UNITED STATES FOOD AND DRUG ADMINISTRATION

Recordkeeping and Records Access Requirements for Food Facilities

OMB Control No. 0910-0560;
RIN 0910–AI44

SUPPORTING STATEMENT – **Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, agency, or we) rulemaking that helps to implement provisions of the Food Safety and Modernization Act (FSMA) (Pub. L. 111–353). Section 414 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350c) requires that persons who manufacture, process, pack, hold, receive, distribute, transport, or import food into the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. These requirements are codified in the agency's general enforcement regulations at 21 CFR part 1, subpart J – *Establishment, Maintenance, and Availability of Records*. The existing regulations are designed to enable FDA to identify the immediate previous sources and immediate subsequent recipients of foods to address credible threats of serious adverse health consequences or death to humans or animals. This final rule adopts additional recordkeeping requirements for foods designated as high-risk foods in accordance with factors specified by Congress in FSMA. We are listing these foods on a food traceability list (FTL), which is included as a reference for the final rule. In accordance with FSMA, we also are publishing the FTL on our website concurrently with the issuance of the final rule. (See section V.B of this document for more information on the FTL.)

Section 414(a) of the FD&C Act authorizes FDA to access records relating to specific suspect articles of food; records relating to any article of food that is reasonably believed likely to be affected in such a manner; or if we believe that there is a reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences or death to humans or animals. To gain access to these records, an FDA officer or employee must present appropriate credentials and a written notice, at reasonable times and within reasonable limits and in a reasonable manner. Because we believe the information collection provisions under § 1.361 are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) (see FDA's interim final rule of February 23, 2012 (77 FR 10658)), we have not included an estimate of burden associated with these regulations.

We therefore request OMB approval for the information collection provisions established in the referenced rulemaking and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The requirement to establish and maintain records improves our ability to respond to and contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food. The revised regulations will help FDA better prevent or mitigate a foodborne illness outbreak. The recordkeeping requirements are intended to

strengthen public health protections by documenting the movement of foods throughout the supply chain, enabling FDA to identify the source of contaminated foods and aid in the removal of contaminated products from the market. The regulations also help implement statutory provisions governing traceability of high-risk foods. Access to and utilization of traceability records better enables FDA to respond to and contain threats to the public health introduced through foods on the FTL.

Description of Respondents: Respondents to the information collection are persons who manufacture, process, pack, or hold foods that appear on the list of foods for which additional traceability records are required in accordance with section 204(d)(2) of FSMA (i.e., the FTL).

3. Use of Improved Information Technology and Burden Reduction

We anticipate the use of electronic recordkeeping by respondents.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that 98% of respondents are small businesses, as described in Section III.A of the Final Regulatory Impact Analysis (FRIA). Although the recordkeeping requirements mandated by section 414 of the FD&C Act provide no exceptions for small businesses, some relief for small business in the form of exemptions and partial exemptions as set forth in § 1.1305 is available. We also help small businesses comply with FDA requirements through our Regional Small Business Representatives and we have provided Small Business assistance on our website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

Data collection is conducted in accordance with statutory and regulatory requirements. Pursuant to the FD&C Act and the implementing regulations, a record is established for each transaction involving food at the time the transaction occurs. The information cannot be collected less frequently. If the collection is not conducted or is conducted less frequently, persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States would not be in compliance with section 414 of the FD&C Act.

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

There are no special circumstances associated with 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 September 23, 2020 (85 FR 59984), Docket No. FDA-2014-N-0053, we published a proposed rule inviting public comment on the proposed information collection. Our responses to the comments are found in Section V of the final rule.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

This ICR collects personally identifiable information (PII) or information of a personal nature. The PII collected is for business contact purposes only and includes business name, business address, business telephone numbers. The business contact information is maintained and stored at the vendor facility. Although PII is collected and stored at the vendor facility, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, we do not use name or any other personal identifier to routinely retrieve records from the information collected. We also minimized the PII to be collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

The information collection does not specify confidentiality. However, all confidential information received by FDA is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by our regulations at 21 CFR part 20.

11. Justification for Sensitive Questions

This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1 – Estimated One-Time Recordkeeping Burden

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
ONE TIME: Reading and understanding the new requirements	323,872	1	323,872	16.8[1]	5,441,050
§ 1.1315; traceability plan (one-time set-up)	212,368	1	212,368	6.2	1,316,682
Training personnel	34,737	10.5	364,739	4.2	1,531,904
Total	570977		900979		8,289,635

[1] There is likely to be more than one reader at each large firm. The estimated average sum over all readers of the time spent reading and understanding the rule at each firm is 16.8 hours.

