4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-4250]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishment, Maintenance, and Availability of Records; Additional Traceability Records for Certain Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our recordkeeping and records access requirements for food facilities.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2025-N-4250 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Establishment, Maintenance, and Availability of Records; Additional Traceability Records for Certain Foods." Received comments, those filed in a timely manner (see ADDRESSES), will be

placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

OMB Control Number 0910-0560--Extension

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 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 of 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 received 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).

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, including persons that engage in both interstate and intrastate commerce.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

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 and 1.1425	15	1	15	10	150
Total			20		200

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

Table 2--Estimated Annual Recordkeeping Burden[1]

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)	261,152
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			2,981,605,187		23,071,935

[1] 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)).

Our estimated burden for the information collection reflects an overall increase of 4,227,299 hours but a corresponding decrease of 4,973,420 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 of 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.

Lowell M. Zeta

Acting, Deputy Commissioner for Policy, Legislation, and International Affairs

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