

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.

Any person who will be adversely affected by this regulation may at any time on or before October 3, 1996, file with the Dockets Management Branch (address above) written objections thereto. 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 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.

Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Monsanto Material Safety Data Sheet for Monsanto Product Name DEQUEST 2010 DEFLOCCULANT and SEQUESTANT.

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: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. Section 173.315 is amended in the table in paragraph (a)(2) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

**§ 173.315 Chemicals used in washing or to assist in the lye peeling of fruits and vegetables.**

* * *	* * *
(a) * * *	
(2) * * *	

July 13, 1995 (60 FR 36150), FDA announced that a food additive petition (FAP 5A4459) had been filed by Ecolab Inc., 370 North Wabasha St., St. Paul, MN 55102. The petition proposed to amend the food additive regulations in § 173.315 *Chemicals used in washing or to assist in the lye peeling of fruits and vegetables* (21 CFR 173.315) to provide for the safe use of a mixture of peroxyacetic acid, acetic acid and hydrogen peroxide to control microbial growth in water contacting fruits and vegetables.

An antimicrobial solution used to wash fruits and vegetables is potentially subject to regulation as a food additive under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348), or as a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136(u)), depending upon the status of the fruit or vegetable. FDA regulates antimicrobial solutions as food additives under the act when such solutions are used on processed food.

Substances	Limitations
* * *	* * *
1-Hydroxyethylidene-1,1-diphosphonic acid.	May be used only with peroxyacetic acid. Not to exceed 4.8 ppm in wash water. Limited to use on fruits and vegetables that are not raw agricultural commodities.
* * *	* * *

\* \* \*

Dated: August 26, 1996.

Fred A. Shank,  
Director, Center for Food Safety and Applied Nutrition.  
[FR Doc. 96-22286 Filed 8-30-96; 8:45 am]  
BILLING CODE 4160-01-F

**21 CFR Part 173**

**[Docket No. 95F-0161]**

**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, acetic acid, and hydrogen peroxide to reduce the microbial load in water used to wash certain fruits and

vegetables. Elsewhere in this issue of the Federal Register, FDA is also publishing a document that provides for the safe use of a mixture of peroxyacetic acid, acetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) to reduce the microbial load in water used to wash certain fruits and vegetables. This action is in response to a petition filed by Ecolab Inc.

**DATES:** Effective September 3, 1996; written objections and requests for a hearing by October 3, 1996.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3072.

**SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of

The Environmental Protection Agency (EPA) regulates antimicrobial solutions as pesticide chemicals under FIFRA when the solutions are used on raw agricultural commodities.

Under section 201(q)(1) of the act (21 U.S.C. 321(q)(1)), as amended by the Food Quality Protection Act of 1996, the term "pesticide chemical" means a pesticide as defined in FIFRA. Under FIFRA's regulatory scheme, an antimicrobial solution used on or in processed food does not come within the definition of the term pesticide. FIFRA defines a pesticide as any substance intended for preventing, destroying, repelling, or mitigating any pest (7 U.S.C. 136(u)); the definition of pest includes "fungus" (7 U.S.C. 136(t)). However, excluded from the definition of fungus are rust, smut, mildew, mold, yeast, and bacteria on or in processed food (7 U.S.C. 136(k)). Therefore, by definition, an antimicrobial solution used on or in processed food is not a pesticide because it does not prevent, destroy, repel, or mitigate a "pest," within the meaning of that term (7 U.S.C. 136(t)). Thus, such a solution is not a pesticide chemical under the act.

FDA received one comment in response to the notice of filing of this petition. The comment expressed concern that the chemical mixture appeared to be a biocide and may require FIFRA pesticide registration. The comment also stated that the preparation would be regulated more accurately under § 178.1010 *Sanitizing solutions* (21 CFR 178.1010).

As noted above, an antimicrobial formulation used on raw agricultural commodities is regulated as a pesticide chemical and thus, may require registration under FIFRA, as well as a tolerance established under section 408 of the act (21 U.S.C. 346a). Similarly, FDA has jurisdiction over antimicrobial solutions used on processed foods. Thus, consistent with FDA's jurisdiction, FDA's approval of this formulation is limited to its use in washing fruits and vegetables other than those that are raw agricultural commodities. This approval is consistent with the division of responsibility between FDA and EPA over solutions of this type. FDA has, however, referred the petitioner to EPA in order to ascertain whether FIFRA pesticide registration and a tolerance under section 408 of the act are required for any uses not regulated by FDA. Thus, FDA's decision in this final rule takes into consideration the

jurisdictional question between FDA and EPA raised by the comment.

