label shall also clearly and conspicuously disclose, either in close proximity to that asterisk or elsewhere on the label, the following statement:

*[The encircled ''E''] means this bulb meets Federal minimum efficiency standards.

(i) If the statement is not disclosed on the principal display panel, the asterisk shall be followed by the following statement:

See [Back,Top, Side] panel for details.

(ii) For purposes of this paragraph (e), the encircled capital letter ''E'' shall be clearly and conspicuously disclosed in color-contrasting ink on the label of any covered product that is a general service fluorescent lamp and will be deemed ''conspicuous,'' in terms of size, if it appears in typeface at least as large as either the manufacturer's name or logo or another logo disclosed on the label, such as the ''UL'' or ''ETL'' logos, whichever is larger.

(3)(i) A manufacturer or private labeler who distributes general service fluorescent lamps, compact fluorescent lamps, or general service incandescent lamps (including incandescent reflector lamps) without labels attached to the lamps or without labels on individual retail-sale packaging for one or more lamps may meet the disclosure requirements of paragraphs (e)(1) and (e)(2) of this section by making the required disclosures, in the manner and form required by those paragraphs, on the bulk shipping cartons that are to be used to display the lamps for retail sale.

(ii) Instead of labeling any covered product that is a general service fluorescent lamp with the encircled ''E'' and with the statement described in paragraph (e)(2) of this section, a manufacturer or private labeler who would not otherwise put a label on such a lamp may meet the disclosure requirements of that paragraph by permanently marking the lamp clearly and conspicuously with the encircled ''E''.

* * * * *

By direction of the Commission, Commissioner Thompson dissenting.

Donald S. Clark,

Secretary.

[FR Doc. 98–19212 Filed 7–17–98; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 94F–0040]

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 chlorine dioxide as an antimicrobial agent in water used to wash certain fruits and vegetables. This action is in response to a petition filed by the National Food Processors Association.

DATES: The regulation is effective July 20, 1998; written objections and requests for a hearing by August 19, 1998.

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–217), 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 24, 1994 (59 FR 13970), FDA announced that a food additive petition (FAP 4A4415) had been filed by the National Food Processors Association, 1401 New York Ave. NW., Washington, DC 20005. The petition proposed that the food additive regulations be amended to provide for the safe use of chlorine dioxide to disinfect waters in contact with fresh fruits and vegetables intended for human consumption. In its evaluation of the petition, the agency has concluded that the water is not disinfected, but the microbial contamination of the water is reduced.

An antimicrobial added to water used to wash fruits and vegetables may be 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 may be subject to regulation as a pesticide chemical under section 408 of the act (21 U.S.C. 346a), depending upon the status of the fruit or vegetable which is washed with the antimicrobial solution. FDA regulates antimicrobials added to water used in food and for food processing.[1] An antimicrobial substance added to water used to wash fruits and vegetables that are not raw agricultural commodities[2] is an antimicrobial ''used in food and for food processing.'' EPA regulates, as pesticides under FIFRA (7 U.S.C. 136(u)) and as pesticide chemicals under section 201(q) of the act, antimicrobial substances directed against microbes in water used to wash raw agricultural commodities.

The petition proposed the use of chlorine dioxide in water for contact with fresh fruits and vegetables, regardless of whether such fruits and vegetables are raw agricultural commodities or processed food. This proposed use would include uses subject to EPA regulatory authority, as well as FDA jurisdiction. Because FDA can act only to approve those uses subject to its jurisdiction, the approval set out in this final rule is limited to the use of chlorine dioxide in water used to wash fruits and vegetables that are not raw agricultural commodities. Any person who wishes to request an approval for the use of chlorine dioxide in water used to wash raw agricultural commodities should consult with EPA to ascertain whether a FIFRA pesticide registration and a section 408 of the act tolerance or exemption from the requirement for such tolerance would be required by EPA.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of chlorine dioxide to reduce the microbial contamination of water used to wash fruits and vegetables, other than raw agricultural commodities, is safe and that the additive will achieve its intended technical effect. FDA has also considered the safety of chlorine dioxide breakdown products, i.e., chlorite and chlorate, and concludes

[1] This is consistent with the memorandum of understanding (MOU) between FDA and the Environmental Protection Agency (EPA) on the jurisdiction over substances in drinking water (44 FR 42775, July 20, 1979). Moreover, an antimicrobial that is added to water used in food and for food processing is an antimicrobial that is used in or on a ''processed food.'' The use of an antimicrobial in or on processed food is subject to FDA's regulatory authority as a food additive under section 409 of the act. Such use is not a pesticide use because pests that are in or on processed food are excepted from the definition of fungus in 7 U.S.C. 136(k) and from the definition of pest in 40 CFR 152.5. Therefore, such an antimicrobial is neither a ''pesticide'' under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136(u)) nor a ''pesticide chemical'' under section 201(q) of the act (21 U.S.C. 321(q)).

[2] Such nonraw agricultural commodities include, for example, those that are cut, peeled, sliced, chopped, ground, irradiated, or cooked.

that residues of these compounds would be removed from the treated produce if the treatment with chlorine dioxide is followed by a potable water rinse or by blanching, cooking or canning. Therefore, the agency is including in the regulation the requirement that treatment of fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse or by blanching, cooking or canning. Based on the agency's conclusions concerning this proposed use, the regulations in 21 CFR 173.300 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.

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.

Any person who will be adversely affected by this regulation may at any time on or before August 19, 1998, 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.

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

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, 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 173.300 is amended by revising paragraph (b) to read as follows:

§ 173.300 Chlorine dioxide.

* * * * *

(b)(1) The additive may be used as an antimicrobial agent in water used in poultry processing in an amount not to exceed 3 parts per million (ppm) residual chlorine dioxide as determined by Method 4500–ClO_2 E, referenced in paragraph (a) of this section, or an equivalent method.

(2) The additive may be used as an antimicrobial agent in water used to wash fruits and vegetables that are not raw agricultural commodities in an amount not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500–ClO_2 E, referenced in paragraph (a) of this section, or an equivalent method. Treatment of the fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse or by blanching, cooking, or canning.

Dated: July 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–19314 Filed 7–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F–0405]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

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 aluminum borate as an antistatic agent and/or antifogging agent for olefin polymers intended for use as packaging materials in contact with food. This action is in response to a petition filed by Shikoku Chemical Corp.

DATES: The regulation is effective July 20, 1998; written objections and requests for a hearing by August 19, 1998.

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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 25, 1997 (62 FR 50387), FDA announced that a food additive petition (FAP 7B4559) had been filed by Shikoku Chemical Corp., c/o SRS International Corp., suite 1000, 1625 K St. NW., Washington, DC 20006–1604. The petition proposed to amend the food additive regulations in § 178.3130 *Antistatic and/or antifogging agents in food-packaging materials* (21 CFR 178.3130) to provide for the safe use of aluminum borate as an antistatic and/or antifogging agent for olefin polymers complying with 21 CFR 177.1520(c) as packaging materials intended for use in contact with food.

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, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.3130 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the