

United States Food and Drug Administration

Establishment, Maintenance, and Availability of Records; Additional Traceability Records for  
Certain Foods--21 CFR Part 1, Subparts J and S

OMB Control No. 0910-0560

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) regulations and programs that help to implement provisions of the Food Safety and Modernization Act (FSMA) (Pub. L. 111-353). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 added section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350c), which was added by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which 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 in the agency's general enforcement regulations at 21 CFR part 1, subpart J. The FDA Food Safety Modernization Act (FSMA) signed in 2011, required FDA to establish additional recordkeeping requirements for facilities that manufacture, process, pack, or hold foods the Agency designates as high-risk to facilitate the rapid and effective traceability of such foods. These requirements are codified in the agency's general enforcement regulations at 21 CFR part 1, subpart S. Part 1, subpart J (21 CFR 1.326 through 1.368) sets forth the requirements for recordkeeping and records access. Part 1, subpart S (21 CFR 1.1300 through 1.1465) provides additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods FDA has designated as high-risk in accordance with factors specified by Congress; we have listed these foods on the Food Traceability List (FTL) on our website at <https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list>. The requirement to establish and maintain records improves our ability to respond to, and further contain, threats of serious adverse health consequences or death from contaminated food.

*Part 1, Subpart J*

Information maintained under these regulations helps us identify and quickly locate contaminated or potentially contaminated food and inform the appropriate individuals and food facilities of specific terrorist threats. Our 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.

The information collection provisions of § 1.361 are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of an administrative action, investigation, or audit involving an agency against specific

individuals or entities. The regulations at 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under § 1.361. Accordingly, we have not included an estimate of burden hours associated with § 1.361.

### *Part 1, Subpart S*

Part 1, subpart S, in accordance with FSMA, establishes additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods that the Agency has designated as high-risk foods (i.e., placed on the “Food Traceability List” (FTL)) in accordance with section 204(d) (2) of FSMA. Persons are required to maintain records containing information on critical tracking events in the supply chain for FTL foods. Part 1, subpart S will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. These additional recordkeeping requirements strengthen public health protections by documenting the movement of foods on the FTL throughout the supply chain, enabling FDA to more rapidly and effectively identify the source of contaminated foods and aid in the removal of contaminated products from the market. Records required under this subpart must be maintained for 2 years from the date they were created or obtained. For more information about requirements for additional traceability records for certain foods visit our website at <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods>, which also includes a guide that provides key data elements for recordkeeping (<https://www.fda.gov/media/163132/download?attachment>).

The information and records required under part 1, subpart S vary depending on the type of supply chain activities performed with respect to an FTL food. For harvesting and cooling of foods on the FTL, records must include information about the location for the immediate subsequent recipient, commodity, quantity, location of farm and harvest area or cooling area, date of harvest or cooling, and the reference document type and reference document number (§ 1.1325). For the initial packing of a raw agricultural commodity on the FTL, including sprouts, for each traceability lot you initially pack, records must include and link the traceability lot to information about the commodity, date harvested and received, quantity, location of farm and harvest and/or cooling area, name and phone number of harvester, and the reference document type and reference document number (§ 1.1330). For the first land-based receiver of food on the FTL, for each traceability lot obtained from a fishing vessel, records must include and link the traceability lot to the traceability lot code assigned, product description, quantity, harvest date range and locations, location of land-based receiver, date the food landed, and the reference document type and reference document number (§ 1.1335). For each traceability lot of a food on the FTL that you ship or receive, records must include and link the traceability lot to the traceability lot code, product description, quantity, location description of either the immediate subsequent recipient or the immediate previous source, location description of either from which you shipped or for where the food was received, date the food was shipped or received, location description for the traceability lot code source, and the reference document type and reference document number (§§ 1.1340 and 1.1345). For each traceability lot of food that is on the FTL that is transformed, records must include and link the traceability lot to the traceability lot code, product description, quantity, date transformed, and the reference document type and reference document number (§ 1.1350). Part 1, subpart S also requires that persons who manufacture, process, pack, or hold foods listed on the FTL to maintain records demonstrating the creation and establishment of a traceability plan (§ 1.1315).

A respondent may submit a citizen petition to FDA to request modified requirements or exemptions from the requirements of subpart S (§ 1.1370). In addition to the requirements of a citizen petition (21 CFR 10.30), a respondent must: (a) specify the food or type of entity to which the modified requirements or exemption would apply; (b) specify the proposed modifications to the requirements; and (c) provide information demonstrating that the proposed modification or exemption of the requirements are not necessary to protect the public health.

