written inquiry, must respond in writing pursuant to this section. This may be accomplished by filing the properly completed BE–13 report (BE–13A, BE–13B, BE–13D, BE–13E, or BE–13 Claim for Exemption).

(b) *Who must report.* A BE–13 report is required of any U.S. business enterprise, except certain private funds, see exception in item (b.4.), in which:

(1) A foreign direct investment in the United States relationship is created;

(2) An existing U.S. affiliate of a foreign parent establishes a new U.S. business enterprise, expands its U.S. operations, or acquires a U.S. business enterprise, or;

(3) BEA requests a cost update (Form BE–13E) for a U.S. business enterprise that previously filed Form BE–13B or BE–13D.

(4) Certain private funds are exempt from reporting on the BE–13 survey. If a U.S. business enterprise is a private fund and does not own, directly or indirectly, 10 percent or more of another business enterprise that is not also a private fund or a holding company, it is not required to file any BE–13 report except to indicate exemption from the survey if contacted by BEA.

(c) *Forms to be filed.* Depending on the type of investment transaction, U.S. affiliates would report their information on one of five forms—BE–13A, BE–13B, BE–13D, BE–13E, or BE–13 Claim for Exemption.

(1) Form BE–13A—Report for a U.S. business enterprise when a foreign entity acquires a voting interest (directly, or indirectly through an existing U.S. affiliate) in that U.S. business enterprise including segments, operating units, or real estate; and

(i) The total cost of the acquisition is greater than $40 million; and

(ii) By this acquisition, the foreign entity now owns at least 10 percent of the voting interest (directly, or indirectly through an existing U.S. affiliate) in the acquired U.S. business enterprise.

(2) Form BE–13B—Report for a U.S. business enterprise when it is established by a foreign entity or by an existing U.S. affiliate of a foreign parent; and

(i) The expected total cost to establish the new U.S. business enterprise is greater than $40 million; and

(ii) The foreign entity owns at least 10 percent of the voting interest (directly, or indirectly through an existing U.S. affiliate) in the new U.S. business enterprise.

(3) Form BE–13D—Report for an existing U.S. affiliate of a foreign parent when it expands its operations to include a new facility where business is conducted, and the expected total cost of the expansion is greater than $40 million.

(4) Form BE–13E—Report for a U.S. business enterprise that previously filed Form BE–13B or BE–13D. Form BE–13E collects updated cost information and will be collected annually for three years after the year of the establishment or expansion of the U.S. business enterprise.

(5) Form BE–13 Claim for Exemption—Report for a U.S. business enterprise that:

(i) was contacted by BEA but does not meet the requirements for filing Forms BE–13A, BE–13B, or BE–13D; or

(ii) whether or not contacted by BEA, met all requirements for filing Forms BE–13A, BE–13B, or BE–13D except the $40 million reporting threshold.

(d) *Due date.* The BE–13 forms are due no later than 45 calendar days after the acquisition is completed, the new U.S. business enterprise is established, the expansion is begun, the cost update is requested, or a notification letter is received from BEA by a U.S. business enterprise that does not meet the filing requirements for the survey.

[FR Doc. 2025–16832 Filed 9–2–25; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. FDA–2022–F–2725]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Hydrogen Peroxide

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the food additive regulation to provide for the safe use of hydrogen peroxide in food as an antimicrobial agent, oxidizing and reducing agent, and bleaching agent, and to remove sulfur dioxide. We are taking this action in response to a food additive petition filed by Cargill, Inc. (Cargill or petitioner).

DATES: This order is effective September 3, 2025. The incorporation by reference of certain material listed in the order is approved by the Director of the Federal Register as of September 3, 2025. Either electronic or written objections and requests for a hearing on the order must be submitted by 11:59 p.m. Eastern Time on October 3, 2025. See section VIII of this document for further information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept objections until 11:59 p.m. Eastern Time at the end of October 3, 2025. Objections 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 objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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 objections submitted to the Dockets Management Staff, FDA will post your objection, 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–2022–F–2725 for ''Secondary Direct Food Additives Permitted in Food for Human Consumption; Hydrogen Peroxide.'' Received objections, 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 an objection with confidential information that you do not wish to be made publicly available, submit your objections 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.'' We will review this copy, including the claimed confidential information, in our 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: Karen Hall, Office of Food Chemical Safety, Dietary Supplements, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–9195; or Keronica C. Richardson, Office of Policy, Regulations, and Information. Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 21, 2022 (87 FR 70752), FDA announced that we filed a food additive petition (FAP 2A4833) submitted by ToxStrategies on behalf of Cargill, Inc., 15407 McGinty Rd., Wayzata, MN 55391. The petition proposed that FDA amend the food additive regulations in 21 CFR 173.356 to provide for the safe use of hydrogen peroxide (CAS Reg. No. 7722–84–1) as an antimicrobial agent, oxidizing and reducing agent, and bleaching agent, and to remove sulfur dioxide. FDA is also updating the reference for specifications for hydrogen peroxide established in § 173.356(a) by incorporating by reference the monograph for hydrogen peroxide in the 14th edition of the Food Chemicals Codex, effective June 1, 2024 (FCC 14 hydrogen peroxide monograph). The current food additive regulation for the use of hydrogen peroxide (§ 173.356) indicates that the additive must meet the specifications in the 7th edition of the FCC (FCC 7), and Cargill indicated in the petition that hydrogen peroxide will meet the specifications in the 12th edition of the FCC (FCC 12). Since we received the petition, the FCC has been updated to the 14th edition (FCC 14). The specifications for hydrogen peroxide in FCC 7 and FCC 12 are identical to those in FCC 14. Therefore, we are amending § 173.356(a) by adopting, and incorporating by reference, the FCC 14 hydrogen peroxide monograph.