FDA disagrees with the comment to the extent that it suggests that the solution in question should be regulated as a sanitizing solution. The petitioned use for this formulation is to reduce the microbial load in water used to wash fruits and vegetables, consistent with the technical effect listed in 21 CFR 170.3(o)(2). This use is different from its use as a sanitizing solution. Because the petitioned conditions of use differ from those for a sanitizing solution, approval under § 173.315 is necessary and appropriate. The point of this comment is not entirely clear. To the extent that this comment suggests that the solution is not safe for use as a washing solution for fruits and vegetables, the agency has determined that the petitioned use is safe.

FDA has evaluated data in the petition and other relevant material. As part of its review, FDA evaluated the safety of each of the components of the antimicrobial solution. Based on this information, the agency concludes that the proposed use of the additive is safe, that it will achieve its intended technical effect of reducing the microbial load in water used to wash fruits and vegetables, and that therefore, the regulations in § 173.315 should be 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 information 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.

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.

Any person who will be adversely affected by this regulation may at any time on or before October 3, 1996, file

with the Dockets Management Branch (address above) written objections thereto. 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 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: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. Section 173.315 is amended in the table in paragraph (a)(2) by alphabetically adding two new entries under the headings "Substances" and "Limitations" to read as follows:

**§ 173.315 Chemicals used in washing or to assist in the lye peeling of fruits and vegetables.**

\* \* \* \* \*

(a) \* \* \*

(2) \* \* \*

Substances	Limitations
* * *	* * *
Hydrogen peroxide.	Used in combination with acetic acid to form peroxyacetic acid. Not to exceed 59 ppm in wash water. Limited to use on fruits and vegetables that are not raw agricultural commodities.
Peroxyacetic acid.	Prepared by reacting acetic acid with hydrogen peroxide. Not to exceed 80 ppm in wash water. Limited to use on fruits and vegetables that are not raw agricultural commodities.
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Dated: August 26, 1996.  
Fred R. Shank,  
*Director, Center for Food Safety and Applied Nutrition.*  
[FR Doc. 96-22287 Filed 8-30-96; 8:45 am]  
BILLING CODE 4160-01-F

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.  
ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (Admiralty) of the Navy has determined that USS HOPPER (DDG 70) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: August 1, 1996.

FOR FURTHER INFORMATION CONTACT: Lieutenant M.W. Kerns, JAGC, U.S. Navy, Assistant Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332-2400, Telephone number: (703) 325-9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR Part 706. This amendment provides notice that the

Deputy Assistant Judge Advocate General (Admiralty) of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS HOPPER (DDG 70) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I, paragraph 2(f)(i) pertaining to placement of the masthead light or lights above and clear of all other lights and obstructions; Annex I, paragraph 3(a) pertaining to the location of the forward masthead light in the forward quarter of the vessel, and the horizontal distance between the forward and after masthead lights; and, Annex I, paragraph 3(c) pertaining to placement of task lights not less than two meters from the fore and aft centerline of the ship in the athwartship direction. The Deputy Assistant Judge Advocate General (Admiralty) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR Parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

Accordingly, 32 CFR Part 706 is amended as follows:

PART 706—[AMENDED]

1. The authority citation for 32 CFR Part 706 continues to read:

Authority: 33 U.S.C. 1605.

2. Table Four, Paragraph 15 of § 706.2 is amended by adding the following entry:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

*	*	*	*	*
Vessel			Num-ber	Horizontal distance from the fore and aft centerline of the vessel in the athwartship direction
*	*	*	*	*
USS HOPPER .....			DDG 70	1.83 meters.
*	*	*	*	*

3. Table Four, Paragraph 16 of § 706.2 is amended by adding the following entry:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

*	*	*	*	*
Vessel			Num-ber	Obstruction angle relative ship's headings
*	*		*	*
USS HOPPER .....		DDG 70	102.25 thru 112.50°	
*	*		*	*

4. Table Five of § 706.2 is amended by adding the following entry:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

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