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

0910-NEW
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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. Section 103 of FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create new section 418 which contains requirements applicable to food facilities and mandates agency rulemaking. Section 418(a) requires the owner, operator, or agent in charge of a facility to evaluate the 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 of the monitoring. Section 418(a) specifies that the purpose of the preventive controls is to "prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 [of the FD&C Act] or misbranded under section 403(w) [of the FD&C Act] …."

In addition to those areas specified in section 418(a), sections 418(b)-(i) contain more specific requirements applicable to facilities. These include corrective actions (§ 418(e)), verification (§ 418(f)), a written plan and documentation (§ 418(h)), and reanalysis of hazards (§ 418(i)). 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]."

Proposed § 117.175 would add a new section that would list the records that would be required by provisions in subpart C and require that such records be established and maintained. The records in proposed § 117.175 that facilities must establish and maintain include records that document the monitoring of preventive controls as required by § 117.140(c), corrective actions as required by § 117.140(d), and verification activities as required by § 117.150(g)).

This is a new information collection for 21 CFR Part 117.

2. Purpose and Use of the Information Collection

Federal Government: These records required under the proposed rule will assist FDA in determining facility compliance with good manufacturing practices and ensure that hazards at a food facility are adequately being controlled for.

Records will be examined for food facility inspections and in the event of an outbreak or other food safety incident involving the food manufactured at the facility. The records will ensure that the facility is in compliance with all federal food safety laws and will also help identify the source of any food safety problems.

Documentation sent to FDA to attest to qualified facility status will inform FDA of businesses that do not need to comply with subpart C of this proposed rule-making.

3. Use of Improved Information Technology and Burden Reduction

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). FDA is not requiring electronic submission. We expect that most of the facilities will maintain most of their records in electronic format.

The format of records that are used is up to the food manufacturing facility.

For qualified facilities that need to document to FDA their status as such, FDA encourages electronic submission of such information and will provide a web portal for submission of such information.

4. Efforts to Identify Duplication and Use of Similar Information

Facilities may already maintain many of the records that FDA is newly proposing to require under this proposed rule. Many of these records would be kept because it would be a normal, good business practice to do so. In cases where the facilities already create and maintain records that would be required by this proposed rule, there would be no additional burden. We are not requiring that facilities create a duplicate record if a record meeting the rule requirements already exists.

5. Impact on Small Businesses or Other Small Entities

Most of the facilities under this proposed rule-making would be considered small businesses. We estimate that 97,169 out of a total of 97,646 facilities, or about 99.5 percent, are small. Many of these small businesses will be able to obtain qualified facility status and thus will not have to comply with a large portion of this proposed rule. In addition, small businesses and very small businesses will receive a delayed implementation date for the requirements of this rule to be undertaken.

FDA is requiring very little information to be sent to the agency. Rather, facilities need to have the documentation on hand in case of a facility inspection or food safety emergency.

6. Consequences of Collecting the Information Less Frequently

It is expected that facilities will need to attest to their status as “qualified” biennially.

For all facilities that do not have qualified status, records for various provisions of the rule must be kept for two years. The records will need to be created hourly, daily, weekly, monthly,

quarterly, yearly, etc. depending on the type of record. In most cases the facility will determine the appropriate level of creation for each record.

For example, one facility may decide to monitor the facility environment for pathogens on a monthly basis, therefore creating a monthly record. Another facility may need to check calibration on a cooker in the facility every hour, therefore creating an hourly record.

The facility will need to create and maintain records at the appropriate level to show FDA and food safety suppliers that they are in compliance with food safety laws and that all food safety hazards are being adequately controlled for.

There are no legal obstacles to reduce the burden.

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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA is providing an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of January 16, 2013 (78 FR 3646).

On April 20, 2011, FDA held a public meeting entitled "FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities" (Federal Register of April 13, 2011; 71 FR 20588). The purpose of the public meeting was to provide interested persons with an opportunity to discuss implementation of the provisions in section 418 of the FD&C Act. Although the meeting included introductory presentations by the FDA, the primary purpose of the meeting was to listen to our stakeholders. In order to meet that goal, FDA provided multiple opportunities for individuals to express their views, including by providing opportunities for individuals to make presentations at the meeting during an open public and webcast comment session, whereby participants could make presentations in person or via webcast, and during another listening session that was held at the end of the day. Various stakeholders made presentations during these public sessions, including presentations made by representatives from consumer groups, industry trade associations, food companies, and state agencies. The major topics discussed in these comments included food allergens and the importance of allergen controls, verification and the importance of testing, submission of food safety plans to FDA, education and training on preventive controls, the need for flexibility in the regulations, modified requirements for certain packaged food items not exposed to the environment, on-farm manufacturing, processing, packing and holding activities, and states partnering with the FDA to conduct inspections.

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

Table 1-Estimated Annual Recordkeeping Burden					
21 CFR Part 1, Subpart 110	No. Of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
110.175(a)(1) food safety plan	25,614	1	25,614	110	2,817,540
110.175(a)(2) monitoring records	16,668	730	12,167,640	0.05 (3 minutes)	608,382
110.175(a)(3) corrective actions records	18,291	2	36,582	1	36,582
110.175(a)(4) verification records	16,668	244	4,066,992	0.05 (3 minutes)	203,350
110.175(a)(5) Records that document applicable training for the qualified individual.	47,484	1	47,484	0.25 (15 minutes)	11,871
Total annual burden hours					3,677,725

We estimate that 25,614 food manufacturers and wholesalers subject to subpart C will need to create a food safety plan (117.175(a)(1)) which is a compilation of many written food safety procedures. We estimate that creation of the food safety plan will require 110 hours. The total hour burden on an annual basis is 25,614 facilities x 110 hours = 2,817,540 hours. (row 1)

