

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 request supports Food and Drug Administration (FDA, agency, or we) regulations. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added 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 in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. These requirements are codified under 21 CFR sections 1.326 through 1.363.

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 regulations require that records for non-transporters include the name and full contact information of sources, recipients, and transporters, an adequate description of the food, including the quantity and packaging, and the receipt and shipping dates (§§ 1.337 and 1.345). Required records for transporters include the names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may be used if they contain all the required information and are retained for the required time period.

Section 101 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) amended section 414(a) of the FD&C Act and expanded FDA’s access to records. FDA may 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, a 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.

In the Federal Register of September 23 2020 (85 FR 59984), we published a proposed rule to revise the information collection provisions. If finalized, provisions in 21 CFR part 1, subpart S,

would implement section 204(d)(1) of FSMA, which requires FDA to establish traceability recordkeeping requirements, in addition to the requirements under section 414 of the FD&C Act and 21 CFR part 1, subpart J (the subpart J requirements) for facilities that manufacture, process, pack, or hold foods that the Agency has designated as high-risk foods (i.e., placed on the “Food Traceability List”) in accordance with section 204(d)(2) of FSMA. The proposed subpart S recordkeeping, reporting, and disclosure requirements are intended to strengthen public health protections by improving FDA’s ability to trace the movement of foods throughout the supply chain to identify the source of contaminated foods and aid in the removal of contaminated products from the market. Access to and utilization of such records would better enable FDA to respond to and contain threats to the public health introduced through foods on the Food Traceability List (“listed foods”). Existing regulations in subpart J set forth traceability recordkeeping requirements for firms that manufacture, process, pack, transport, distribute, receive, hold, or import food. We are proposing to establish additional recordkeeping requirements for foods on the Food Traceability List.

2. Purpose and Use of the Information Collection

Information in the records maintained under these regulations will assist FDA to quickly identify and locate contaminated or potentially contaminated food that might be affected by deliberate or accidental contamination and to inform the appropriate individuals and food facilities of specific terrorist threats.

Description of Respondents: Except as specified otherwise, the requirements in the proposed rule apply to 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 (the Food Traceability List).

3. Use of Improved Information Technology and Burden Reduction

We anticipate the use of electronic recordkeeping.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Under section 414 of the FD&C Act, FDA is specifically charged with the safety of United States food supply. We believe the information collection requirements found in the applicable regulations do not duplicate those associated with other food safety requirements.

5. Impact on Small Businesses or Other Small Entities

We estimate that ten percent (10%) of respondents are small businesses. The recordkeeping requirements of these regulations are mandated by section 414 of the FD&C Act, and there is no statutory exception for small businesses. We help small businesses comply with our requirements through our Regional Small Business Representatives and we have provided Small Business assistance on the agency’s 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 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) we published a proposed rule inviting public comment on the information collection.

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 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.

Privacy Act

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 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.

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

We estimate the burden of the information collection as follows:

Estimated One-Time Recordkeeping Burden

Proposed Activity	No. of Respondents	No. of Records per Respondent	Total Annual Records	Average Burden per Record (in hours)	Total Hours
Reading and understanding the new recordkeeping requirements	422,145	1	422,145	3.3	1,393,079
§ 1.1315; traceability program records (one-time set-up)	130,063	1,000	130,063,000	0.03 (2 minutes)	3,901,890
Training personnel	96,644	3	289,932	2	579,864
Total					5,874,833

We assume all potential respondents to the information collection will incur burden for reading and understanding the proposed regulations. Based on our experience with similar information collection, we assume that reading and understanding the new requirements will require an average of 3.3 hours for each of the 422,145 respondents, for an estimated burden of 1,393,079 hours. In addition, some firms will incur a one-time burden of establishing traceability program records under proposed § 1.1315. We estimate that 130,063 firms will need 0.03 hours to establish each of an average of 1,000 records, for an estimated one-time burden of 3,901,890 hours. Additionally, upon reviewing the regulations and implementing procedures to satisfy the information collection, we expect that some firms will incur burden associated with training employees in procedures for properly documenting key data elements identified in the proposed regulations. We estimate that 96,644 firms will need to conduct an average of 2 hours of training with respect to an average of 3 records, for a total of 579,864 hours. Cumulatively, this results in a total of 5,874,833 one-time burden hours for respondents.

