was first manufactured into a covered lumber product). For purposes of determination, Province of Manufacture is the first province where the subject merchandise underwent a change in tariff classification to the tariff classes cited in this paragraph (a). The Province of Manufacture Code should replace the Country of Origin code on the CF 7501, Entry Summary form. For electronic Automated Broker Interface (ABI) entry summaries, the Canadian Province Code should be transmitted in positions 6–7 of the A40 records. These requirements apply only for imports of certain softwood lumber products for which the Country of Origin is Canada.

(b) All other imports from Canada, including certain softwood lumber products not covered in paragraph (a) of this section, will require the two-letter designation of the Canadian Province of Origin to be reported on U.S. entry summary records. This information is required only for United States imports that under applicable Customs rules of origin are determined to originate in Canada. For nonmanufactured goods determined to be of Canadian origin, the Province of Origin is defined as the Province where the exported goods were originally grown, mined, or otherwise produced. For goods of Canadian origin that are manufactured or assembled in Canada, with the exception of the certain softwood lumber products described in paragraph (a) of this section, the Province of Origin is that in which the final manufacture or assembly is performed prior to exporting that good to the United States. In cases where the province in which the merchandise was manufactured or assembled or grown, mined, or otherwise produced is unknown, the province in which the Canadian vendor is located can be reported. For those reporting on paper forms the Province of Origin code replaces the country of origin code on the CF 7501, Entry Summary form.

(c) All electronic Automated Broker Interface (ABI) entry summaries for imports originating in Canada also require the new Canadian Province of Origin code to be transmitted for each entry summary line item in the A40 record positions 6–7.

(d) The Province of Origin code replaces the Country of Origin code only for imports that have been determined, under applicable Customs rules, to originate in Canada.

Valid Canadian Province/Territory Codes are:

XA—Alberta
XB—New Brunswick
XC—British Columbia
XM—Manitoba
XN—Nova Scotia
XO—Ontario
XP—Prince Edward Island
XQ—Quebec
XS—Saskatchewan
XT—Northwest Territories
XW—Newfoundland
XY—Yukon Territory

Dated: November 21, 1996.

Martha Farnsworth Riche,

Director, Bureau of the Census.

Concurred:

Dated: November 1, 1996.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff & Trade Enforcement), Department of the Treasury.

[FR Doc. 96–30398 Filed 11–27–96; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 96F–0031]

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 1,2-benzisothiazolin-3-one as a biocide in rubber latex for use in the manufacture of rubber articles intended for repeated use in contact with food. This action is in response to a petition filed by Reichhold Chemicals, Inc.

DATES: Effective November 29, 1996; written objections and requests for a hearing by December 30, 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 8, 1996 (61 FR 4783), FDA announced that a food additive petition (FAP 3B4389) had been filed by Reichhold Chemicals, Inc., P.O. Box 13582, Research Triangle Park, NC 27709–3582. The petition proposed to amend the food additive regulations in § 177.2600 *Rubber articles intended for repeated use* (21 CFR 177.2600) to provide for the safe use of 1,2-benzisothiazolin-3-one as a biocide in rubber latex for use in the manufacture of rubber articles intended 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 carcinogenic polychlorinated dibenzo-*p*-dioxins and dibenzofurans as residual impurities in 1,2-benzisothiazolin-3-one. Residual amounts of reactants and manufacturing aids, such as polychlorinated dibenzo-*p*-dioxins and dibenzofurans, are commonly found as contaminants in chemical products, including food additives.

I. 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'' of the statute, 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 additives anticancer or Delaney clause (section 409(c)(3)(A) of the act) 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 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 the Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, 1,2-benzisothiazolin-3-one, will result in exposure to the additive of no greater than 0.16 parts per billion (ppb), which equates to an

estimated daily intake (EDI) of 0.5 micrograms per person per day (µg/p/d) (Ref. 1). The agency has also calculated the estimated daily intake of the migrating impurities associated with the additive under the most severe conditions of its intended use: bis(2-carbamoyl phenyl)disulfide, 5-chloro-1,2-benzisothiazolin-3-one, bis(2-dimethylcarbamoylphenyl)disulfide, and 6-chloro-1,2-benzisothiazolin-3-one, and the probable concentrations of these four migrants and the solvent impurity (dipropylene glycol) from the additive's use in contact with food. The agency estimated the potential daily intakes of the four impurities to be 0.4, 1.8, 1.4, and 1.8 nanograms/p/d, and the daily intake of the solvent impurity to be 9 µg/p/d, respectively (Ref. 1). The additive may also contain small amounts of the carcinogenic impurities, polychlorinated dibenzo-*p*-dioxins and dibenzofurans.

