Current Good Manufacturing Practice, Hazard Analysis,
and Risk-Based Preventive Controls For Human Food

0910-0751
RIN 0910-AG36
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Public Law 111–353) was signed into law. The legislation enables FDA to better protect the public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act to establish a modernized, prevention-based food safety system. Specifically, section 103 of FSMA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act, the act) to create new section 418. Section 418(a) requires the owner, operator, or agent in charge of a facility to evaluate hazards that could affect food manufactured, processed, packed, or held by the facility; identify and implement preventive controls; monitor the performance of those controls; and maintain records demonstrating compliance. Sections 418(b)-(i) contain more specific requirements applicable to facilities, including corrective actions (§ 418(e)), verification (§ 418(f)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). Finally, section 103(e) of FSMA creates a new section 301(uu) in the FD&C Act (21 U.S.C. 331(uu)) to prohibit "[t]he operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 [of the FD&C Act]." Accordingly, FDA has promulgated regulations to implement the provisions of FSMA, and on September 17, 2015, the agency issued a final rule. This information collection request supports the reporting, recordkeeping, and third-party disclosure requirements associated with the final rule and codified in 21 CFR part 117.

2. Purpose and Use of the Information Collection

Respondents to the information collection are owners, operators, or agents-in-charge of food facilities required to register under section 415 of the FD&C Act. There are approximately 83,819 such facilities. Information collected under the rule will assist FDA in determining facility compliance with current good manufacturing practice requirements and in ensuring that food safety systems include hazard analysis and risk-based preventive controls. Records will be examined during food facility inspections and in the event of an outbreak or other food safety incident involving the food manufactured at the facility.

In addition, certain "qualified" facilities may be subject to modified requirements under the rule. Qualified facilities must report their status as such a facility and are thus subject to the reporting requirements identified in the regulations.

3. Use of Improved Information Technology and Burden Reduction

Reporting requirements under the rule solicit what the agency believes is the minimal information necessary. At this time the information may be submitted to FDA either electronically or by mail, however we encourage electronic submissions. We are currently developing both paper and electronic forms to facilitate the reporting process and expect to make drafts available for comment in the near future.

We expect most respondents will fulfill the recordkeeping requirements under the rule electronically where facilities may format their records in a manner they determine most appropriate. Records must be available upon FDA request during inspection or to review a food safety incident.

4. Efforts to Identify Duplication and Use of Similar Information

Facilities may already maintain much of the information now required under the rule. As FDA has been Congressionally mandated to implement this rulemaking under FSMA, we believe that duplication of the information collection from another source is unlikely.

5. Impact on Small Businesses or Other Small Entities

FDA has made an effort to minimize the impact of the rule on small businesses. While the effective date of the rule is one year from the date of publication in the Federal Register, small business will have a two year effective date, and very small businesses will have a three year effective date. The agency believes the staggered effective dates will benefit smaller businesses and lower compliance costs. Additionally, the agency is developing and will issue small entity compliance guides to assist facilities in meeting the rule's requirements.

6. Consequences of Collecting the Information Less Frequently

Information collection under the rule is determined by the applicable regulatory requirements including the food safety plan of the respondents' facilities. If corrective actions are necessary, further monitoring will be conducted. Data can be collected hourly, daily, weekly, or yearly as determined by the hazards encountered in a particular manufacturing process. FDA believes that the information collection schedules reflected in the rule represent the least amount of burden necessary to ensure the effectiveness of the regulations and ensure food safety.

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

FDA published a proposed rule in the Federal Register of January 16, 2013 (78 FR 3646); supplemental rulemaking in the Federal Register of September 29, 2014 (79 FR 58524); and a

final rule on September 17, 2015 (80 FR 55907). Comments received in response to the rulemaking are filed under Docket No. FDA-2011-N-0920 and are addressed in the final rule (80 FR at 56133).

This rulemaking is the result of significant stakeholder engagement, beginning before the initial proposed rule. In response to extensive stakeholder input on the proposed rule, key provisions were revised in the supplemental notice of proposed rulemaking. After the supplemental notice of proposed rulemaking, more outreach was conducted to the stakeholder community to ensure that the risk-based, preventive requirements in this final rule are practical and protective of the public health.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents associated with this collection of information.

10. Assurance of Confidentiality Provided to Respondents

There is no assurance of confidentiality associated with this collection of information.

11. Justification for Sensitive Questions

This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden associated with this final rule below. Our estimates are based on our experience with similar information collections and in consideration of feedback during rulemaking. More detailed information regarding our calculations may be found within the agency's Final Regulatory Impact Analysis (FRIA), Reference No. 38, under Docket No. FDA-2011-N-0920.