Estimated Annual Reporting Burden

Proposed 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			22		202

Proposed §§ 1.1300 and 1.1305 set forth the scope and applicability of the regulations, as well as identify certain foods and persons that would be exempt from the additional recordkeeping requirements. Proposed §§ 1.1360 through 1.1400 discuss how respondents to the information collection may request modified requirements and exemptions from the subpart S

requirements for certain foods or types of entities. If the proposed rule is finalized, the regulations would explain the procedures and identify the content and format elements that should be included in such requests submitted to FDA, as well as the procedures FDA will follow when proposing modified requirements or exemptions on its own initiative. Specifically, the proposed regulations provide that respondents requesting modified requirements and exemptions must petition the Agency under our regulations in § 10.30. In accordance with the proposed regulations, FDA will publish a notification in the *Federal Register* requesting information and views on a submitted petition. Based on our experience with similar information collection, we assume few requests for modified requirements or exemptions will be submitted to the Agency and therefore provide a base estimate of five submissions annually, as reflected in table 10, row 1. Assuming each submission requires an average of 10 hours to prepare, this results in a total of 50 hours. We invite comment on the estimated burden associated with requests for modified requirements or exemptions from the proposed requirements.

Proposed §§ 1.1410 through 1.1455 pertain to waivers from the subpart S requirements for individual entities and types of entities. If the rule is finalized, these regulations would specify that the procedures for submitting waiver requests for types of entities are governed by § 10.30 and would identify requisite content and format elements for such requests. The regulations would further specify that requests for waivers for individual entities are to be made via written requests (not governed by § 10.30). Based on our experience with similar information collection, we believe that slightly more waiver requests (compared to requests for modified requirements or an exemption) will be submitted and we therefore provide a base estimate of 15 submissions annually, as reflected in table 10, row 2. Assuming each submission requires an average of 10 hours to prepare, this results in a total of 150 hours. We invite comment on the estimated burden associated with requests for waivers from the proposed requirements.

Finally, proposed § 1.1465 provides for FDA publication of proposed updates to the Food Traceability List in the Federal Register, which would include the opportunity for public comment on proposed changes. Because we believe that, on an annualized basis, the burden associated with submitting comments on a proposed change to the Food Traceability List would be negligible, we provide a minimal estimate of one response requiring 1 burden hour annually, as reflected in table 10, row 3. We invite comment on the estimated burden associated with requesting views on a proposed updated Food Traceability List.

Estimated Annual Recordkeeping Burden

Proposed 21 CFR Recordkeeping	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
§ 1.1305; partial exemption under: (e)(2)--commingled RACs; (h)(2)--retail food establishments; (i)(2)--farms; (j)(2)--fishing	1	1	1	1	1

Proposed 21 CFR Recordkeeping	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
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§ 1.1315; traceability program general records (recurring)	130,063	1,000	130,063,000	0.004 (15 seconds)	520,252
§ 1.1325; grower (non-sprout growers)	9,408	1,000	9,408,000	0.03 (2 minutes)	282,240
§ 1.1325; grower (sprout growers)	51	1,000	51,000	0.07 (4 minutes)	3,570
§ 1.1330; first receiver	12,700	1,000	12,700,000	0.03 (2 minutes)	381,000
§ 1.1335; receiver	265,610	1,000	265,610,000	0.004 (15 seconds)	1,062,440
§ 1.1340; transformer	5,244	1,000	5,244,000	0.03 (2 minutes)	157,320
§ 1.1345; creator	222	1,000	222,000	0.03 (2 minutes)	6,660
§ 1.1350; shipper (wholesalers/warehouses /distribution centers; includes disclosure requirement)	12,657	48,333	611,750,781	0.008 (30 seconds)	4,894,006
§ 1.1350; shipper (other shippers; includes disclosure requirement)	16,936	1,000	16,936,000	0.06 (3.5 minutes)	1,016,160
Total					8,323,649

Proposed § 1.1305 provides for certain exemptions and partial exemptions from the proposed subpart S requirements. For the proposed partial exemptions for farm to school programs and for retail food establishments with respect to food produced on a farm and sold directly to the retail food establishment, we conclude that any burden under the proposed rule would be negligible because most retail food establishments and farms already keep the records they would be required to keep under the partial exemptions (i.e., the name and address of the farm that was the source of the food) as part of their standard business practices. For these reasons, we therefore provide a minimum estimate of one respondent requiring 1 hour to establish one record, resulting in an estimated burden of 1 hour. We invite comment on the estimated burden associated with these partial exemptions in proposed § 1.1305.

