



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-0499]

Agency Information Collection Activities; Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice

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 collection provisions of our regulations mandating the application of hazard analysis and critical control point (HACCP) principles to the processing of fruit and vegetable juices.

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-2026-N-0499 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and

Importing of Juice." 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, PRABranch@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.

Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing and Importing of Juice--21 CFR Part 120

OMB Control Number 0910-0466--Extension

This information collection supports FDA's regulations in part 120 (21 CFR part 120), which govern the application of HACCP principles to the processing of fruit and vegetable

juices. HACCP is a preventative system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(4)). Specifically, regulations in 21 CFR 120.12 provide for records documenting the establishment, implementation, and continued application of a HACCP system. The rationale in establishing a HACCP system of preventive controls is to design and check the process so that the final product is not contaminated. Under HACCP, processors of fruit and vegetable juices establish and follow a preplanned sequence of operations and observations (the HACCP plan) designed to avoid or eliminate one or more specific food hazards, and thereby ensure that their products are safe, wholesome, and not adulterated; in compliance with section 402 of the FD&C Act. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements are narrowly tailored to focus on the development of appropriate controls and document those aspects of processing that are critical to food safety.

HACCP records are retained by respondents and presented to FDA upon inspection. We use the information to determine compliance with applicable requirements. Products not in compliance with applicable statutory and regulatory requirements may be adulterated under the FD&C Act and subject to enforcement action.

In an effort to reduce burden and assist respondents, our website (<https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/juice-haccp>) offers guidance for industry, training and education, and background information to assist the food industry in developing and implementing a Juice HACCP. All agency guidance documents are issued in accordance with our good guidance practice regulation in 21 CFR 10.115, which provides for public comment at any time.

Description of Respondents: Respondents to this information collection are processors of fruit and vegetable juices (plants identified in our official establishment inventory plus very small apple juice and very small orange juice manufacturers).

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

Table 1.--Estimated Annual Recordkeeping Burden¹

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
120.6(c) and 120.12(a)(1) and (b); written monitoring and correction records for Sanitation Standard Operating Procedures	1,875	365	684,375	0.1 (6 minutes)	68,438
120.7; 120.10(a); and 120.12(a)(2), (b) and (c); written hazard analysis of food hazards	2,300	1.1	2,530	20	50,600
120.8(b)(7) and 120.12(a)(4)(i) and (b); recordkeeping system that documents monitoring of the critical control points and other measurements as prescribed in the HACCP plan	1,450	14,600	21,170,000	0.01 (1 minute)	211,700
120.10(c) and 120.12(a)(4)(ii) and (b); document all corrective actions taken in response to a deviation from a critical limit	1,840	12	22,080	0.1 (6 minutes)	2,208
120.11(a)(1)(iv) and (a)(2) and 120.12 (a)(5) and (b); records showing that process monitoring instruments are properly calibrated, and that end-product or in-process testing is performed in accordance with written procedures	1,840	52	95,680	0.1 (6 minutes)	9,568
120.11(b) and (c); and 120.12(a)(5) and (b); record validation that the HACCP plan is adequate to control food hazards that are likely to occur	1,840	1	1,840	4	7,360
120.11(c) and 120.12(a)(5) and (b); document revalidation of the hazard analysis upon any changes that	1,840	1	1,840	4	7,360

might affect the original hazard analysis (applies when a firm does not have a HACCP plan because the original hazard analysis did not reveal hazards likely to occur)					
120.14(a)(2), (c), and (d) and 120.12(b); importers of fruit or vegetable juices, or their products used as ingredients in beverages, have written procedures to ensure that the food is processed in accordance with our regulations in part 120	308	1	308	4	1,232
120.8(a), 120.8(b), and 120.12(a)(3), (b), and (c); written HACCP plan	1,560	1.1	1,716	60	102,960
Total			21,980,369		461,426

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

Based on a review of the information collection since its last OMB approval, we have made no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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