with Boeing Service Bulletin 767–57–0021, Revision 1, dated September 14, 1989; Revision 2, dated July 26, 1990; or Revision 5, dated June 15, 1995.

* * * * *

Issued in Renton, Washington, on August 14, 1996.

Neil D. Schalekamp,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–21232 Filed 8–20–96; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 92F–0475]

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 phosphorylated tall oil fatty acids as pigment dispersants in polymeric films intended for use in contact with food. This action is in response to a petition filed by SCM Chemicals.

DATES: Effective August 21, 1996; written objections and requests for a hearing September 20, 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: 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 February 9, 1993 (58 FR 7789), FDA announced that a food additive petition (FAP 3B4350) had been filed by SCM Chemicals, c/o 1001 G St. NW., suite 500 West, Washington, DC 20001 (formerly, 1100 G St. NW., Washington, DC 20001). The petition proposed to amend the food additive regulations to add a new § 178.3725 *Pigment dispersants* (21 CFR 178.3725) to provide for the safe use of phosphorylated tall oil fatty acids as pigment dispersants in polymeric films intended for use in contact with food.

In the FDA evaluation of the safety of this food additive, the agency has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of dimethyl hydrogen phosphite, which is a carcinogenic impurity resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as dimethyl hydrogen phosphite, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the so-called ''general safety clause'' section 409(c)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additive anticancer, or Delaney, clause of the act section 409(c)(3)(A) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to the impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive, *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, phosphorylated tall oil fatty acids, will result in exposure to no greater than 2.3 parts per billion (ppb) of the additive in the daily diet (3 kilogram (kg)) or an estimated daily intake (EDI) of 7 microgram per person per day (µg/person/day) (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that the estimated small dietary exposure to this additive is safe.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by dimethyl hydrogen phosphite, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of dimethyl hydrogen phosphite has two aspects: (1) Assessment of the worst-case exposure to the impurity from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of probable exposure to humans.

A. Dimethyl Hydrogen Phosphite

FDA has estimated the hypothetical worst-case exposure to dimethyl hydrogen phosphite from the petitioned use of the additive as a pigment dispersant in polymeric films to be 0.009 ppb in the daily diet (3 kg), or 27 nanograms/person/day (Ref. 1). The Cancer Assessment Committee (CAC) of the Center for Food Safety and Applied Nutrition (CFSAN) reviewed data from a 103- week carcinogenic bioassay on dimethyl hydrogen phosphite in F344/N rats and $B6C3F_1$ mice conducted by the National Toxicology Program (NTP). The results of the bioassay on dimethyl hydrogen phosphite demonstrated that the material induced lung and forestomach neoplasms in male rats when administered by gavage in corn oil. The agency used the data reviewed by the CAC to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the proposed use of the additive.

Based on the estimated worst-case exposure to dimethyl hydrogen phosphite of 7 µg/person/day, FDA's CFSAN estimates that a worst-case upper-bound limit of lifetime human risk from the use of the subject additive is 1.4×10^{-9}, or 1.4 in one billion (Refs. 4 and 5). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to dimethyl hydrogen phosphite is likely to be substantially less than the worst-case exposure, and therefore, the upper-bound lifetime human risk would be less. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to dimethyl hydrogen phosphite would result from the proposed use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of dimethyl hydrogen phosphite present as an impurity in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which dimethyl hydrogen phosphite may be expected to remain as an impurity following production of the additive, the agency would not expect the impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime human risk from exposure to the impurity, even under worst-case assumptions, is very low, less than 1.4 in a billion.

III. Conclusion

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed use of the additive as a pigment dispersant in polymeric films intended for use in contact with food is safe. Based on this information, the agency has also concluded that the additive will achieve its intended technical effect. Therefore, the agency concludes that a new § 178.3725 should be added to part 178 (21 CFR part 178) 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.

IV. Environmental Impact

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.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before September 20, 1996, file with the Dockets Management Branch (address above) written objection 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 objection 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.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Branch (HFS–247) to the Indirect Additives Branch (HFS–216) concerning FAP 3B4350: Dietary Concentrations of the Additive and the Impurity (dimethyl hydrogen phosphite), April 28, 1994.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger and J. K. Marquis, S. Karger, New York, NY, pp. 24–33, 1985.

3. ''Toxicology and Carcinogenesis Studies of Dimethyl Hydrogen Phosphite,'' National Toxicology Program, Technical Report, #287, November 1985.

4. Memorandum from Executive Secretary, Cancer Assessment Committee (HFS–227) to Chairman, Cancer Assessment Committee, and Chairman, Quantitative Risk Assessment Committee: ''Tentative, Worst-case Risk Assessment for Dimethyl Hydrogen Phosphite,'' January 4, 1996.