The requirements in §§ 1.1315 through 1.1350 would identify respondents who are subject to the respective recordkeeping provisions, including with respect to general traceability program records and records documenting the critical tracking events of growing, receiving (including by first receivers), transforming, creating, and shipping foods on the Food Traceability List. The requirements specify when certain records should be established and the key data elements that must be documented.

We provide recordkeeping burden estimates associated with these recordkeeping requirements. The number of respondents, number of records, and time per recordkeeping activity is consistent with figures included in our PRIA for the proposed rule (Ref. 26). Although we note that shippers of listed foods must also disclose required records in accordance with proposed § 1.1350(b), we have included this burden as part of our recordkeeping estimate

for this provision. This is because we believe that this disclosure burden would be minimal since, with the exception of certain information that farms must disclose (addressed in table 12 below), respondents must establish and maintain such information under the proposed rule. We invite comment on the estimated burden associated with both recordkeeping and disclosure provisions in §§ 1.1315 and 1.1325 through 1.1350 of the proposed rule.

Proposed § 1.1355 would exempt listed foods to which a kill step has been applied from all subsequent requirements of the proposed rule, provided that a record of application of the kill step is maintained. Because firms that apply a kill step to a food are required to document this activity under other FDA regulations (e.g., 21 CFR 113.100, 21 CFR 117.190(a)(2)), the proposed requirement to maintain a record of application of a kill step to listed foods would not create an additional recordkeeping burden for such firms under the proposed rule.

Proposed § 1.1455 discusses the maintenance and accessibility of records. Under proposed § 1.1455(b)(3), when necessary to help FDA prevent or mitigate a foodborne illness outbreak, assist in the implementation of a recall, or otherwise address a threat to the public health, respondents may be asked to make available within 24 hours of request by an authorized FDA representative an electronic sortable spreadsheet containing the information they are required to maintain under subpart S, for the foods and date ranges specified in the request. We anticipate that most firms will never be the subject of such a request, because the proposed provision only applies to situations where there is a threat to the public health. Furthermore, we believe that such spreadsheets can be created using software that is readily available and that is commonly used for other general business purposes. In situations where the firm does not maintain records electronically, the information for the specific foods and date ranges could be input manually into such software. We therefore estimate any additional burden posed by proposed § 1.1455(b)(3) would be negligible.

Estimated Annual Disclosure Burden

Proposed Disclosure Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure (in hours)	Total Hours
§ 1.1350(b)(2); farms	9,459	1,000	9,459,000	0.004	37,836
Total					

In addition to the disclosures that entities other than farms must make under proposed § 1.1350(b), farms would incur additional burden attributable to requirements to disclose information (if applicable) about the origination, harvesting, cooling, and packing of the food the farm shipped. In table 12 we estimate that 9,459 farms will need to make 1,000 such disclosures, resulting in a total disclosure burden of 37,836 hours. We invite comment on this estimated disclosure burden for farms under proposed § 1.1350(b)(2).

12b. Annualized Cost Burden Estimate

Consistent with our Economic Impact of Analysis, we estimate associated costs as follows:

One-time and Recurring Recordkeeping Costs of the General Records, 1.1315 Provision (2018\$)			
	Primary	Low	High
Number of affected establishments	130,063	30,107	306,464
Number of FTL lots per establishment	1,000	500	2,000
Time to of establish records (hours)	0.03	0.02	0.05
Time to of maintain records (hours)	0.004	0.003	0.006
Labor cost of hourly employee	\$37.50	\$37.50	\$37.50
Per establishment one-time cost	\$1,250	\$313	\$3,750
One-time cost of general records	\$162,578,510	\$9,408,569	\$1,149,240,155
Per establishment recurring cost	\$156	\$52	\$417
Recurring cost of general records	\$20,322,314	\$1,568,095	\$127,693,351

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

We estimate no capital, start-up, operating or maintenance costs associated with this information collection.

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

This is a proposed revision to an approved information collection.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.