equipment. Applicants may donate or sell the commodities or software to be exported. Reexport to other end-users or end-uses is not authorized.

(ii) Commodities and software may be approved for export to U.S. news bureaus in Cuba whose primary purpose is the gathering and dissemination of news to the general public. In addition to the examples of commodities and software listed in paragraph (b)(4)(i) of this section, certain telecommunications equipment necessary for the operation of news organizations (e.g., 33M bit/s data signaling rate or less) may be approved for export to U.S. news bureaus.

* * * * *

Dated: February 26, 1997.

Sue E. Eckert,

Assistant Secretary for Export Administration.

[FR Doc. 97–5169 Filed 2–28–97; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 93F–0028]

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 3,6-bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole-1,4-dione (C.I. Pigment Red 254) as a colorant in polymers intended for use in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective March 3, 1997; written objections and requests for a hearing by April 2, 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: Richard H. White, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3094.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of March 17, 1993 (58 FR 14402), FDA announced that a food additive petition (FAP 3B4349) had been filed by Ciba-Geigy Corp., 315 Water St., Newport, DE 19804–2434 (currently c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001). The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of 3,6-bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole-1,4-dione (C.I. Pigment Red 254) as a colorant in polymers intended for use in contact with food.

In its evaluation of the safety of this food additive, FDA reviewed the safety of the additive 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 may contain minute amounts of polychlorinated biphenyls (PCB's), which are carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants, manufacturing aids, and their constituent impurities, and byproducts, such as PCB's, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the so-called ''general safety clause'' of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the food 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 additives anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed to be 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 food additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

II. Safety of the Petitioned Use of the Additive

FDA estimates that the petitioned use of the food additive, 3,6-bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole-1,4-dione (C.I. Pigment Red 254), will result in exposure to no greater than 0.2 parts per billion (ppb) of the food additive in the daily diet (3 kilograms (kg)) or an estimated daily intake (EDI) of 0.6 micrograms (µg) 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 (acute toxicity and mutagenicity studies) on the additive and concludes that the small dietary exposure resulting from the proposed use of the 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 lifetime human risk presented by PCB's, carcinogenic chemicals that may be present as impurities in the additive. This risk evaluation of PCB's has two aspects: (1) Assessment of the worst-case exposure to these impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of worst-case exposure to humans.

A. PCB's

FDA has estimated the hypothetical worst-case exposure to PCB's from the petitioned use of the food additive as a colorant in polymers to be less than $1x10^{-4}$ parts per trillion of the daily diet (3 kg), or 0.3 picograms (pg)/person/day (Ref. 3). The agency used data from a carcinogenesis bioassay on PCB's, conducted by Norback and Weltman (Ref. 4), to estimate the upper-bound limit of lifetime human risk from exposure to these chemicals resulting from the proposed use of the food additive (Ref. 5). The results of the bioassay on a PCB mixture (Aroclor 1260) demonstrated that the material was carcinogenic for male and female rats under the conditions of the study. The test material caused significantly increased incidence of hepatocellular tumors in both female and male rats.

Based on the estimated worst-case exposure to PCB's of 0.3 pg/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the use of the subject additive is less than $7.5x10^{-13}$, or 8 in 10 trillion (Refs. 6 and

7). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to PCB's is likely to be substantially less than the potential worst-case exposure, and therefore, the upper-bound limit of lifetime human risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to PCB's 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 PCB's present as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which PCB's may be expected to remain as impurities following production of the additive, the agency would not expect these impurities to become components of food at other than extremely low levels; and (2) the upper-bound limit of lifetime human risk from exposure to these impurities, even under worst-case assumptions, is very low, less than 8 in 10 trillion.

III. Conclusion on Safety

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive as a colorant in polymers in contact with food is safe, that the food additive will achieve its intended technical effect, and that the regulations in § 178.3297 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.

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 April 2, 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.

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 dated September 15, 1993, from the Chemistry Review Branch (HFS–247) to the Indirect Additives Branch (HFS–216), concerning ''FAP 3B4349 (MATS #678, M2.1)—Ciba-Geigy Corp. (CG)—Irgazin DPP Red BO (Cromophtal DPP Red BP) as a colorant in all polymers. Submission dated 10–29–92.''