FDA does not ordinarily consider chronic toxicological testing 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 from acute toxicity studies and subchronic studies in rat and dog on the additive. No adverse effects were reported in these studies.

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 the carcinogenic chemicals, polychlorinated dibenzo-*p*-dioxins and dibenzofurans, that may be present as impurities in the additive. This risk evaluation of these carcinogenic impurities has two aspects: (1) Assessment of the worst-case exposure to the impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

*A. Polychlorinated Dibenzo-p-*dioxins and Dibenzofurans

FDA has estimated the worst-case exposure to polychlorinated dibenzo-*p*-dioxins and dibenzofurans from the petitioned use of the additive as discussed below. Because little is known about the toxicity of polychlorinated dibenzo-*p*-dioxins and dibenzofurans except 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD), the agency utilized the toxicity equivalency factor (TEF) method (Ref. 3) to relate the toxicity of the polychlorinated dibenzo-*p*-dioxins and dibenzofurans in terms of an equivalent amount of toxicologically well characterized TCDD, and used the TEF's adopted by the North Atlantic Treaty Organization (Ref. 4) (see 59 FR 17384, April 12, 1994). Summing the equivalent EDI's for each polychlorinated dibenzo-*p*-dioxin and dibenzofurans present as an impurity gives the total exposure to these polychlorinated compounds in terms of a total equivalent EDI for TCDD of 0.0039 picogram (pg)/p/d (Ref. 1).

Using data from a 2-year chronic toxicity and carcinogenicity study by Kociba et. al., (Ref. 5) on TCDD fed to rats, the agency estimated the upper-bound level of lifetime human risk from exposure to TCDD toxic equivalents resulting from the use of 1,2-benzisothiazolin-3-one as a food contact biocide in repeat-use rubber articles intended for contact with food. The results of the bioassay on TCDD showed that the material was carcinogenic for rats under the conditions of the study in that the test material caused significantly increased incidences of hepatocellular carcinomas and adenomas as well as squamous cell carcinomas of the lung, hard palate, nasal turbinates, and tongue. FDA further concluded that given the paucity of TCDD bioassay data, the Kociba et. al., bioassay provided the appropriate basis on which to calculate an estimate of the upper-bound level of lifetime carcinogenesis risk from exposure to TCDD toxic equivalents stemming from the use of the subject additive (1,2-benzisothiazolin-3-one) as a biocide in repeat-use rubber articles.

The agency used a linear-at-low-dose extrapolation method from the doses used in the Kociba et al., bioassay and the tumor incidence data based upon the original classification of tumors found in that study to estimate the upper-bound risk presented by the very low levels of TCDD toxic equivalents encountered under the actual conditions of use of the additive as a biocide in repeat-use rubber articles. This procedure is not likely to underestimate the actual risk from very low doses and may in fact exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. In so doing, FDA estimated a carcinogenic unit risk of 16 x 10^{-6} for an intake of 1 pg/kilogram (kg) body weight/d of TCDD toxic equivalents (Ref. 6).

As noted, the carcinogenic unit risk assessed above by FDA was based on the original tumor incidence data from the Kociba bioassay (Ref. 5). Following FDA's risk assessment discussed above, however, a group of pathologists, the Pathology Working Group (PWG), reanalyzed the slides of the liver tumors observed in the Kociba bioassay using the National Toxicology Program's 1986 classification system for liver tumors (Ref. 7). FDA has reviewed the results of this reanalysis and agrees with the classification of the tumors made by PWG. Using the results of this revised reading of the Kociba study slides, FDA estimates a carcinogenic unit risk of 9 x 10^{-6} for an intake of 1 pg TCDD equivalents/kg body weight/d (Ref. 8). Using this carcinogenic unit risk and an upper-bound total exposure to polychlorinated dibenzo-*p*-dioxins and dibenzofurans present in the additive in terms of a total equivalent EDI for TCDD of 0.0039 pg/person/d, FDA estimates that the upper-bound limit of risk of cancer would be 5.9 x 10^{-10} from the proposed use of the subject additive (Ref. 9). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime averaged individual exposure to polychlorinated dibenzo-*p*-dioxins and dibenzofurans is expected to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to polychlorinated dibenzo-*p*-dioxins and dibenzofurans 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 polychlorinated dibenzo-*p*-dioxins and dibenzofurans as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because low levels of polychlorinated dibenzo-*p*-dioxins and dibenzofurans 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 limits of lifetime risk from exposure to these impurities, even under worst-case assumptions, are very low, less than 5.9 in 10 billion for polychlorinated dibenzo-*p*-dioxins and dibenzofurans.

