



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date
From Associate Director for Compliance
Bureau of Foods (HFF-300)

Subject Amendment to §176.170 Components of paper and paperboard in contact with aqueous and fatty foods - Food Additive Petition 3B3700 - ACTION

To Director, Bureau of Foods (HFF-1)

OBJECTIVE

This food additive regulation is for the signature of the Director of the Bureau of Foods, HFF-1, because it does not involve novel or controversial issues, and does not involve any question about the applicability of the Delaney Clause. This regulation is for publication in the Federal Register.

FACTS

The order (Tab A) would amend §176.170 to provide for the use of pentanoic acid, 4,4-bis[(gamma-omega-perfluoro-C₈-20-alkyl)thio] derivatives, compounds with diethanolamine, as an oil and water repellent for paper and paperboard. This repellent is not now regulated as a food additive.

DISCUSSION

The Division of Chemistry and Physics finds that the additive is adequately identified and that it will accomplish its intended technical effect. The Division estimates, based on extraction studies with water, acetic acid, and heptane, that the concentration of the additive in the daily diet from this use would be 0.018 ppm, resulting in an estimated daily intake of 0.05 mg/day.

The Division of Toxicology concludes that the additive is safe for its petitioned uses. This conclusion is based on "virtually nil" migration, oral LD₅₀ studies in animals, and a 30-day subacute oral study in rats.

The Environmental Impact Section has reviewed the environmental impact of this action and concludes that the issuance of the order will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. A copy of their finding and supporting evidence is attached (Tab C) for display at the Dockets Management Branch.

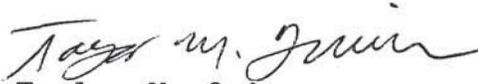
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The Division of Food and Color Additives concludes that Regulatory Flexibility and Impact Analyses are not necessary because this action is exempt from the Regulatory Flexibility Act and Executive Order 12291.

RECOMMENDATION

We recommend that the attached document (Tab A) be signed and published in the Federal Register.


Taylor M. Quinn

Enclosures:

Tab A - Document
Tab B - Filing Notice
Tab C - Finding of No Significant Impact

DECISION

Recommended course of action:

Approved _____ Disapproved _____ Date _____

Prepared by: HFF-334, John L. Herrman, 472-5690, 08/02/83

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