



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0721]

Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 information collection requirements for the accreditation of third-party certification bodies to conduct food safety audits and issue certifications.

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

REGISTER]. 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 postmarked or the delivery service acceptance receipt is 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-2019-N-0721 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications.” 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), 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.

Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and To Issue

Certifications--21 CFR part 1; subpart M

OMB Control Number 0910-0750--Extension

FDA provides for accreditation of third-party certification bodies (CBs) to conduct food safety audits of eligible foreign food facilities, and issue food and facility certifications, pursuant to the FDA Food Safety Modernization Act. In accordance with 21 CFR part 1.600, Subpart M, FDA uses certifications issued by accredited third-party auditors/CBs in deciding whether to admit certain imported food into the United States that FDA has determined poses a food safety risk and in deciding whether an importer is eligible to participate in a program for expedited review and entry of food imports. Except for limited circumstances in which we may directly accredit CBs to participate in the accredited third-party audits and certification program, we will recognize accreditation bodies (ABs) to accredit third-party auditors/CBs. Use of accredited third-party CBs and food and facility certifications has helped us prevent potentially harmful

food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply.

This collection of information increases efficiency by reducing the number of redundant audits to assess compliance with applicable food safety requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations.

We estimate that there are about 200,000 foreign food and feed exporters that offer their food and feed for import into the United States. These foreign food and feed exporters include approximately 130,000 food and feed production facilities and approximately 71,000 farms. A proportion of these foreign food and feed exporters may offer food subject to mandatory certification requirements under section 801(q) of the FD&C Act (21 U.S.C. 381(q)(3)). In that case, the eligible entities must either comply with this collection of information to obtain certification from a CB accredited under the third-party program to continue exporting their food products into the United States, or a foreign government designated by FDA, or lose their access to U.S. markets. We assume that in any given year, 75 foreign food and feed exporters will be subject to section 801(q) of the FD&C Act.

We estimate that 25 ABs will accredit CBs that will conduct food safety audits of foreign eligible entities that offer food or feed for import to the United States. We also estimate that approximately 207 CBs accredited by the 25 AB applicants will comply with the collection of information to participate in the program. In addition, we expect that one CB will apply and participate in the third-party program via direct accreditation by FDA under this collection of information.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden¹

21 CFR Part 1; Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping (in hours)	Total Hours

§ 1.625	25	426	10,600	0.25 (15 minutes)	2,663
§ 1.624(c)	25	1	25	8	200
§ 1.657(d)	208	1	208	8	1,664
§ 1.652	208	48.5	10,088	0.083 (5 minutes)	837
§ 1.653(b)(2)	208	48.5	10,088	0.083 (5 minutes)	837
§ 1.656(c)	208	0.25	52	1	52
Total Annual Recordkeeping Burden					6,253

¹ There are no operations and maintenance costs associated with annual recordkeeping burden.

Table 2 -- Estimated Annual Reporting Burden¹

21 CFR Part 1; Subpart M	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response (in hours)	Total Hours
§ 1.634	25	1	25	8	200
§ 1.673	1	1	1	10	10
§ 1.623(a)	25	8.79	220	0.25 (15 minutes)	55
§ 1.623(b)	25	1	25	0.25 (15 minutes)	6
§ 1.653(b)(1)	208	48.5	10,088	0.25 (15 minutes)	2,522
§ 1.656(a) ²	207	48.5	10,040	0.25 (15 minutes)	2,510
§ 1.656(a) ³	207	48.5	10,040	0.25 (15 minutes)	2,510
§ 1.656(a) ⁴	1	55.4	55	0.25 (15 minutes)	14
§ 1.656(b) ⁵	207	1	207	0.25 (15 minutes)	52
§ 1.656(b) ⁶	1	1	1	0.25 (15 minutes)	1
§ 1.656(c)	208	0.25	52	0.25 (15 minutes)	13
§ 1.656(e) ⁷	208	0.25	52	0.25 (15 minutes)	13
§ 1.656(e) ⁸	207	0.25	52	0.25 (15 minutes)	13
Total Annual Reporting Burden					7,919

¹ There are no operating or maintenance costs associated with annual reporting.

² Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to their accrediting ABs.

³ Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to the FDA.

⁴ Annual reporting of regulatory audit reports by directly accredited CBs to the FDA.

⁵ Annual reporting of self-assessment by accredited CBs to their recognized ABs.

⁶ Annual reporting of self-assessment by directly-accredited CBs to the FDA.

⁷ Annual reporting of serious risk to public health by CBs accredited under the third-party program to eligible entities.

⁸ Annual reporting of serious risk to public health by accredited CBs to their recognized ABs.

The total annual recordkeeping burden by 25 recognized ABs and 208 CBs accredited under the third-party program is estimated at 6,253 hours (see table 1). We assume that all ABs that apply for recognition in the program become recognized and all CBs that apply for accreditation are accredited. The total annual reporting burden by 25 recognized ABs and 208 CBs accredited under the program is estimated at 7,919 hours (see table 2).

We have adjusted our burden estimate since last OMB approval of the information collection to reflect the removal of burden associated with one-time recordkeeping activities resulting from the implementation of new provisions. This results in an overall decrease of 60,650 annual burden hours.

Dated: February 13, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-02806 Filed: 2/19/2019 8:45 am; Publication Date: 2/20/2019]