5. Memorandum from Executive Secretary, Cancer Assessment Committee (HFS–227) to Chairman, Cancer Assessment Committee, and Chairmen, Quantitative Risk Assessment Committee: ''Risk Assessment for Dimethyl Hydrogen Phosphite (DMHP),'' June 26, 1996.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

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

2. New § 178.3725 is added to subpart D to read as follows:

§ 178.3725 Pigment dispersants.

Subject to the provisions of this regulation, the substances listed in this section may be safely used as pigment dispersants in food-contact materials.

Substances	Limitations
Phosphorylated tall oil fatty acids (CAS Reg. No. 68604–99–9), prepared by the reaction of dimethyl hydrogen phosphite with tall oil fatty acids.	For use only at levels not to exceed 1.0 percent by weight of the pigment. The pigmented polymeric films may contact all food under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter.

Dated: August 13, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–21229 Filed 8–20–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD13–96–002]

RIN 2115–AE47

Drawbridge Operation Regulations; Ebey Slough, Marysville WA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily amending the regulations governing the operation of the twin State Route 529 drawbridges across Ebey Slough, mile 1.6, at Marysville, Washington. The temporary regulations will permit the swingspan to remain closed for several months so that the mechanical and electrical systems of the bridge can be overhauled. The closed period is February 1, 1997 to June 1, 1997.

EFFECTIVE DATES: This rule is effective from February 1, 1997, to June 1, 1997.

ADDRESSES: Unless otherwise noted, documents referred to in this preamble are available for inspection and copying at 915 Second Avenue, Room 3410, Seattle, Washington. Normal office hours are between 7:45 a.m. and 4:15 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: John E. Mikesell, Chief, Plans and Programs Section, Aids to Navigation and Waterways Management Branch, (Telephone: (206) 220–7270).

SUPPLEMENTARY INFORMATION:

Regulatory History

On February 21, 1996, the Coast Guard published a notice of proposed rulemaking entitled Drawbridge Operation Regulations; Ebey Slough, Marysville, WA, in the Federal Register (61 FR 6589). No comments were received in response to this notice.

Background and Purpose

At the request of the Washington State Department of Transportation, the Coast Guard is temporarily amending the regulations governing the operation of the State Route 529 drawbridge across Ebey Slough, Washington. Currently, this bridge is required to open for the passage of vessels if one hour notice is provided. The temporary regulations will permit the drawspan to remain closed for several months so that the mechanical and electrical systems of the bridge can be overhauled. The existing drawbridge operation regulations currently in effect will automatically be restored as soon as the temporary regulations expire on June 1, 1997.

Discussion of Comments and Changes

The Coast Guard did not receive any comments to the notice of proposed rulemaking and the rule is being adopted as proposed.

Regulatory Evaluation

This temporary rule is not a significant regulatory action under 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 been exempted from review 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 rule to be so minimal that a full regulatory evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This expectation is based on the fact that there is very little commercial use of the waterway and the fact that the upper reaches of Ebey Slough beyond the State Route 529 drawbridge can be reached by an alternate route using Steamboat Slough.

Small Entities

For the reasons stated in Regulatory Evaluation above, the Coast Guard finds that the impact on small entities, if any, is not substantial. Therefore, the Coast Guard certifies under 5 U.S.C. 605 (b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this action will not have a significant impact on a substantial number of small entities. The impact on small entities is expected to be minimal because of the minimal use of the waterway and the alternate route through Steamboat Slough.

Collection of Information

This action contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard has considered the environmental impact of this action and concluded that, under section 2.B.2. of Commandant Instruction M16475.B, this proposal is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons set out in the preamble, the Coast Guard amends part 117 of title 33, Code of Federal Regulations, as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Effective February 1, 1997, to June 1, 1997, paragraph (h) of § 117.1059 is temporarily suspended and a new paragraph (j) is added to read as follows:

§ 117.1059 Snohomish River, Steamboat Slough, and Ebey Slough.

* * * * *

(j) The draws of the SR 529 highway bridge across Ebey Slough, mile 1.6, at Marysville, need not open for the passage of vessels from February 1, 1997, until June 1, 1997.

Dated: June 26, 1996.

J. David Spade,

Rear Admiral, U.S. Coast Guard Commander, 13th Coast Guard District.

[FR Doc. 96–21087 Filed 8–20–96; 8:45 am]

BILLING CODE 4910–14–M

33 CFR Part 117

[CGD13–96–001]

RIN 2115–AE47

Drawbridge Operation Regulations; Snohomish River, Everett, WA

AGENCY: Coast Guard, DOT.

ACTION; Temporary final rule.

SUMMARY: The Coast Guard is temporarily amending the regulations governing the operation of the twin State Route 529 drawbridges across the