Focused Mitigation Strategies to Protect Food Against Intentional Adulteration
Proposed Rule

RIN 0910-AG63
OMB Control No. 0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

This proposed regulation implements three provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act, as amended by the FDA Food Safety Modernization Act (FSMA), that relate to 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. FDA is implementing the intentional adulteration provisions in sections 418, 419, and 420 of the FD&C Act in this rulemaking.

This is a new information collection for 21 CFR Part 121.

2. Purpose and Use of the Information Collection

This proposed rule would establish various food defense measures that an owner, operator, or agent in charge of a facility would be required to implement to protect against the intentional adulteration of food. Specifically facilities need to prepare and implement a written food defense plan that includes actionable process steps, focused mitigation strategies, and procedures for monitoring, corrective actions, and verification.

We expect the proposed rule, if finalized as proposed, would help 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 would be required to identify and implement focused mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation.

3. Use of Improved Information Technology and Burden Reduction

The proposed does not require the use of electronic recordkeeping, but we encourage this approach. The recordkeeping required by this rule-making does not need to be submitted to FDA. Records must be kept on hand in case FDA requests the records (for inspection or to review a food safety incident). We expect that most of the facilities will maintain most of their records in electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

This proposed rule would establish new requirements for food facilities. Therefore we do not anticipate this rule-making to cause any duplication of existing requirements.

5. Impact on Small Businesses or Other Small Entities

The proposed rule would not apply to a qualified facility, except that the facility would be required to provide for official review, upon request, documentation that was relied upon to demonstrate that the facility qualifies for this exemption.

As proposed, a qualified facility would be: (1) A very small business (i.e., a business that has less than $10,000,000 in total annual sales of food, adjusted for inflation), or (2) a facility that meets two requirements, i.e., (a) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and (b) the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

The high threshold value for annual sales, ($10 million) significantly reduces any burden of this rule-making on small businesses. In addition, small businesses (i.e., those employing fewer than 500 persons) would have 2 years after the effective date to comply with proposed part 121. Very small businesses (i.e., businesses that have less than $10,000,000 in total annual sales of food, adjusted for inflation) would be considered a qualified facility and would have 3 years after the effective date to comply with proposed §121.5(a).

6. Consequences of Collecting the Information Less Frequently

The facility will need to create and maintain records at the appropriate level (e.g., hourly, weekly, monthly, quarterly or yearly basis) to show FDA that they are in compliance with food safety laws and that all food safety hazards are being adequately controlled for.

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

The proposed rule published in the FEDERAL REGISTER on December 24, 2013 (78 FR 78013).

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Proposed § 121.325 would establish that all records required by proposed part 121 will be 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 received under this rule.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: There are 14,260 food production facilities that are part of 4,624 firms with more than $10 million in annual sales that are estimated to have actionable process steps and thus will need to comply with this proposed rule. We found 47,416 firms with less than $10 million in annual sales that may need to show documentation of exemption.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity; Proposed 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	1,541	1	1,541	40	61,640
Actionable Process Steps; 121.130	4,753	1	4,753	7.5	35,648
Focused Mitigation Strategies; 121.135(b)	4,278	1	4,278	21.33	91,250
Monitoring and Corrective Actions; 121.140(a), 121.145(a)(1)	14,260	1	14,260	200	2,852,000
Training; 121.160	415,847	1	415,847	0.67	277,231
Records; 121.305, 121.310	4,624	1	4,624	5	23,120
Exemption for Food from Qualified facilities; 121.5	47,416	1	47,416	0.5	23,708
Total					3,364,597

[1] There are no operating and maintenance costs associated with this collection of information.

Reporting Burden

The proposed rule would not apply to a qualified facility, except that qualified facilities would be required to provide for official review, upon request, documentation that was relied upon to demonstrate that the facility meets this exemption. We do not know how often facilities will need to show this information to inspectors on an annual basis. Therefore, we do not estimate a reporting burden here. However, we do estimate a recordkeeping burden associated with the collection and retention of this information (see discussion of Recordkeeping Burden).

Recordkeeping Burden

Requirements for Food Defense Plan
The proposed rule under § 121.126 requires that the owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food defense plan. There are 4,624 firms that will need to create a food defense plan. We estimate that it will take a one-time burden of 40 hours to create such a plan. We annualize this estimate and present the burden in Table 1 row 1 ((40 x 4,624)/3).

Actionable Process Steps
In addition to the creation of the food defense plan at the firm level, each of the 14,260 food production facilities covered by the proposed rule are estimated to have actionable process steps, for which they must spend time identifying and specifying under § 121.130 for the food defense plan. We estimate that an individual at the level of an operations manager will have a one-time burden of an average of 7.5 hours identifying the actionable process steps in that facility. We annualize this one-time burden and present it in Table 1 row 2 ((14,260 x 7.5 hours)/3).