Reporting

Table 1 – Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
117.201(e); qualified facility	37,134	0.5	18,567	0.5	9,284

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

Qualified facilities must report their status as such a facility every 2 years; status will likely be reported electronically through a web portal maintained by FDA. We estimate that approximately 37,134 qualified facilities will spend 0.5 hours every 2 years reporting to FDA

their status as a qualified facility, for a total annual burden of 9,284 hours (37,134 facilities x 0.5 responses annually x 0.5 hours per response).

Recordkeeping

Table 2 – Estimated Annual Recordkeeping Burden[1]

21 CFR Part 1; Subpart 117	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
117.126(c) and 117.170(d); food safety plan and reanalysis	46,685	1	46,685	110	5,135,350
117.136; assurance records	16,285	1	16,285	0.25	4,071
117.145(c); monitoring records	8,143	730	5,944,390	0.05	297,220
117.150(d); corrective actions and corrections records	16,285	2	32,570	1	32,570
117.155(b); verification records	8,143	244	1,986,892	0.05	99,345
117.160; validation records	3,677	6	22,062	0.25	5,515
117.475(c)(7)-(c)(9); supplier records	16,285	10	162,850	4	651,400
117.180(d); training records for preventive controls qualified individual	46,685	1	46,685	0.25	11,671
TOTAL					6,237,142

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

We estimate approximately 46,685 facilities will need to create a food safety plan, which is a compilation of many written food safety procedures. We further estimate that creation of the food safety plan will require 110 hours, averaged among facilities. Multiplying these figures (46,685 facilities x 110 hours) provides our estimate of 5,135,350 hours.

We estimate the burden associated with assurance records to be approximately 4,071 hours, allotting 15 minutes per record averaged over an estimated 16,285 establishments.

We believe the burden associated with keeping monitoring records is 297,220 hours. This figure was reached by estimating that approximately 8,143 facilities will need to keep additional records of the monitoring that they do of different activities within their food facilities. We then estimate that this will result in an average of 730 records per recordkeeper; and that it will take 3 minutes (0.05 hours) per record for the activity.

We estimate the recordkeeping burden associated with corrective action records is 32,570 hours. This estimate was reached by calculating that 2 times per year 16,285 facilities will have corrective actions to document and that this activity will take one hour per record.

We estimate that recordkeeping burden associated with verification records is 99,345 hours. This figure was calculated by estimating that 8,143 will need to keep the requisite verification records; averaging 244 records per recordkeeper; and then for 3 allotting minutes (0.05 hours) per record.

We estimate the recordkeeping burden associated with validation records to be 5,515 hours. This figure was calculated by estimating that 3,677 facilities will keep records of six validation activities for an average of 22,062 records per recordkeeper, and then factoring 15 minutes (0.25 hours) per record.

We estimate the recordkeeping burden associated with supplier records to be 651,400 hours. This figure was calculated by estimating that approximately 16,285 establishments will maintain an average of 10 applicable records and that the total time for this activity will be about 4 hours per record.

We estimate the recordkeeping burden associated with training for the preventive controls qualified individual to be 11,671. This figure is based on approximately 46,685 establishments needing to document the training of their preventive controls qualified individuals, and by allotting 15 minutes (0.25 hours) for the activity.

Finally, under § 117.206(a)(5) facilities are required to keep records documenting (1) the monitoring of temperature controls for refrigerated packaged food, (2) the corrective actions taken when there is a problem with the control of temperature for refrigerated packaged food, and (3) the verification activities relating to the temperature control of refrigerated packaged food; however, we believe that the keeping of such records is already common industry practice and therefore we have not estimated a burden for this activity.

Third-Party Disclosure

Table 3 – Estimated Annual Third-Party Disclosure Burden

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
117.201(e); disclosure of food manufacturing facility address	37,134	1	37,134	0.25	9,284

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

Under § 117.201(e) qualified facilities must include the address of the facility where the food is manufactured in their label. We estimate the hour burden of this disclosure is 15 minutes per disclosure. This requirement will cause the 37,134 qualified facilities to spend 0.25 hours adding their address to their new labels for a total hour burden of about 9,284 hours (37,134 facilities x

0.25 hours per response).

12b. Annualized Cost Burden Estimate

- We measure costs based on the best available information from government, industry, and academic sources. All wage rates used are identified and discussed more fully in the agency's FRIA, Reference 38 of the final rule and filed under Docket No. FDA-2011-N-0920.

Annualized Cost Burden Estimate			
Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Qualified Individual	5,135,350	$56.00	$287,579,600
Industrial Production Manager	1,101,792	$47.78	$52,643,622
Food Manufacturing Production Worker	18,568	$19.91	$369,689
Total			$340,592,911

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

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

14. Annualized Cost to the Federal Government

These activities will be covered by existing resource allocations. Therefore, we are estimating zero cost to the Federal government as a result of this rulemaking.

15. Explanation for Program Changes or Adjustments

This is a new information collection request.

16. Plans for Tabulation and Publication and Project Time Schedule

Information will not be published for statistical use.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.