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 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

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 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.886 is amended by revising paragraph (c)(2) to read as follows:

§ 172.886 Petroleum wax.

* * * * *

(c) * * *

(2) Poly(alkylacrylate) (CAS Reg. No. 27029–57–8), made from long chain (C_{16}–C_{22}) alcohols and acrylic acid, or poly(alkylmethacrylate) (CAS Reg. No. 179529–36–3), made from long chain (C_{18}–C_{22}) methacrylate esters, having:

(i) A number average molecular weight between 40,000 and 100,000;

(ii) A weight average molecular weight (MW_w) to number average molecular weight (MW_n) ratio (MW_w/MW_n) of not less than 3; and

(iii) Unreacted alkylacrylate or alkylmethacrylate monomer content not in excess of 14 percent, as determined by a method entitled ''Method for Determining Weight-Average and Number-Average Molecular Weight and for Determining Alkylacrylate Monomer Content of Poly(alkylacrylate) used as Processing Aid in Manufacture of Petroleum Wax,'' which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Petroleum wax shall contain not more than 1,050 parts per million of poly(alkylacrylate) or poly(alkylmethacrylate) residues as determined by a method entitled ''Method for Determining Residual Level of Poly(alkylacrylate) in Petroleum Wax,'' which is incorporated by reference. Copies are available from the addresses cited in this paragraph.

* * * * *

Dated: August 5, 1999.

Janice F. Oliver,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–20889 Filed 8–12–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 98F–0014]

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 acidified solutions of sodium chlorite as an antimicrobial agent in processing water and ice intended for use in contact with seafood. This action is in response to a petition filed by Bio-Cide International, Inc.

DATES: The regulation is effective August 13, 1999; written objections and requests for a hearing by September 13, 1999. 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 certain publications in § 173.325(e) (21 CFR 173.325(e)), effective August 13, 1999.

ADDRESSES: Written objections may be sent 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 January 26, 1998 (63 FR 3749), FDA announced that a food additive petition (FAP 8A4568) had been filed by Bio-Cide International, Inc., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in 21 CFR part 173 to provide for the safe use of acidified sodium chlorite solutions in processing water and ice intended for use in contact with seafood. In its evaluation of the petition, the agency has concluded that the microbial population of the water and ice is reduced, as long as a residual level of available acidified solution of sodium chlorite is maintained.

Under the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA) (Public Law 105–324), the use of an acidified solution of sodium chlorite used as an antimicrobial agent in water and ice that are used to rinse, wash, thaw, transport, or store seafood is subject to regulation by FDA as a food additive. Such solutions are to be used ''in water that comes in contact with the food in the preparing, packing, or holding of the food for commercial purposes,'' and therefore, such use is exempt from the definition of the term ''pesticide chemical'' (21 U.S.C. 321(q)(1)(B)(i)). Moreover, as stated in the ''Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances'' (63 FR 54532 at 54541, October 9, 1998), FDA discussed, in the context of its jurisdiction over antimicrobial substances, what constitutes ''processing'' of seafood, which interpretation is unchanged by ARTCA. FDA stated that fish that is harvested is ''processed.'' Consequently, activities done postharvest to seafood, such as handling, storing, preparing, heading, eviscerating, shucking, or holding, would be activities done to ''processed food,'' not raw agricultural

commodities. Therefore, under ARTCA, fish processing operations and commercial fishing vessels would not be considered a ''field'' or a ''treatment facility where raw agricultural commodities are the only food treated'' (21 U.S.C. 321(q)(1)(B)(i)), and thus, an antimicrobial applied to water to which seafood is added at such locations would not be subject to regulation as a ''pesticide chemical,'' but instead would be subject to regulation as a ''food additive'' under the Federal Food, Drug, and Cosmetic Act (the act).

Although the use of an acidified solution of sodium chlorite as an antimicrobial agent in water and ice that are used to rinse, wash, thaw, transport, or store seafood is regulated under section 409 of the act (21 U.S.C. 348) as a food additive, this intended use may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to market acidified solutions of sodium chlorite for such use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive to reduce the microbial contamination of water and ice that are used to rinse, wash, thaw, transport, or store seafood is safe, will achieve its intended technical effect, and therefore, that the regulation in § 173.325 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 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 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 on or before September 13, 1999, 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 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 173.325 is amended by redesignating paragraph (d) as paragraph (e), and by adding new paragraph (d) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(d) The additive is used as an antimicrobial agent in water and ice that are used to rinse, wash, thaw, transport, or store seafood in accordance with current industry standards of good manufacturing practice. The additive is produced by mixing an aqueous solution of sodium chlorite with any GRAS acid to achieve a pH in the range of 2.5 to 2.9 and diluting this solution with water to achieve an actual use concentration of 40 to 50 parts per million (ppm) sodium chlorite. Any seafood that is intended to be consumed raw shall be subjected to a potable water rinse prior to consumption.

* * * * *

Dated: August 5, 1999.

Janice F. Oliver,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–20890 Filed 8–12–99; 8:45 am]

BILLING CODE 4160–01–F

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Reinstatement of Exchange Visitors Who Fail To Maintain Valid Program Status

AGENCY: United States Information Agency.

ACTION: Interim Final Rule with request for comments.

SUMMARY: This is an Interim Final Rule with request for comments being made by the United States Information Agency (hereinafter ''the Agency''). The rule will amend the Agency's Exchange Visitor Program regulations regarding reinstatement of J–1 exchange visitors to valid program status. This Interim Final Rule supersedes the Agency's Statement of Policy which was published in the **Federal Register** on April 24, 1997.

EFFECTIVE DATE: This Interim Final Rule is effective on August 13, 1999. Comments regarding this rulemaking will be accepted until September 13, 1999.

ADDRESSES: United States Information Agency, Office of the General Counsel, 301 Fourth Street, SW, Room 700, Washington, DC 20547–0001.

FOR FURTHER INFORMATION CONTACT: Lorie J. Nierenberg, Office of the General Counsel, United States Informaiton Agency, 301 Fourth Street, SW, Washington, DC 20547; telephone (202) 619–6084.