

accomplished in accordance with Boeing Alert Service Bulletin 747-53A2420, dated March 26, 1998.

(1) Perform a detailed visual inspection to detect cracks in accordance with Figure 2 of the alert service bulletin.

(i) Repeat the detailed visual inspection thereafter at intervals not to exceed 25 flight cycles, until the requirements of paragraph (a)(1)(ii) are accomplished.

(ii) Within 500 flight cycles after accomplishment of the initial detailed visual inspection, accomplish paragraph (a)(2) of this AD.

(2) Perform a one-time open hole high frequency eddy current (HFEC) inspection to detect cracks in accordance with Figure 3 of the alert service bulletin.

Accomplishment of this action constitutes terminating action for the repetitive inspection requirements of this AD.

(b) For airplanes that have accumulated 18,000 or more total flight cycles as of the effective date of this AD: Within 25 flight cycles after the effective date of this AD, inspect the upper chord, web, and strap of the upper deck floor beams at BS 340 through BS 440 inclusive, and the upper deck floor beams at BS 500 and BS 520, on the right and left sides of the airplane, in accordance with paragraph (b)(1) or (b)(2) of this AD. The inspections shall be accomplished in accordance with Boeing Alert Service Bulletin 747-53A2420, dated March 26, 1998.

(1) Perform a detailed visual inspection to detect cracks in accordance with Figure 2 of the alert service bulletin.

(i) Repeat the detailed visual inspection thereafter at intervals not to exceed 25 flight cycles, until the requirements of paragraph (b)(1)(ii) are accomplished.

(ii) Within 250 flight cycles after accomplishment of the initial detailed visual inspection, accomplish paragraph (b)(2) of this AD.

(2) Perform a one-time open hole HFEC inspection to detect cracks in accordance with Figure 3 of the alert service bulletin. Accomplishment of this action constitutes terminating action for the repetitive inspection requirements of this AD.

(c) If any cracking is found during any inspection required by this AD, prior to further flight, repair in accordance with a method approved by the Manager, Seattle Aircraft Certification Office, FAA, Transport Airplane Directorate.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(f) The inspections shall be done in accordance with Boeing Alert Service Bulletin 747-53A2420, dated March 26, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on May 11, 1998.

Issued in Renton, Washington, on April 20, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 92F-0290]

Indirect Food Additives: Polymers

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 poly(*p*-oxyphenylene *p*-oxyphenylene *p*-carboxyphenylene) resins as a component of food-contact articles intended for repeated use. This action responds to a petition filed by ICI Americas, Inc.

DATES: This regulation is effective April 24, 1998; written objections and requests for a hearing by May 26, 1998.

ADDRESS: 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: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3098.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of August 27, 1992 (57 FR 38840), FDA announced that a food additive petition (FAP 2B4333) had been filed by ICI Americas, Inc.,

Concord Pike and Murphy Rd., Wilmington, DE 19897 (now Victrex USA, Inc., 601 Willowbrook Lane, West Chester, PA 19382). The petition proposed to amend the food additive regulations to provide for the safe use of polyetheretherketone resins as articles or components of articles intended to contact food. Polyetheretherketone resins are also known by the chemical name poly(*p*-oxyphenylene *p*-oxyphenylene *p*-carboxyphenylene). The petition stated that the subject resins are intended only for repeated use in contact with food.

In its evaluation of the safety of this additive, FDA 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 hydroquinone as a byproduct impurity of its production. Hydroquinone has been shown to cause cancer in test animals. Residual amounts of reactants and byproduct impurities, such as hydroquinone, are commonly found as contaminants in chemical products, including food additives.

II. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause," a food additive cannot be approved for a particular use unless a fair evaluation of the evidence 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 additives anticancer, or Delaney, clause (section 409(c)(3)(A)) further of the act (21 U.S.C. 348(c)(3)(A)) further 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 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 standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive (*Scott v. FDA*, 728 F.2d. 322 (6th Cir. 1984)).

III. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, poly(*p*-oxyphenylene *p*-oxyphenylene *p*-carboxyphenylene), will result in exposure to no greater than 0.75 parts per billion of oligomers derived from the additive in the daily diet (3 kilograms) or an estimated daily intake (EDI) of 2.3 micrograms per person per 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 dietary exposure resulting from the petitioned use of this additive is safe.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by hydroquinone, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of hydroquinone has two aspects: (1) Assessment of exposure to the impurity from the petitioned use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of exposure to humans.

A. Hydroquinone

FDA has estimated the exposure to hydroquinone from the petitioned use of the additive as a component of repeated-use articles intended to contact food to be no more than 0.4 part per trillion in the daily diet, or 1.2 nanograms (ng)/person/day (Ref. 1). The agency used data from 1989 National Toxicology Program rodent bioassays on hydroquinone (Ref. 3), and a 1991 publication by Shibata et al. summarizing results of rodent bioassays on hydroquinone (Ref. 4), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The agency has made an assumption that the results of these studies demonstrate that hydroquinone produced tumors in male and female rats and mice following oral administration for 2 years.

Based on the agency's estimate that exposure to hydroquinone will not exceed 1.2 ng/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 1×10^{-10} , or

1 in 10 billion (Ref. 5). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to hydroquinone is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to hydroquinone would result from the petitioned use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of hydroquinone present as an impurity in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which hydroquinone 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 is very low (1 in 10 billion).

