain the current estimates.

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. After a preliminary assessment we find that the information collection does not collect personally identifiable information (PII) and there are no forms associated with the information collection that would require a Privacy statement under the Privacy Act.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate the burden for this information collection as follows:

Table 1 – Estimated Annual Reporting Burden[1]

Activity; 21 CFR	No. of Respondents,	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Exemption for food from very small businesses; § 121.5	18,080	1	18,080	.50 hrs.	9,040

[1] There are no capital costs, or operating and maintenance costs associated with this collection.

The regulations provide for exemptions. At this time we estimate there are 18,080 firms with less than $10 million in annual sales, exempting them from the requirements. Because facilities must show documentation upon request to verify their exempt status under the regulations (§121.5; exemptions), we have characterized this as a reporting burden. We estimate preparing and updating relevant files will require an average of 30 minutes per respondent for a total annual burden of 9,040 hours (30 minutes x 18,080), as reflected in Table 1.

Table 2—Estimated Annual Recordkeeping Burden

Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
Food defense plan; § 121.126	3,247	1	3,247	23 hrs.	74,681
Actionable process; § 121.130	9,759	1	9,759	20 hrs.	195,180
Mitigation strategies; § 121.135(b)	9,759	1	9,759	20 hrs.	195,180
Monitoring, Corrective Actions, Verification §§ 121.140, 121.145	9,759	1	9,759	175	1,707,825
Training; § 121.160	367,203	1	367,203	.6699 hrs.	244,802
Records; § 121.305, § 121.310	9,759	1	9,759	10 hrs.	97,590
TOTAL			409,486		2,515,258

[1] There are no capital costs, or operating and maintenance costs associated with this collection.

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 estimated recordkeeping burden associated with these activities totals 2,515,258 annual recordkeeping burden hours and 409,486 annual recordkeeping responses.

We estimate an average of 3,247 firms will continue to need to create a food defense plan under § 121.126, that a one-time burden of 60 hours will be needed to create a plan, and that a burden of 10 hours will be required to update the plan. We annualize this estimate by dividing the total number of burden hours (70) over a 3-year period as reflected in table 2, row 1.

Under § 121.130, each of the estimated 9,759 food production facilities will identify and specify actionable process steps for its food defense plan. We estimate that an individual at the level of an operations manager incurs a burden of 20 hours for this activity, as reflected in table 2, row 2.

Under § 121.135(b), each of the estimated 9,759 food production facilities must identify and implement mitigation strategies to provide assurances that any significant vulnerability at each step is significantly minimized or prevented, ensuring that the food manufactured, processed, packed, or held by the facility will not be adulterated. We do not specify a specific number or set of mitigation strategies to be implemented. Some of the covered facilities are already implementing mitigation strategies. We estimate that it requires an average of 20 hours per facility to satisfy the recordkeeping burden associated with these activities for a total of 195,180 hours, as reflected in table 2, row 3.

We estimate that the recordkeeping activities associated with monitoring, documenting mitigation strategies, and implementing necessary corrective actions require first-line supervisors or others responsible for quality control an average of 175 hours for each recordkeeping, and that these provisions apply to each of the 9,759 facilities. This results in a total of 1,707,825 annual burden hours, as reflected in table 2, row 4.

We estimate that recordkeeping activities associated with training under § 121.60 total 244,802 annual burden hours, as reflected in table 2, row 5. We estimate that there are 1.2 million employees working at the regulated facilities and that 30 percent of them (367,203) require training. We estimate that the average burden for the associated recordkeeping activity is approximately 40 minutes (or .67 hours) per record.

Finally, we estimate the 9,759 food production facilities will fulfill the recordkeeping requirements under §§ 121.305 and 121.310, and that it will require an average of 10 hours per record, as reflected in table 2, row 6.

12b. Annualized Cost Burden Estimate

The mean hourly wage of an operations manager in the food manufacturing industry is $53.56 (Bureau of Labor Statistics. May 2012 National Industry-Specific Occupational Employment and Wage Estimates . NAICS 311000 - Food Manufacturing. [Online] 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 of time $80.34 ($53.56*1.5 = $80.34). The overall estimated cost incurred by the respondents, then is $202,802,101.30 (2,524,298 burden hours x $80.34/hr).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 would generally occur as part of routine or for-cause establishment inspection activities. FDA estimates that its review of the retained records would take five hours per inspection. FDA estimates the hourly cost for review and evaluation will be $16.33 to $55.46 per hour, the GS-5/Step 1 rate to the GS 13/Step 10 rate for the Washington-Baltimore locality pay area for the year 2012. To account for overhead, we increased our estimate by 50 percent, making the total cost $24.50 to $83.19 per hour. The midpoint of this range is $53.85 per hour. Thus, FDA estimates the cost to the Federal Government for the review of records to be $269.25 per review ($53.85/hour x 5 hours). FDA estimates that it will review records for an average of 500 inspections per year. Thus, FDA estimates that the total annual cost to the Federal Government for reviewing records during inspections would be $134,625 ($269.25 x 500 inspections).

15. Explanation for Program Changes or Adjustments

We retain our currently approve estimate for the information collection. We continue to evaluate the associated activities and accompanying burden as the effective dates continue to be realized and the regulations implemented.

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 under

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.