Mitigation Strategies
The proposed rule requires firms to identify and implement focused 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 such facility will not be adulterated. The proposed rule does not specify a specific number or set of focused mitigation strategies to be implemented. Some of the covered facilities are already implementing these mitigation strategies. The costs of these focused mitigation strategies are a mix of initial capital costs and annual personnel costs. The average initial capital cost of these focused mitigation strategies is about $10,000 per facility. We annualize these costs and add them to the average annual capital costs associated with these strategies of about $2,300 per facility. We take into account that about 70 percent of facilities already have mitigation strategies implemented. Therefore, of the 14,260 total food facilities, only 30 percent of these, or 4,278 will need to incur this burden. The annualized capital costs associated with focused mitigation strategies are then presented in Table 1 row 3 [($10,000/3) + $2,300) x 4,278].

We estimate that physical inspection of cleaned equipment as a mitigation strategy will require first-line supervisors and other people responsible for quality control to spend about six minutes per inspection, and that there will be 100 to 300 inspections per year, resulting in a time cost of between 10 and 30 hours per year, per facility, or an average of 20 hours. We estimate that about 70 percent of facilities already employ this mitigation strategy, so this cost will be borne by 30

percent of facilities. We also estimate a one-time burden associated with establishing procedures to prohibit staff from bringing personal items into the manufacturing area as a mitigation strategy. This one time burden will require one individual at the level of an operations manager and one legal analyst, between one and three hours, or an average of two hours each, per facility. We annualize this burden. Table 1 row 3 shows the total burden of creating and implementing mitigation strategies ((20 hours + 4 hours/3) x 4,278).

Monitoring and Corrective Actions

We estimate that monitoring and documenting the focused mitigation strategies, and implementing corrective action as needed, will require first-line supervisors and other people responsible for quality control to spend between 100 and 300 hours per year (average 200 hours), per facility. Table 1 row 4 shows this burden estimate (200 hours x 14,260).

Training

Personnel and supervisors assigned to actionable process steps must receive appropriate training in food defense awareness and their respective responsibilities in implementing focused mitigation strategies under proposed § 121.160. All training received in accordance with this section must be documented in records. We estimate that the training and documentation will require between zero and two hours, or an average of one hour, per employee when the proposed rule takes effect or when a new employee is hired. We also estimate that between 10 percent and 50 percent, or an average of 30 percent, of all workers and supervisors in covered facilities are assigned to work at actionable process steps. We annualize the one hour initial burden for training per worker assigned to actionable process steps (60 minutes / 3). In addition, employee turnover in the food manufacturing industry is high, so we estimate that turnover is about 33 percent for the covered facilities. With a turnover of 33 percent, the annual training burden per job will be about 20 minutes per position requiring training (60 minutes x 0.33= 19.8 minutes). Adding the annual training burden to the annualized initial burden yields an annual training burden of 40 minutes per job at an actionable process step (20 minutes + 20 minutes = 40 minutes). There are about 1.4 million employees in firms covered by the proposed rule so the total annualized burden of the training required by the proposed rule will be about $4.8 million (40 minutes x 1,386,156 x 30% = 16,633,872 minutes or 277,231 hours). We show this burden in Table 1 row 5.

Maintaining Records

The 4,624 firms covered by the proposed rule will also face an annual burden to document compliance with the food defense plan and update it as appropriate under proposed §§ 121.305 and 121.310. We estimate that the overall documentation will take one individual at the level of an operations manager, and also a legal analyst between zero and ten hours, or an average of five hours each per firm. We show this burden in Table 1 row 6 (5 hours x 4,624).

Exemption for Food Produced by Qualified Facilities

Businesses that are exempt from the proposed rule because they are qualified facilities must be prepared to give to FDA inspectors the documentation that was relied upon to demonstrate that the facility meets the exemption. We found 47,416 firms with less than $10 million in annual sales; exempting them from the proposed rule. It is these facilities that may need to show documentation upon request to verify their exempt or qualified facility status under proposed § 121.5 Exemptions. We estimate that this preparation and updating of files will take one individual at the level of an

operations manager between zero and one hour, with a mean estimate of 30 minutes each year for a total annual burden of 23,708 hours (30 minutes x 47,416). We show this burden in Table 1 row 6.

Third Party Disclosure Burden
We have not identified any Third Party Disclosure burdens as a result of this proposed rule-making.

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 is then about $270,311,723 (3,364,597 burden hours x $80.34/hr).

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

21 CFR Part 121	Capital Costs
Focused Mitigation Strategies § 121.135(b)	$24,097,974
Total one-time capital costs	$24,097,974

14. Annualized Cost to the Federal Government

FDA's review of the retained records would generally occur as part of its 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 to 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, this cost is increased 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

This is a new data collection.

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

We are not seeking approval not to display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.