

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 96F-0242]

Indirect Food Additives: Paper and Paperboard Components

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 additional safe use of perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(γ , ω -perfluoroC₄₋₂₀alkylthio)methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide, as an oil and water repellent for paper and paperboard intended for use in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective March 7, 1997; written objections and requests for a hearing by April 7, 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 July 18, 1996 (61 FR 37483), FDA announced that a food additive petition (FAP 6B4513) had been filed by Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419-8300. The petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the additional safe use of perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(γ , ω -perfluoroC₄₋₂₀alkylthio)methyl]-1,3-propanediol, polyphosphoric acid and

ammonium hydroxide, as an oil and water repellent for paper and paperboard intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive in paper and paperboard products in contact with non-alcoholic foods under condition of use C through G as described in Table 2 of § 176.170(c) is safe, that the additive will have the intended technical effect, and, therefore, that § 176.170 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. No comments were received during the 30 day comment period specified in the filing notice for comments on the environmental assessment submitted with the petition.

Any person who will be adversely affected by this regulation may at any time on or before April 7, 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 176

Food additives, Food packaging.

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 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: Secs. 201, 402, 406, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348, 379e).

2. Section 176.170 is amended in the table in paragraph (a)(5) by revising the entry for "Perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(γ , ω -perfluoroC₄₋₂₀alkylthio)methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide" under the heading "Limitations" to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

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| * | * | * | * | * |
| (a) | * | * | * | |
| (5) | * | * | * | |

List of Substances	Limitations
<p style="text-align: center;">* * *</p> <p>Perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(γ,ω-perfluoroC₄₋₂₀alkylthio)methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide.</p> <p style="text-align: center;">* * *</p>	<p style="text-align: center;">* * * *</p> <p>For use only as an oil and water repellent at a level not to exceed 0.44 percent perfluoroalkyl actives by weight of the finished paper and paperboard in contact with non-alcoholic foods under condition of use H as described in Table 2 of paragraph (c) of this section; and in contact with food of types III, IV-A, V, VII-A, and IX described in Table 1 of paragraph (c) of this section under conditions of use C through G as described in Table 2 of paragraph (c) of this section.</p> <p style="text-align: center;">* * * *</p>

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Dated: February 7, 1997.
 Fred R. Shank,
Director, Center for Food Safety and Applied Nutrition.
 [FR Doc. 97-5558 Filed 3-6-97; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08-97-005]

RIN 2115-AE47

Drawbridge Operation Regulation; Inner Harbor Navigation Canal, LA

AGENCY: Coast Guard, DOT.
ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the regulation for the operation of the L&N Railroad/Old Gentilly Road bascule span drawbridge across the Inner Harbor Navigation Canal, mile 3.4 in New Orleans, Orleans Parish, Louisiana, to authorize it to remain closed to navigation between the hours of 8 a.m. and noon and between the hours of 1 p.m. and 5 p.m. daily, from March 6, 1997 through May 19, 1997. This action is necessary for the fender system to be repaired and portions of it replaced.

DATES: This temporary final rule is effective beginning at 8 a.m. on March 6, 1997 and ending at 5 p.m. on May 19, 1997.

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, room 1313, 501 Magazine Street, New Orleans, Louisiana 70130-3396 between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The

telephone number is (504) 589-2965. Eighth Coast Guard District Bridge Administration Branch maintains the public docket for this temporary final rule.

FOR FURTHER INFORMATION CONTACT: Phil Johnson, Bridge Administration Branch, at the address given above, telephone (504) 589-2965.

SUPPLEMENTARY INFORMATION:

Drafting Information: The principal persons involved in drafting this regulation are Phil Johnson, Project Manager, Eighth Coast Guard District Bridge Administration Branch, and Lieutenant Commander Jim Wilson, Project Attorney, Eighth Coast Guard District Legal Office.

Discussion of Rule

Notice of this repair was not provided in time to issue a notice of proposed rulemaking. Unsafe condition of the bridge fender system warrants the closures so that remedial work can be accomplished. For the same reason, good cause exists to make this temporary rule effective in less than 30 days after publication.

The L&N Railroad/Old Gentilly Road bascule span drawbridge across the Inner Harbor Navigation Canal, mile 3.4 in New Orleans, has a vertical clearance of one foot above high tide in the closed to navigation position. The horizontal clearance of the bridge is only 93 feet. A crane barge will be required to occupy the majority of this very narrow channel in order to reconstruct the fender system. The Coast Guard is temporarily changing the regulation for the operation of the L&N Railroad/Old Gentilly Road bascule span drawbridge across the Inner Harbor Navigation Canal, mile 3.4 in New Orleans, Orleans Parish, Louisiana, to authorize it to remain closed to navigation between the hours of 8 a.m. and noon and between the hours of 1 p.m. and 5 p.m. daily, from March 6, 1997 through May 19, 1997.

This action is necessary for the fender system to be repaired and portions of it

replaced. The barged and related equipment will be removed from the channel from noon until 1 p.m. and from 5 p.m. until 8 a.m. daily at which time the bridge may be opened to pass marine traffic.

Navigation on the waterway consists of tugs with tows, including crane barges, jack-up boats, oil industry crew vessels, fishing vessels, sailing vessels and other recreational craft. The fender system of the bridge has sustained considerable damage from numerous vessel strikes, compromising its ability to protect the bridge. It must be rehabilitated for the safety of rail as well as for vehicular traffic.

The Port of New Orleans has requested this temporary final rule so that the fender system can be repaired and portions of it replaced. The short term inconvenience, attributable to a delay of vessel traffic for a maximum of four hours, is outweighed by the long-term benefits to be gained in the interest of safety.

Regulatory Evaluation

This temporary final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential cost and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the Regulatory Policies and Procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this temporary final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this temporary final rule will have a significant economic impact on a substantial number of small entities. "Small