A respondent may submit to FDA a written request or a citizen petition to waive one or more requirements (§§ 1.1415 and 1.1425). In addition to the requirements for submitting a citizen petition (§ 10.30), a respondent must: (a) specify the type of entity to which the waiver would apply; (b) provide information demonstrating why the requirements requested to be waived would result in an economic hardship for the entity, including information about the unique circumstances faced by the entity that result in unusual economic hardship from the application of these requirements; and (c) why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act; and (d) provide information demonstrating that the waiver would not otherwise be contrary to the public interest.

The information collection provision of § 1.1455(c)(3)(ii) is exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations at 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records for which there is a requirement to provide the records in an electronic sortable spreadsheet under § 1.1455(c)(3)(ii). Accordingly, we have not included an estimate of burden hours associated with § 1.1455(c)(3)(ii). We therefore request OMB approval for the information collection provisions discussed in this supporting statement.

## 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.

The recordkeeping requirements 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 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 this collection of information are persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States who are required to establish, maintain, and provide records. Respondents are from the private sector (for-profit businesses).

## 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. Although the recordkeeping requirements mandated by section 414 of the FD&C Act provide no exceptions for small businesses, some relief for small businesses 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 provide 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 accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of December 9, 2025 (90 FR 57074). One stakeholder provided multiple comments. Although the commenter generally supported collections of information to support public safety, there were several comments that questioned the extent of the number of food facilities creating and maintaining records and whether the necessity to maintain such records had practical utility. Another comment offered concern with the cost to comply for smaller businesses.

As explained earlier in this document, this collection of information supports regulations in 21 CFR part 1, subparts J and S. FDA codified the subpart J regulations to support the Bioterrorism Act (Pub. L. 107-188) and, subsequently, implemented additional recordkeeping requirements in subpart S for foods we have designated as high-risk foods in accordance with factors specified by Congress in FSMA (Pub. L. 111-353). In other words, FDA implemented these regulations and required this collection of information as directed by Congress.

These recordkeeping requirements are appropriate and necessary to protect the public health. These traceability recordkeeping requirements help FDA rapidly and effectively identify recipients of certain foods to prevent or mitigate a foodborne illness outbreak and address threats of serious adverse health consequences or death as a result of such foods being adulterated under the FD&C Act. The requirements will reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving

the ability to quickly and efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated foods from the marketplace, and develop mitigation strategies to prevent future contamination. If all facilities did not create and maintain records, there would be instances that FDA would not be able to quickly and effectively identify recipients of contaminated food. That could result in additional serious adverse health consequences or death. It could also adversely impact the food industry by not being able to identify specific lot numbers or batches of product in question, resulting in overly broad recall requests that affect entire segments of the industry. 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. However, in the promulgating regulations to implement the statutory requirements, FDA provides relief for small businesses in the form of exemptions and partial exemptions set forth in §§ 1.327 and 1.1305. FDA also help small businesses comply with our requirements through our Regional Small Business Representatives and via the agency's website at <https://www.fda.gov/industry/small-business-assistance>. The regulations also allow for requests to modify or exempt requirements and for waivers.

#### 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*

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

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, and business telephone numbers. The PII is collected and stored at the vendor facility. FDA determined that although PII is collected, 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, FDA does not use name or any other personal identifier to retrieve records from the information collected.

##### *The Freedom of Information Act*

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b) (1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

#### 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 this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden <sup>1</sup>

Activity; 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Requests for modified requirements and exemptions; 1.1370	5	1	5	10	50
Requests for waivers; 1.1415 through 1.1425	15	1	15	10	150
Total			20		200

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records maintenance; 1.337, 1.345, and 1.352	379,493	1	379,493	7	2,656,451
Create and establish traceability plan; 1.1315	212,368	1	212,368	8	1,698,944
Records for harvesting or cooling; 1.1325	9,570	575	5,502,750	0.07 (4 minutes)	385 ,193
Records for initial packer; 1.1330;	4,313	865	3,730,745	0.07 (4 minutes)	26 1,152
Records for first land-based receiver; 1.1335	367	1,471	539,857	0.03 (2 minutes)	16, 196
Records for shipper and receiver; 1.1340 and 1.1345	502,000	5,900	2,961,800,000	0.006 (20 seconds)	17, 770,800
Transformer; 1.1350	8,574	1,101	9,439,974	0.03 (2 minutes)	283 ,199
Total	1116685		2,981,605,187		23,071,935

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The revised estimated annual burden reflects updates to the consideration of burden. We believe that the burden for part 1, subpart J was inadvertently omitted from the previous approval, so we are adding it here. However, we believe some of the considerations for burden should have been incorporated with PRA activities instead of being considered independently. Lastly, considerations of burden for §§ 1.1465(a) and 1.1455(c)(3)(ii) do not apply to the PRA so we have removed this burden. Section 1.1465(a) is a general solicitation for comment, which is not considered “information” under the PRA regulations (5 CFR 1320.3(h)(4)). Activities under § 1.1455(c)(3)(ii) applies to an investigation, audit, or action after a case file is opened for a specific party, which is exempt from OMB review as discussed earlier in this document (5 CFR 1320.4(a)(2)).