Hydrogen peroxide is affirmed as generally recognized as safe (GRAS) under 21 CFR 184.1366 for use as an antimicrobial agent, oxidizing and reducing agent, and bleaching agent, and to remove sulfur dioxide in specific foods at specified maximum treatment levels (46 FR 44439, September 4, 1981, and 51 FR 27172, July 30, 1986). As a condition of use, § 184.1366(d) requires that residual hydrogen peroxide be removed during the processing of food by appropriate physical and chemical means. In addition, § 184.1366(c) incorporates the requirement under § 184.1(b)(2) that a substance affirmed as GRAS with specific limitations may be used in food only within such limitations, including the category of food, functional use, and level of use, and that any additional uses require a food additive regulation. Therefore, any additional uses of hydrogen peroxide in processing food beyond those limitations set out in § 184.1366 require a food additive regulation.

The food additive regulations were subsequently amended to add § 173.356 (76 FR 11328, March 20, 2011) to approve the use of hydrogen peroxide as an antimicrobial agent in the production of modified whey by ultrafiltration methods. As a condition of use, § 173.356(b) requires that residual hydrogen peroxide be removed from the whey during processing by appropriate chemical or physical means.

The petition proposed to amend § 173.356 to provide for the use of hydrogen peroxide in food, including meat and poultry, as an antimicrobial agent, oxidizing and reducing agent, and bleaching agent, and to remove sulfur dioxide, in accordance with good manufacturing practice, provided that residual hydrogen peroxide is removed from the food during processing by appropriate chemical or physical means. We note that the current use as an antimicrobial agent in the production of modified whey listed in § 173.356 is encompassed by the broader uses proposed in this petition.

II. Evaluation of Safety

FDA reviewed data in the petition and other relevant material to evaluate the safety of the petitioned uses. Cargill discussed that hydrogen peroxide is inherently unstable and will dissociate into water and oxygen and that any measurable amounts of hydrogen peroxide would be required to be removed from food during processing by appropriate chemical or physical means (*e.g.,* during washing stages or decomposition during drying stages). Given the unstable nature of hydrogen peroxide and the requirement that residual hydrogen peroxide be removed, we concur that the petitioned uses will not result in an increased dietary exposure to hydrogen peroxide (Ref. 1).

In support of the petitioned uses of hydrogen peroxide, Cargill summarized the available toxicological data and information on hydrogen peroxide. Most of the data and information have been previously submitted to and reviewed by FDA as part of other regulatory submissions. None of these data and information raise new safety concerns regarding the use of hydrogen peroxide under the intended conditions of use. As the proposed uses are not expected to increase dietary exposure to hydrogen peroxide, FDA has no safety concerns regarding the petitioned uses of hydrogen peroxide (Ref. 2).

III. Incorporation by Reference

FDA is incorporating by reference the monograph for hydrogen peroxide from the FCC, 14th ed., 2024, which was approved by the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may purchase a copy of the material from the

U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852, 1–800–227–8772, *https://www.usp.org/.* You may inspect a copy at Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, between 9 a.m. and 4 p.m., Monday through Friday.

The FCC 14 hydrogen peroxide monograph sets forth a standard for purity and identity for hydrogen peroxide. The FCC 14 hydrogen peroxide monograph provides specifications and analytical methodologies to identify the substance and establish acceptable purity criteria.

As background, the current food additive regulation for the use of hydrogen peroxide (§ 173.356) indicates that the additive must meet the specifications of the hydrogen peroxide monograph in FCC 7. The petitioner indicated that the hydrogen peroxide petitioned in FAP 2A4833 complies with the specifications in the monograph for hydrogen peroxide in FCC 12. During our review of this petition, we noted that the most recent edition of the FCC was FCC 14. The specifications for hydrogen peroxide in FCC 14 are identical to those in both FCC 7 and FCC 12. Therefore, we are amending § 173.356(a) by adopting, and incorporating by reference, the FCC 14 hydrogen peroxide monograph.