The burden for keeping monitoring records (117.175(a)(2)) follows the same pattern as that for the training records. We estimate that there are 16,668 facilities subject to subpart C that will need to keep additional records of the monitoring that they do of

different activities within their food facilities. Based on estimates of monitoring created, when appropriate, throughout the Regulatory Impact Analysis, we estimate that each of the 16,668 facilities will keep records of 730 of monitoring activities and that each record can be made in about 3 minutes (0.05 hours) for a total hour burden of 608,382. (row 2)

For the burden for corrective action records (117.175(a)(3) we estimate that twice per year 18,291 facilities subject to subpart C will have corrective actions to document. The documentation of those corrective actions is expected to take one hour for each record for a total hour burden of 36,582. (row 3)

The burden for keeping verification records (117.175(a)(4)) follows the same pattern as that for monitoring records. We estimate that there are 16,668 facilities subject to subpart C that will need to keep additional records of the verification that they do of different monitoring activities within their food facilities. We estimate that each of the 16,668 facilities will keep records of 244 of verification events and that each record can be made in about 3 minutes (0.05 hours) for a total hour burden of 203,350. (row 4)

We estimate that 47,484 food manufacturers and wholesalers subject to subpart C will need to document the training of their qualified individual (117.175(a)(5)). We estimate that this will require 15 minutes (0.25 hours) per facility total for a total hour burden of 11,871. (row 5)

Under 117.206(a)(5) facilities subject to subpart C 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. We believe that the keeping of such records is already common industry practice and will not constitute an additional paperwork burden.

Reporting Burden

Table 2 shows the estimated annual reporting burden associated with this proposed rule. Qualified facilities must report their status as such a facility every two years; status will likely be reported electronically through a web portal maintained by FDA. This requirement will cause the 36,689 qualified facilities to spend one-half hour every two years reporting to FDA their status as a qualified facility for a total annual hour burden of about 9,172 hours (36,389 facilities x 0.5 responses annually x 0.5 hours per response).

Table 2- Estimated Annual Reporting Burden					
20 CFR Section (Or FDA Form #)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
110.201(a) Qualified facility	36,689	0.5	18,344.50	0.5 (30 minutes)	9,172
Total burden hours					9,172

Third Party Disclosure Burden

Under 117.201(d) qualified facilities must add the address of the facility where the food is manufactured to their label. The hour burden of this disclosure is zero as this will be a coordinated label change; facilities will likely be updating their labels anyway, so adding the address to the label will not constitute an additional paperwork burden.

12b. Annualized Cost Burden Estimate

We measure costs based on the best available information from government, industry, and academic sources. We list some common conventions used throughout the cost analysis here.

All wage rates used come from the Bureau of Labor Statistics, Occupational Employment Statistics, May 2010, National Industry-Specific Occupational Employment and Wage Estimates, under NAICS 311000 - Food Manufacturing; http://bls.gov/oes/current/naics3_311000.htm Wages are increased by 50 percent to account for overhead.

- Qualified Individuals Mean Wage Rate: Qualified individuals are the persons who have completed training in the development and application of food safety systems or are otherwise qualified through job experience to develop or apply a food safety system. We use two estimates of a wage rate for a qualified individual in this analysis depending on the specific task the individual is performing. One wage estimate is that of a General and Operations manager earning a mean hourly wage of $52.76; we add 50 percent for fringe benefits and other overhead costs ($26.38) for a total estimate of $79.14.

- Industrial Production Manager Mean Wage Rate: Our estimate for the mean hourly wage rate for Production Managers is $61.44 including fringe benefits and other overhead. We derive our estimate from the Bureau of Labor Statistics mean hourly wage rate for General and Operations Managers working in the food industry as shown in NAICS code 311000, Food Manufacturing in 2010 (http://bls.gov/oes/current/naics3_311000.htm) of $40.96 and we add 50 percent for fringe benefits and other overhead costs ($20.48) for a total estimate of $61.44. We use this wage rate throughout the analysis when a wage rate for a production manager is needed.

- Food Manufacturing Production Worker (Nonsupervisory) Mean Wage Rate: Our estimate for the mean hourly wage rate for food manufacturing workers (nonsupervisory) is $19.91 including fringe benefits and other overhead. We derive our estimate from the Bureau of Labor Statistics mean hourly wage rate in the food industry as shown in NAICS code 311000, Food Manufacturing in 2010, Team Assemblers 51-2092 (http://bls.gov/oes/current/naics3_311000.htm) of $13.27 and we add 50 percent for fringe benefits and other overhead costs ($6.64) for a total estimate of $19.91.

Table 3- Costs of burden hours

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Annual Costs			
Qualified Individual	1,955,760	$79.14	$154,778,846
Industrial Production Manager	1,135,029	$61.44	$69,736,182
Food Manufacturing Production Worker	586,936	$19.91	$11,685,896
Total			$236,200,924

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

Table 4- Estimated Annual Recordkeeping Burden

21 CFR Part 1, Subpart 110	Operating and Maintenance Costs	Capital Costs (annualized)
117.175(a)(1) food safety plan	0	$47,492,324
117.175(a)(2) monitoring records	$7,988,551	0
117.175(a)(3) corrective actions records	$12,274,439	0
117.175(a)(4) verification records	$50,860,864	0
Total annual costs	$71,123,854	$47,492,324

The capital costs associated with implementing this food safety plan are $47,492,324 (annualized over 3 years) for all facilities affected. (row 1)

The operating and maintenance costs associated with monitoring are $7,988,551 for all facilities affected. (row 2)

The operating and maintenance costs associated with corrective actions are $12,274,439 for all facilities affected. (row 3)

The operating and maintenance costs associated with verification are $50,860,864 for all facilities affected. (row 4)

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 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 of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.