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. Memorandum dated February 21, 1995, from the Chemistry Review Branch (HFS–247) to the Indirect Additives Branch (HFS–216), concerning ''FAP 3B4349 (MATS #678, M2.7)—Ciba-Geigy Corp. (CG)—Irgazin DPP Red BO (Cromophtal DPP Red BP) as a colorant in all polymers. Submission dated 8–31–94.''

4. Norback, D. H., and R. H. Weltman, ''Polychlorinated Biphenyl Induction of Hepatocellular Carcinoma in the Sprague-Dawley Rat,'' *Environmental Health Perspectives*, 60:97–105, 1985.

5. Gaylor, D. W., and R. L. Kodell, ''Linear Interpolation Algorithm for Low Dose Risk Assessment of Toxic Substances,'' *Journal of Environmental Pathology and Toxicology*, 4:305–312, 1980.

6. Memorandum, Report of the Quantitative Risk Assessment Committee, August 18, 1995.

7. Memorandum dated October 11, 1996, from the Quantitative Risk Assessment Committee (HFS–16) to the Indirect Additives Branch (HFS–216) concerning ''Clarification of QRAC Memorandum of August 18, 1995, re FAPs 9B4158 and 3B4349.''

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. Section 178.3297 is amended in the table in paragraph (e) by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
3,6-Bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole-1,4-dione (C.I. Pigment Red 254, CAS Reg. No. 84632–65–5)	For use only at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H, described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: February 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–5077 Filed 2–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–97–002]

RIN 2115–AE46

Special Local Regulations: Intracoastal Waterway, St. Augustine, FL

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Special local regulations are being adopted for the ''Blessing of the Fleet'' ceremony. The event will be held from 11 a.m. to 3 p.m. Eastern Standard Time (EST) on March 23, 1997. The regulated area includes those waters between the Bridge of Lions and the Fish Island Marina Daybeacon #2 in the Matanzas River, St. Augustine, Florida. The anticipated concentration of participant and spectator vessels will create an unusual hazard on the navigable waters. The regulations are needed to provide for the safety of life on navigable waters during the event.

EFFECTIVE DATE: This rule becomes effective 9 a.m. EST and terminates at 3 p.m. EST on Sunday, March 23, 1997.

FOR FURTHER INFORMATION CONTACT: Ensign G. Watson, Project Officer, Coast Guard Group Mayport Florida, (904) 247–7398.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impractical. The information to hold the event was not received until January 17, 1997, leaving insufficient time to publish proposed rules prior to the event or to provide a delayed effective date.

Discussion of Regulations

The event requiring this regulation is a ''Blessing of the Fleet'' ceremony. There will be 150 participating vessels in single file, parade style, transiting the Intracoastal Waterway from the Bridge of Lions south to Daybeacon number #2, and returning north to the Bridge of Lions. Approximately ten spectator craft are expected. The total number of vessels in the regatta area creates an extra hazard to the safety of life on the navigable waters.

The regulated area includes those waters between the Bridge of Lions and the Fish Island Marina Daybeacon #2, LLNR 35420, position 29–52.15N, 081–18.12W, in the Matanzas River, St. Augustine, Florida. Datum: NAD 1983. The event requires that vessel traffic control be implemented within the area of the Intracoastal Waterway between the Bridge of Lions and Daybeacon number #2. This regulation provides that entry into the regulated area, by other than parade participants or spectator craft, is prohibited, unless authorized by the Patrol Commander. After termination of the ''Blessing of the Fleet'' ceremony, all vessels may resume normal operations.

Spectator craft will be allowed to enter the regulated area; however, vessel mooring, anchoring, and movement restrictions will be directed by Coast Guard and local law enforcement officials.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs 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. The regulation will only be in effect for a total of 5 hours on the date of the ceremony.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' include independently owned and operated businesses that are not dominant in their field and that otherwise qualify as ''small business concerns'' under section 3 of the Small Business Act (15 U.S.C. 632).

The Coast Guard certifies under section 605 (b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this rule will not have a significant economic impact on a substantial number of small entities because the regulation will be in effect for a total of 5 hours in a limited area of the Intracoastal Waterway in St. Augustine.

Collection of Information

These regulations contain 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 proposed rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this rule under paragraph 2.B.2 of Commandant Instruction M16475.1B, (as revised by 59 FR 38654, July 29, 1994). In accordance with that instruction, specifically section 2.B.4 and 2.B.5, this action has been environmentally assessed (EA completed), and the Coast Guard has concluded that this event will not significantly affect the quality