IV. Conclusion

Based on the relevant data available to FDA and information in the petition, we conclude that there is reasonable certainty that no harm will result from the use of hydrogen peroxide in food as an antimicrobial agent, oxidizing and reducing agent, and bleaching agent, and to remove sulfur dioxide, in accordance with good manufacturing practice, and that such use will achieve its intended technical effects. Additionally, we are amending § 173.356(a) by adopting, and incorporating by reference, the FCC 14 hydrogen peroxide monograph.

V. Public Disclosure

In accordance with 21 CFR 171.1(h), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), FDA will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Paperwork Reduction Act of 1995

This order contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

If you will be adversely affected by one or more provisions of this order, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to this order may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

IX. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

Our review of this petition was limited to section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348). This order is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) through (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this order should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all food additive orders authorizing new uses and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

X. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.*

1. Memorandum from P. Wang, Chemistry Evaluation Branch, Division of Food Ingredients, to K. Hall, Regulatory Review Branch, Division of Food Ingredients, Human Foods Program (HFP), FDA, May 6, 2025.
2. Memorandum from J. Gingrich, Toxicology Review Branch, Division of Food Ingredients, to K. Hall, Regulatory Review Branch, Division of Food Ingredients, Human Foods Program (HFP), FDA, May 7, 2025.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Revise § 173.356 to read as follows:

§ 173.356 Hydrogen peroxide.

Hydrogen peroxide (H_2O_2, CAS Reg. No. 7722–84–1) may be safely used to treat food in accordance with the following conditions:

(a) Hydrogen peroxide meets the specifications of Hydrogen Peroxide, Food Chemicals Codex, 14th edition, effective June 1, 2024, which is incorporated by reference into this section. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration (FDA) and at the National Archives and Records Administration (NARA). Contact FDA at: the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday; phone: 240–402–7500; email: *IBR_Material_Inquiries@fda.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852; phone: 800–822–8772; email: *fcc@usp.org;* website: *https://www.usp.org.*

(b) The additive is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter, oxidizing and reducing agent defined in § 170.3(o)(22) of this chapter, and bleaching agent, and to remove sulfur dioxide in accordance with good manufacturing practice.

(c) Residual hydrogen peroxide is removed by appropriate chemical or physical means during the processing of food where it has been used.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16898 Filed 9–2–25; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 432

[EPA–HQ–OW–2021–0736; FRL–8885–03–OW]

RIN 2040–AG22

Clean Water Act Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The United States Environmental Protection Agency (the EPA or Agency) is withdrawing the proposed rule entitled ''Clean Water Act Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category,'' which published in the **Federal Register** on January 23, 2024. After considering public comments on the proposed rule, the EPA has decided not to finalize revised technology-based effluent limitations guidelines (ELGs) or pretreatment standards for the Meat and Poultry Products (MPP) industry, based on exercise of its statutory discretion and judgment that such revisions would not be appropriate.

DATES: As of September 3, 2025, the proposed rule published on January 23, 2024, at 89 FR 4474, is withdrawn. In accordance with 40 CFR part 23, this final action shall be considered issued for the purposes of judicial review at 1 p.m. Eastern Standard Time on September 3, 2025. Under section 509(b)(1) of the Clean Water Act (CWA), judicial review of the Administrator's final action regarding effluent limitations guidelines and pretreatment standards can only be done by filing a petition for review in the United States Court of Appeals within 120 days after the decision is considered issued for purposes of judicial review.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2021–0736. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Steve Whitlock, Engineering and Analysis Division, Office of Water (4303T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: 202–566–1541; email address: *Whitlock.Steve@epa.gov.*

SUPPLEMENTARY INFORMATION:

What other information is available to support this final action?

The action is supported by several documents, including:

- Development Document for Final Action on the Meat & Poultry Products Point Source Category Effluent Limitations Guidelines and Standards (Development Document), Document No. 821–R–25–001. This report summarizes the technical, engineering, and economic analyses that EPA considered in taking the final action, including cost of regulatory options, adverse non-water quality environmental impacts, effluent reductions and associated benefits, and calculation of the effluent limitations considered.
- Docket Index for Final Action for the Effluent Limitations Guidelines and Standards for the Meat and Poultry Products Point Source Category. This document provides a list of the additional memoranda, references, and other information the EPA considered in taking final action on the MPP ELGs.

I. Executive Summary

On January 23, 2024, the EPA proposed to revise the existing technology-based effluent limitations guidelines and standards for the meat and poultry products point source category. The Agency solicited comment on possible revisions and additions to the ELGs for existing and new sources in this category. The EPA took comment on a range of options in the proposed rule. The options included more stringent effluent limitations on total nitrogen, new effluent limitations on total phosphorus, updated effluent limitations for other pollutants, new pretreatment standards for indirect dischargers, and revised production thresholds for some of the subcategories in the existing rule. Additionally, the EPA also considered effluent limitations on chlorides, establishing effluent limitations for *E. coli* for direct dischargers, and including conditional limits for indirect dischargers that discharge to POTWs operating nutrient treatment technologies to remove nutrients. Inherent in the Agency's