necessarily represent interpretations by the Commission.'' 61 FR at 42149 n. 24.

Finally, although the Commission is indefinitely delaying the effective date of the Interpretative Release, CPOs and CTAs may continue to rely on the positions stated therein as ''safe harbor'' positions to aid CTAs and CPOs making use of electronic media pending further statements of the Commission's views. Additionally, the Pilot Program for electronic filing of CPO and CTA disclosure documents, which commenced on October 15, 1996, as originally proposed, is not affected.

Issued in Washington, DC, on December 11, 1996, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 96–31928 Filed 12–13–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 90F–0195]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Curdlan

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 curdlan as a formulation aid, processing aid, stabilizer and thickener or texturizer in foods. This action is in response to a petition filed by Takeda Chemical Industries, Ltd.

DATES: The regulation is effective December 16, 1996. Submit written objections and requests for a hearing by January 15, 1997. 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 21 CFR 172.809(b), effective December 16, 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: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 17, 1990 (55 FR 29106), FDA announced that a food additive petition (FAP 0A4200) had been filed by Takeda Chemical Industries, Ltd., c/o International Research and Development Corp. (now MPI Research), Mattawan, MI 49071, proposing that the food additive regulations be amended to provide for the safe use of β-1,3-glucan derived from *Alcaligenes faecalis* var. *myxogenes*. In the same notice, the agency also announced that the proposed common or usual name of the additive was curdlan.

The agency is accepting curdlan as the common or usual name of the additive. Based on the data in the petition and other relevant material, the agency reached the following conclusions: (1) Curdlan consists of a glucose polymer and a small amount of inorganic salts, mainly sodium chloride, (2) curdlan lacks specific toxicity and the producing organism, *Alcaligenes faecalis* var. *myxogenes*, is nonpathogenic and nontoxicogenic, and (3) there is a history of safe consumption of similar glucose polymers in food. Based on this information, the agency concludes that the proposed food use of curdlan is safe, that the additive will achieve its intended technical effect, and that therefore, the regulations in 21 CFR part 172 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 January 15, 1997 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 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 of the 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: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. New § 172.809 is added to subpart I to read as follows:

§ 172.809 Curdlan.

Curdlan may be safely used in accordance with the following conditions:

(a) Curdlan is a high molecular weight polymer of glucose (β-1,3-glucan; CAS Reg. No. 54724–00–4) produced by pure culture fermentation from the nonpathogenic and nontoxicogenic bacterium *Alcaligenes faecalis* var. *myxogenes*.

(b) Curdlan meets the following specifications when it is tested according to the methods described or referenced in the document entitled ''Analytical Methods for Specification Tests for Curdlan,'' by Takeda Chemical Industries, Ltd., 12–10 Nihonbashi, 2–Chome, Chuo-ku, Tokyo, 103, Japan, 1996, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS–215), 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., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(1) Positive for curdlan.

(2) Assay for curdlan (calculated as anhydrous glucose), not less than 80 percent.

(3) pH of 1 percent aqueous suspension, 6.0–7.5.

(4) Lead, not more than 0.5 mg/kg.

(5) Heavy metals (as Pb), not more than 0.002 percent.

(6) Total nitrogen, not more than 0.2 percent.

(7) Loss on drying, not more than 10 percent.

(8) Residue on ignition, not more than 6 percent.

(9) Gel strength of 2 percent aqueous suspension, not less than $600x10^3$ dyne per square centimeter.

(10) Aerobic plate count, not more than 10^3 per gram.

(11) Coliform bacteria, not more than 3 per gram.

(c) Curdlan is used or intended for use in accordance with good manufacturing practice as a formulation aid, processing aid, stabilizer and thickener, and texturizer in foods for which standards of identity established under section 401 of the act do not preclude such use.

Dated: November 27, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–31809 Filed 12–13–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 178

[Docket No. 96F–0164]

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 expanded safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food. This action is in response to a petition filed by Asahi Denka Kogyo K.K.

DATES: Effective December 16, 1996; written objections and requests for a hearing by January 15, 1997.

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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), 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 May 30, 1996 (61 FR 27085), FDA announced that a food additive petition (FAP 6B4504) had been filed by Asahi Denka Kogyo K.K., 2–13 Shirahata 5–Chome, Urawa City, Saitama 336, Japan. The petition proposed to amend the food additive regulations in § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) to provide for the additional safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene 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 food additive will achieve its intended technical effect, and that therefore, the regulations in § 178.3295 should be amended as set forth below.

FDA's review of this petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition. The Committee noted that for many years, formaldehyde has been known to be a carcinogen by the inhalation route, but it concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two drinking water studies on formaldehyde: (1) A preliminary report of carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1); and (2) a negative study by Til et al. (1989), conducted in the Netherlands (Ref. 2). The Committee reviewed both studies and concluded, concerning the Soffritti study, ''* * * that data, reported were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde'' (Ref. 3). This conclusion is based on a lack of critical details in the study, questionable histopathological conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

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 January 15, 1997 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