## 12b. Annualized Cost Burden Estimate

The annual hour cost burden to respondents is \$1,030,401,549.10 per year. We estimate that the average hourly wage for the employee maintaining records would be equivalent to a GS-5/Step-1 level in the locality pay area of Washington-Baltimore in 2026, approximately \$22.33/hour. To account for overhead costs, we double this wage to \$44.66/hour. Thus, the overall estimated cost incurred by respondents is \$1,030,401,549.10 (23,072,135 burden hours × \$44.66/hr).

Table 3.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting	200	\$44.66	\$8,932.00
Recordkeeping	23,071,935	\$44.66	\$1,030,392,617.10
Total			\$1,030,401,549.10

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

There are no capital, start-up, operating, or maintenance costs associated with this 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 \$577.80 per review. In this calculation of cost, we estimate the hourly cost for review and evaluation to be \$58.35 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area in 2026. Five hours multiplied by \$58.35 per hour equals \$291.75. To account for overhead, this cost is increased by 100 percent, making the total annualized cost to the Federal government \$583.50 per review. If we inspected 1,000 firms annually, we estimate that the total annual cost to the Federal government would be \$583,500 ( $583.50 \times 1,000$ ).

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall increase of 4,227,299 hours but a corresponding decrease of 5,371,888 records. We attribute the increase in hours to the return of burden for part 1, subpart J along with adjustments to the average burden per recordkeeping. We attribute the decrease in records due to the reconsideration of activities such as learning new requirements and training staff and incorporating the time for these activities as part of the actual information collection.

Table 4.--Changes or Adjustments to Burden Estimates

Activity/CFR Section	Previously Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for Change (Estimate Revision/Programmatic)
Part 1, subpart J (1.326 through 1.368)	0	2,656,451	+2,656,451	The burden for part 1, subpart J was inadvertently omitted from the previous approval, so it is being added now.
ONE TIME: Reading and understanding the new requirements	5,441,050	0	-5,441,050	Reading and understanding a policy does not in itself create an IC. Reading and understanding the requirements of this ICR has been incorporated into the burden estimates throughout.
1.1315; traceability plan (one-time set-up)	1,316,682	1,698,944	+382,262	The average burden per recordkeeping has been updated from 6.2 hours to 8 hours per recordkeeping. This estimate also incorporates the time for

				reading and understanding the requirements.
Training personnel (one-time and recurring)	2,270,508	0	-2,270,508	Training personnel is not a PRA activity. However, this activity has been incorporated into the burden estimates throughout.
1.1465(a); Comments on proposed revisions to the Food Traceability List	1	0	-1	“Information” does not generally include facts or opinions submitted in response to general solicitations of comments from the public, published in the <i>Federal Register</i> . 5 CFR 1320.3(h)(4).
Seed lot records (sprout growers)	3,352	0	-3,352	Burden related to this IC has been incorporated into the line for § 1.1330.
1.1325; harvester and cooler	165,295	385,193	+219,898	The average burden per recordkeeping has been updated from 1.8 minutes to 4 minutes per recordkeeping.
1.1330; initial packer	72,634	261,152	+188,518	The average burden per recordkeeping has been updated from 1.2 minutes to 4 minutes per recordkeeping. Further, the burden separately attributed to seed lot records has been included here.
1.1335; first land-based receiver	10,797	16,196	+5,399	The average burden per recordkeeping has been updated from 1.1 minutes to 2 minutes per recordkeeping.
1.1340 and 1.1345; shipper and receiver	9,374,319	17,770,800	+8,396,481	The lines for §§ 1.1340 and 1.1345 were combined due to very similar recordkeeping activities. The average burden per recordkeeping has been updated from 22 seconds for § 1.1340 and 11 seconds for § 1.1345 to 20 seconds per recordkeeping for both sections.
1.1350; transformer	188,799	283,199	+94,400	The average burden per recordkeeping has been updated from 1.2 minutes to 2 minutes per recordkeeping.
1.1455(c)(3)(ii); electronic sortable spreadsheet upon request	1,200	0	-1,200	Section 1.1455(c)(3)(ii) applies to an investigation, audit, or action after a case file is opened for a specific

				party, which 5 CFR 1320.4(a) (2) exempts from OMB review.
Total	18,844,636	23,071,935	+4,227,299	

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.