

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 01F-0142]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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 poultry carcasses, poultry parts, and organs. This action is in response to a petition filed by Ecolab, Inc.

DATES: This rule is effective September 19, 2001. Submit written objections and requests for a hearing by October 19, 2001. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in § 173.370 as of September 19, 2001.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3074.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of March 30, 2001 (66 FR 17430), FDA announced that a food additive petition (FAP 1A4728) had been filed by Ecolab, Inc., Ecolab Center, 370 Wabasha St., St. Paul, MN 55102. The petition proposed 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 poultry carcasses, poultry parts, and organs.

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 poultry carcasses, poultry parts, and organs. Therefore, 21 CFR 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 listed above. 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 (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections 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 (address above) written objections by October 19, 2001. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which 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 shall be submitted and shall be identified with the docket number found in the brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

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 paragraphs (b) and (c) to read as follows:

§ 173.370 Peroxyacids.

* * * * *

(b)(1) The additive is used as an antimicrobial agent on red meat carcasses 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.

(2) The additive is used as an antimicrobial agent on poultry carcasses, poultry parts, and organs in accordance with current industry standards of good manufacturing practice (unless precluded by the U.S. Department of Agriculture's standards of identity in 9 CFR part 381, subpart P) where the maximum concentration of peroxyacids is 220 parts per million (ppm) as peroxyacetic acid, the maximum concentration of hydrogen peroxide is 110 ppm, and the maximum concentration of 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) is 13 ppm.

(c) The concentrations of peroxyacids and hydrogen peroxide in the additive are determined by a method entitled "Hydrogen Peroxide and Peracid (as Peracetic Acid) Content," July 26, 2000, developed by Ecolab, Inc., St. Paul, MN, which is incorporated by reference. The concentration of 1-hydroxyethylidene-

1,1-diphosphonic acid is determined by a method entitled "Determination of 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) Peroxyacid/Peroxide-Containing Solutions," August 21, 2001, developed by Ecolab, Inc., St. Paul, MN, which is incorporated by reference. The Director of the Office of the Federal Register approves these incorporations by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of these methods from the Division of Petition Review, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

Dated: September 6, 2001.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 01-23263 Filed 9-18-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Western Alaska-01-002]

RIN 2115-AA97

Safety Zone; Gulf of Alaska, Southeast of Narrow Cape, Kodiak Island, Alaska

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule; correction.

SUMMARY: The Coast Guard is correcting the effective period for a temporary final rule for a safety zone in the Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, Alaska, that was published in the **Federal Register** on August 21, 2001 and then amended in the **Federal Register** on August 29, 2001. This correction is being made because of a revision in the window of time that the rocket is now scheduled to launch. This correction changes the effective period from 2 p.m. to 7:30 p.m. on September 17, 2001, to the same hours each day from September 21, 2001 through September 29, 2001.

DATES: 33 CFR 165.T-01-002 published August 21, 2001 (66 FR 43776), corrected August 29, 2001 (66 FR 45619), and as further corrected in this document, is effective September 21, 2001 through September 29, 2001.

ADDRESSES: The public docket for this rulemaking is maintained by Coast Guard Marine Safety Office Anchorage, 510 "L" Street, Suite 100, Anchorage, AK 99501. Materials in the public docket are available for inspection and copying at Coast Guard Marine Safety Office Anchorage. Normal office hours are 7:30 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Diane Kalina, Marine Safety Office Anchorage, at (907) 271-6700.

SUPPLEMENTARY INFORMATION: The Coast Guard published a temporary final rule in the **Federal Register** on August 21, 2001, (66 FR 43774) establishing a temporary safety zone in the Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, Alaska, effective from 2 p.m. on August 31, 2001 through 7:30 p.m. on September 15, 2001. We then published a correction in the **Federal Register** on August 29, 2001 (66 FR 45619) changing the effective period to a single day, September 17, 2001, to reflect a change in the launch schedule. The zone is needed to protect the safety of persons and vessels operating in the vicinity during a rocket launch from the Alaska Aerospace Development Corporation (AADC), Narrow Cape, Kodiak Island facility. The AADC recently revised the window of time for the rocket to launch to September 21, 2001 through September 29, 2001. The Coast Guard is amending the effective period of the rule to correspond with the new schedule for the launch. This correction changes the one-day effective period, September 17, 2001, to a 9-day effective period, September 21, 2001 through September 29, 2001.

In rule FR Doc. 01-21083 published on August 21, 2001 (66 FR 43774), as amended by a correction published on August 29, 2001 (66 FR 45619), make the following corrections. On page 43775, in the first column, starting on line 3, remove the words "on September 17, 2001" and add in its place the words "each day between September 21, 2001 and September 29, 2001". On page 43775, in the first column, starting on line 27, remove the words "on September 17, 2001" and add in its place the words "each day between September 21, 2001 and September 29, 2001". On page 43775, in the second column, starting on line 36, remove the words "on September 17, 2001" and add in its place the words "from September 21, 2001 to September 29, 2001". On page 43776, in the second column, starting on line 4, remove the words "from 2 p.m. through 7:30 p.m. on September 21, 2001" and add in its place the words "from 2 p.m. through

7:30 p.m. each day from September 21, 2001 through September 29, 2001".

Dated: September 6, 2001.

W.J. Hutmacher,

Captain, U.S. Coast Guard, Captain of the Port, Western Alaska.

[FR Doc. 01-23340 Filed 9-14-01; 4:51 pm]

BILLING CODE 4910-15-U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MD059/71/98/114-3077; FRL-7057-4]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Rate of Progress Plans, Corrections to the Base Year Inventories, and Contingency Measures for the Maryland Portion of the Philadelphia-Wilmington-Trenton Ozone Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving State Implementation Plan (SIP) revisions submitted by the State of Maryland. These revisions establish the three percent per year emission reduction rate-of-progress (ROP) requirement for the period from 1996 through 2005 for the Maryland portion of the Philadelphia-Wilmington-Trenton ozone nonattainment area (the Philadelphia area), namely Cecil County. EPA is also approving contingency measures for failure to meet ROP and corrections to the 1990 base year inventories of ozone precursor emissions for Cecil County. EPA is approving these revisions in accordance with the requirements of the Clean Air Act.

EFFECTIVE DATE: This final rule is effective on October 19, 2001.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and Maryland Department of the Environment, 2500 Broening Highway, Baltimore, Maryland, 21224.

FOR FURTHER INFORMATION CONTACT: Kristeen Gaffney, (215) 814-2092. Or by e-mail at gaffney.kristeen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 13, 2001 (66 FR 36717), EPA published a notice of proposed