The Estimated One-Time Recordkeeping Burden table reflects several changes to the proposed information collection. The estimated number of respondents for reading and understanding the recordkeeping requirements decreased because of additional exemptions and revisions to exemptions added in the final rule and our use of more recent data sources on the number of covered entities. We also increased the average burden to read and understand the rule from 3.3 hours to 16.8 hours because the length of the rule increased. The number of respondents for the one-time set up costs for the traceability plan ("traceability program records" under the proposed rule) was updated based on updated overall coverage estimates for the number of firms, plus new data on the share of entities that will establish a traceability plan from the ERG expert elicitation study This is now a per-firm rather than per-establishment (facility) burden, and because we have moved from traceability program records to a traceability plan, the number of records per respondent has decreased to one. Finally, we have updated the number of respondents for training personnel based on updated coverage estimates plus newer data from the ERG expert elicitation study. Now training is per-establishment (facility) rather than per-firm. We have also updated the number of records per respondent for training personnel based on the ERG expert elicitation study.

Table 2 – Estimated Annual Reporting Burden

Reporting Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
1.1370; Requests for modified requirements and exemptions	5	1	5	10	50
1.1415 through 1.1425; Requests for waivers	15	1	15	10	150
1.1465(a); Comments on proposed revisions to the Food Traceability List	1	1	1	1	1
Total	21		22		201

We have made no changes to the estimated annual reporting burden associated with the final rule.

Table 3 – Estimated Annual Recordkeeping Burden[1]

21 CFR Recordkeeping	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Training personnel (recurring)	26,053	10.5	273,557	2.7	738,604
Seed lot records (sprout growers)	95	882	83,790	0.04 (2.4 minutes)	3,352
§ 1.1325; harvester	6,058	578	3,501,524	0.03 (1.8 minutes)	105,046
§ 1.1325; cooler	3,511	572	2,008,292	0.03 (1.8 minutes)	60,249
§ 1.1330; initial packer	4,218	861	3,631,698	0.02 (1.2 minutes)	72,634
§ 1.1335; first land-based receiver	367	1,471	539,857	0.02 (1.1 minutes)	10,797
§ 1.1340; shipper	31,434	5,032	158,175,888	0.006 (22 seconds)	949,055
§ 1.1345; receiver	470,580	5,968	2,808,421,440	0.003 (11 seconds)	8,425,264
§ 1.1350; transformer	8,574	1,101	9,439,974	0.02 (1.2 minutes)	188,799
§ 1.1455(c)(3)(ii); electronic sortable spreadsheet upon request	75	1	75	16.0	1,200
Total	550965		2986076095		10,555,000

The revised estimated annual recordkeeping burden table reflects several changes we made to the proposed information collection. First, the list of provisions changed consistent with revisions we made to the critical tracking events (CTEs) and related annual activities such as training personnel. The number of recordkeepers generally decreased because of additional exemptions and revisions to exemptions we added in the final rule and our use of more recent data sources on the number of covered entities. We have also estimated the burden for training personnel as a recurring burden rather than a one-time burden and altered the number of records per recordkeeper for the various provisions based on information from the ERG expert elicitation study. Finally, we have updated the average burden per recordkeeping based on information from the ERG expert elicitation study. Apart from changes to the proposed rule, we also newly estimated the annual burden of formatting traceability information as an electronic sortable spreadsheet upon request by FDA.

Because we have deleted the requirements (in proposed § 1.1350(b)(2)) that farms disclose information (if applicable) about the origination, harvesting, cooling, and packing of food shipped by the farm, we have removed disclosure burden previously included. Under § 1.1325(a)(2) and (b)(2) of the final rule, harvesters and coolers of FTL foods must disclose certain information about those activities to the initial packers of such food. However, as we stated in the preamble to the proposed rule with respect to the disclosure burden for shippers of FTL foods (85 FR 59984 at 60027), we are including the estimate of burden we attribute to the disclosure requirements for harvesters and coolers as part of our recordkeeping burden estimate for these provisions because we believe this disclosure burden will be minimal, since these

respondents must establish and maintain harvesting and cooling information in accordance with those provisions.

12b. Annualized Cost Burden Estimate

As detailed in the FRIA, Section II.F, we estimate associated annualized costs to respondents/recordkeepers to be roughly $570 million.

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

As detailed in the FRIA, Section II.F.3, we estimate associated onetime capital costs to respondents/recordkeepers to be roughly $1.1 billion. Annual operation and maintenance costs are estimated to be $185 million. Note that these costs are also included in the annualized estimated burden reported in section 12b of this document.

14. Annualized Cost to the Federal Government

Our review of the retained records would occur as part of inspection activities. We devote approximately 5 hours per inspection to the inspection of records. We estimate the cost to the Federal government for the review of records retained by a firm to be $491.90 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation to be $49.19 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2020. Five hours multiplied by $49.19 per hour equals $245.95. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal government $491.90 per review. If we inspected 1,000 firms annually, we estimate that the total annual cost to the Federal government would be $491,900 ($491.90 x 1,000).

15. Explanation for Program Changes or Adjustments

The information collection establishes new regulatory requirements applicable to the traceability of foods; introducing a total of 57,210,841,848 hours and 2,986,578,627 records annually, including one-time burden for learning and implementation.

16. Plans for Tabulation and Publication and Project Time Schedule

The information collected will not be published or tabulated.

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

FDA will display the OMB control no. expiration date and explain its significance to respondents as required under 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.