

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

DMB

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Certifier D. Hawkins

[Docket No. 02F-0042]

**Secondary Direct Food Additives Permitted in Food for Human Consumption**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on meat carcasses, parts, trim, and organs. This action is in response to a petition filed by Ecolab, Inc.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*]. Submit written or electronic objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic objections to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3071.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of February 11, 2002 (67 FR 6265), FDA announced that a food additive petition (FAP 2A4731) had been filed by Ecolab Inc., Ecolab Center, 370 N. Wabasha St., St. Paul, MN 55102, proposing to amend the food additive regulations in Part 173 *Secondary Direct Food Additives Permitted in Food for Human Consumption* (21 CFR part 173) to provide for the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on meat parts, trim, and organs.

The agency has previously approved the use of the subject mixture on red meat carcasses (§ 173.370(b)(1)) in response to an earlier petition submitted by Ecolab, Inc. In the evaluation that led to that regulation, the agency considered “red meat” to include the species cattle, swine, sheep, goats, and equine. The United States Department of Agriculture’s Food Safety and Inspection Service (FSIS) uses the term “meat” to refer to these species (9 CFR 301.2). Thus, FDA is removing the term “red” as a descriptor for “meat carcasses” in § 173.370(b)(1) to make its terminology consistent with FSIS.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect as an antimicrobial agent on meat carcasses, parts, trim, and organs.

Therefore, FDA is approving the use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid as an antimicrobial agent on meat carcasses, parts, trim, and organs. Accordingly, § 173.370 is amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has 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. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

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

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which the objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically

so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### **List of Subjects in 21 CFR Part 173**

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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 21 CFR part 173 continues to read as follows:

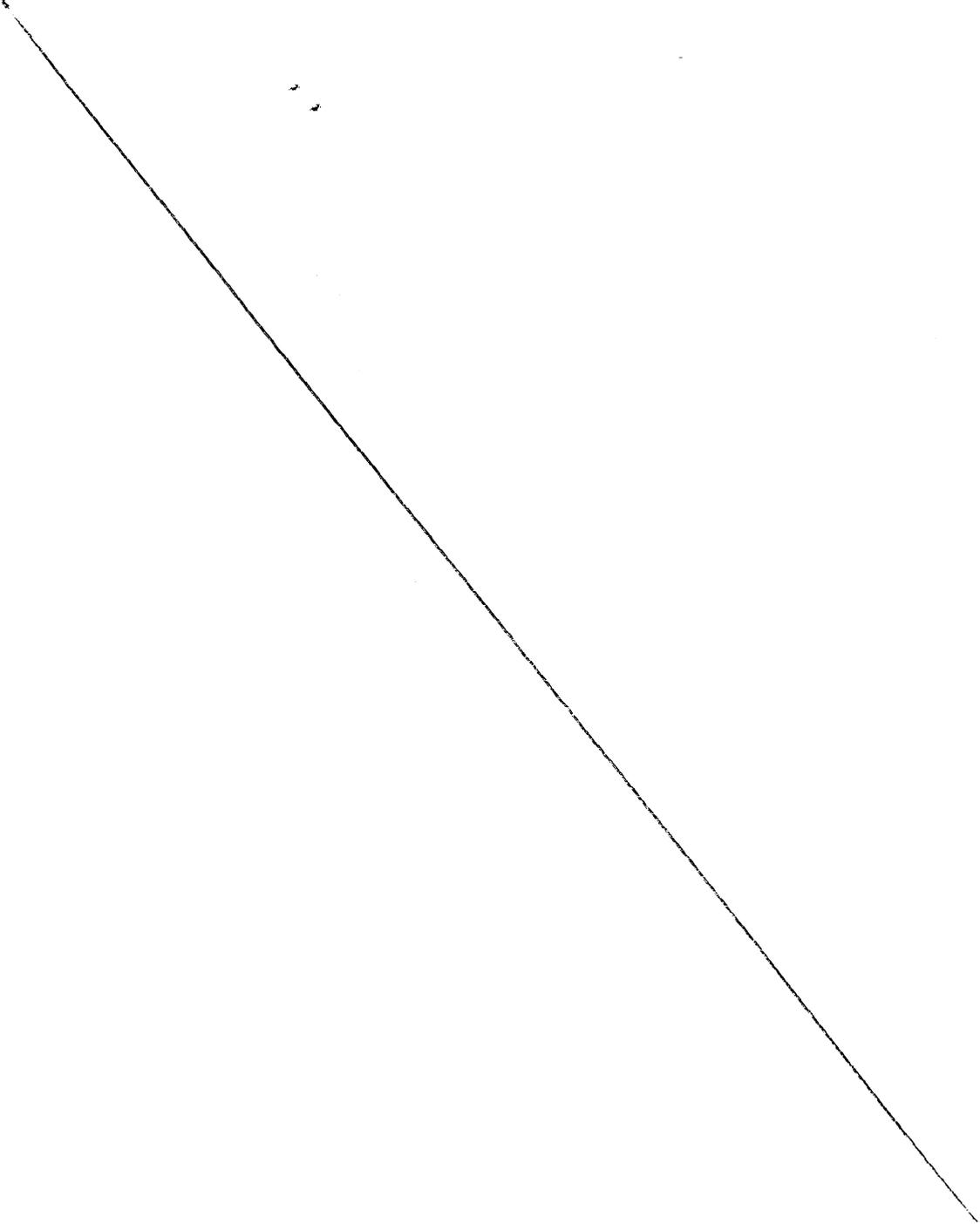
**Authority:** 21 U.S.C. 321, 342, 348.

2. Section 173.370 is amended by revising paragraph (b)(1) to read as follows:

**§ 173.370 Peroxyacids.**

\* \* \* \* \*

(b)(1) The additive is used as an antimicrobial agent on meat carcasses, parts, trim, and organs in accordance with current industry practice where the



maximum concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid, and the maximum concentration of hydrogen peroxide is 75 ppm.

\* \* \* \* \*

Dated: 9/18/02

September 18, 2002.

L. Robert Lake

L. Robert Lake,  
Director,  
Office of Regulations and Policy,  
Center for Food Safety and Applied Nutrition.  
[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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COPY OF THE ORIGINAL**

Dawn P. Hawkins