IV. Conclusion

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 as a component of repeated-use articles intended for contact with food is safe, and that it will achieve its intended technical effect. The agency has also determined, with the petitioner's concurrence, that the additive should be listed by the chemical name, poly(*p*-oxyphenylene *p*-oxyphenylene *p*-carboxyphenylene). Therefore, the agency concludes that a new § 177.2415 (21 CFR 177.2415) should be added to 21 CFR part 177 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.

V. 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.

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 January 30, 1997, from the Chemistry and Environmental Review Team (HFS-207) to the Indirect Additive Branch (HFS-216) entitled "FAP 2B4333 (MATS# 659, M2.5)—Vitrex USA, Inc., Polyetheretherketone (PEEK) as a component of food-contact articles intended for repeat-use. Submission dated 8/9/96."

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

3. "Toxicology and Carcinogenesis Studies of Hydroquinone (CAS No. 123-31-9) in F344/N Rats and B6C3F₁ Mice (Gavage Studies)" National Toxicology Program, Technical Report Series, No. 366.

4. Shibata, M. A., M. Hirose, H. Tanaka, E. Asakawa, T. Shirai, and M. Ito, "Induction of renal cell tumors in rats and mice, and the enhancement of hepatocellular tumor development in mice after long-term hydroquinone treatment" *Japanese Journal of Cancer Research*, 82:1211-1219, 1991.

5. Memorandum dated November 18, 1997, from Division of Health Effects Evaluation (HFS-225), to the Chairman of the Quantitative Risk Assessment Committee (HFS-308) entitled "Worst-case cancer risk assessment for hydroquinone."

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 26, 1998, 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 177

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 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.2415 is added to subpart C to read as follows:

§ 177.2415 Poly(aryletherketone) resins.

Poly(aryletherketone) resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, poly(aryletherketone) resins are

poly(*p*-oxyphenylene *p*-oxyphenylene *p*-carboxyphenylene) resins (CAS Reg. No. 29658–26–2) produced by the polymerization of hydroquinone and 4,4'-difluorobenzophenone, and have a minimum weight-average molecular weight of 12,000, as determined by gel permeation chromatography in comparison with polystyrene standards, and a minimum mid-point glass transition temperature of 142 °C, as determined by differential scanning calorimetry.

(b) *Optional adjuvant substances.* The basic resins identified in paragraph (a) may contain optional adjuvant substances used in their production. These adjuvants may include substances described in § 174.5(d) of this chapter and the following:

Substance	Limitations
Diphenyl sulfone	Not to exceed 0.2 percent by weight as a residual solvent in the finished basic resin.

(c) *Extractive limitations.* The finished food contact article, when extracted at reflux temperatures for 2 hours with the following four solvents, yields in each extracting solvent net chloroform soluble extractives not to exceed 0.05 milligrams per square inch of food contact surface: Distilled water, 50 percent (by volume) ethanol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane. In testing the final food contact article, a separate test sample shall be used for each extracting solvent.

Dated: April 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF STATE

22 CFR Part 50

[Public Notice 2780]

Nationality Procedures

AGENCY: Bureau of Consular Affairs, Department of State.

ACTION: Final rule; correction.

SUMMARY: This document contains corrections to the final regulations published in the **Federal Register** of Wednesday, June 12, 1996 (61 FR 29651). The regulations related to State Department Nationality Procedures. A

misprint occurred which omitted part of one sentence. This correction adds the omitted language. This correction also updates the citation of authorities for Part 50.

DATES: Effective upon April 24, 1998.

FOR FURTHER INFORMATION CONTACT: Edward A. Betancourt, or Michael Meszaros, Overseas Citizens Services, Department of State, 202–647–3666.

SUPPLEMENTARY INFORMATION: In the final rule published on June 12, 1996, the Department revised its procedures concerning loss of nationality. 22 CFR 50.40 describes certain acts for which citizens need not submit evidence of intent to retain U.S. nationality. Because of an error, the last part of the second sentence in 22 CFR 50.40 was omitted. This correction adds the missing sentence. In addition, in the authorities, citations to current sections of the United States Code replace original citations.

PART 50—NATIONALITY PROCEDURES

Accordingly, 22 CFR Part 50 is corrected as follows:

1. The authority section for 22 CFR Part 50 is revised to read as follows:

Authority: 22 U.S.C. 211a, 22 U.S.C. 2051a, 2705, 8 U.S.C. 1104, 1503.

2. In § 50.40(a), add the following in the second sentence after the first occurrence of the word “U.S.”: “citizens who naturalize in a foreign country; take a routine oath of allegiance; or accept

non-policy level employment with a foreign government need not submit”.

Dated: April 15, 1998.

Donna Hamilton,

Acting Assistant Secretary for Consular Affairs.

[FR Doc. 98–10904 Filed 4–23–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CT18–1–7204a; A–1–FRL–5999–2]

Approval and Promulgation of Air Quality Implementation Plans; Connecticut; Alternative Reasonably Available Control Technology for Volatile Organic Compounds at Risdon Corporation in Danbury

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the State of Connecticut. This revision allows an alternative reasonably available control technology (RACT) determination for volatile organic compound (VOC) emissions at Risdon Corporation's Danbury facility which are subject to Connecticut's miscellaneous metal parts and products VOC RACT regulations. The intended effect of this action is to approve the