III. Conclusion

FDA has evaluated data in the petition and other relevant material and concludes that the proposed use of the additive as a biocide in repeat-use rubber articles is safe, that the additive will have the intended technical effect, and therefore, that § 177.2600 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. 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 June 10, 1994, from the Chemistry Review Branch (HFS–247), to the Indirect Additives Branch (HFS–216), concerning FAP 3B4389—Reichhold Chemicals, Inc.—exposure to the food additive and its components (polychlorinated dibenzo-*p*-dioxins and dibenzofurans).

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, pp. 24–33, 1985.

3. EPA 560/5–90–014, Background Document to the Integrate Risk Assessment for Dioxins and Furans from Chlorine Bleaching in Pulp and Papermills, pp. 3-13, July, 1990.

4. Pilot Study on International Information Exchange on Dioxins and Related Compounds, Report No. 178, December, 1988.

5. Kociba, R. J., et al., ''Results of a Two Year Chronic Toxicity and Oncogenicity Study of 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin in Rats,'' *Toxicology and Applied Pharmacology*, 46:279–303, 1978.

6. Report of the Quantitative Risk Assessment Committee, ''Carcinogenic Risk Assessment for Dioxins and Furans in Foods Contacting Bleached Paper Products,'' April 20, 1990.

7. ''2,3,7,8-Tetrachlorodibenzo-*p*-dioxin in Sprague-Dawley Rats,'' Pathco, Inc., March 13, 1990.

8. Report of the Quantitative Risk Assessment Committee, ''Upper-Bound Lifetime Carcinogenic Risk From Exposure to Dioxin Congeners From Foods Contacting Paper Products With Dioxin Levels Not Exceeding 2 ppt,'' January 27, 1993.

9. Memorandum, Report of the Quantitative Risk Assessment Committee, ''Estimation of Upper-Bound Lifetime Risk From Polychlorinated Dibenzo-*p*-dioxins and Dibenzofurans in 1,2-benzisothiazolin-3-one,'' April 2, 1994.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before December 30, 1996, 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: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 177.2600 is amended in paragraph (c)(4)(ix) by alphabetically adding a new entry for 1,2-benzisothiazolin-3-one to read as follows:

§ 177.2600 Rubber articles intended for repeated use.

* * * * *

(c) * * *

(4) * * *

(ix) * * *

1,2-Benzisothiazolin-3-one (CAS Reg. No. 2634–33–5) for use as a biocide in uncured liquid rubber latex not to exceed 0.02 percent by weight of the latex solids, where the total of all items listed in paragraph (c)(4)(ix) of this section does not exceed 5 percent of the rubber product.

* * * * *

Dated: November 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–30510 Filed 11–27–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 5

[Docket No. FR–4154–I–01]

RIN 2501–AC36

Revised Restrictions on Assistance to Noncitizens

AGENCY: Office of the Secretary, HUD.

ACTION: Interim rule.

SUMMARY: Section 214 of the Housing and Community Development Act of 1980 prohibits HUD from making certain financial assistance available to persons other than United States citizens, nationals, or certain categories of eligible noncitizens. This interim rule revises HUD's regulations governing assistance to noncitizens to incorporate the recent statutory amendments made to Section 214 by the Use of Assisted Housing by Aliens Act of 1996 (''Immigration Reform Act''). This rule, however, does not amend the noncitizen requirements for Indian Housing Authorities (IHAs). Further, this rule does not implement the provisions of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (''Welfare Reform Act'') which concern immigration. The changes to HUD regulations required by that Act will be the subject of future rulemaking.

DATES: *Effective date:* November 29 1996.

Comments due date: November 29, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding the interim rule to the Office of General Counsel, Rules Docket Clerk, Room 10276, Department of Housing and