upper-bound limits of lifetime risk from exposure to the impurity, even under worst-case assumptions, is very low, in the range of less than 3.2 in 1 trillion to 1.5 in 100 billion.

III. Conclusion

FDA has evaluated data in the petition and other relevant material and concludes that the proposed use of the additive in adhesives is safe. Based on this information, the agency has also concluded that the additive will have the intended technical effect. Therefore, § 175.105 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 21 CFR 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 from the Chemistry Review Branch (HFS–247), Center for Food Safety and Applied Nutrition (CFSAN), FDA, to the Indirect Additives Branch (HFS–216), CFSAN, FDA, concerning FAP 4B4435—Dow Chemical Co.—exposure to the food additive and its component, propylene oxide, dated March 1, 1995.

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. Dunkelberg, H., ''Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide Upon Intragastric Administration to Rats,'' *British Journal of Cancer*, 46: 924, 1982.

4. Memorandum, ''Report of the Quantitative Risk Assessment Committee,'' CFSAN, FDA, dated April 20, 1995.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before February 26, 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 175

Adhesives, 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 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 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 175.105 is amended in paragraph (c)(5) in the table by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * * * *	
Glycerol polyoxypropylene triol, minimum average molecular weight 250 (CAS Reg. No. 25791–96–2).	For use only in the preparation of polyester and polyurethane resins in adhesives.
* * * * * * *	

Dated: January 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–1143 Filed 1–24–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 93F–0243]

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 4,5,6,7-tetrachloro-2-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinolinyl]-1H-isoindole-1,3(2H)-dione (C. I. Pigment Yellow 138), as a colorant for all food-contact polymers. This action is in response to a petition filed by BASF Corp.

DATES: Effective January 25, 1996; written objections and requests for a hearing February 26, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., 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 August 18, 1993 (58 FR 43898), FDA announced that a food additive petition (FAP 3B4383) had been filed by BASF Corp., 8 Campus Dr., Parsippany, NJ 07054. 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 4,5,6,7-tetrachloro-2-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinolinyl]-1H-isoindole-1,3(2H)-dione (C.I. Pigment Yellow 138, CAS Reg. No. 30125–47–4), as a colorant for all food-contact polymers.

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, minute amounts of carcinogenic polychlorinated dibenzo-*p*-dioxins (PCDD's) have been detected as impurities in tetrachlorophthalic anhydride, one of the reactants used to produce the additive (C. I. Pigment Yellow 138). Residual amounts of reactants and manufacturing aids, such as PCDD's, 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 Petitioned Use of The Additive

FDA estimates that the petitioned use of the additive, C. I. Pigment Yellow 138, will result in exposure to the additive of no greater than 1.8 parts per billion (ppb), which equates to an estimated daily intake (EDI) of 5.4 micrograms per person per day (μg/p/d) (Ref. 1). The agency has also calculated the EDI of the migrating impurities associated with the colorant under the most severe conditions of the colorant's intended use (phenol, tetrachlorophthalic anhydride, 8-aminoquinaldine, and the monocondensation product) and the probable concentrations of these migrants from the colorant's use in contact with food. The agency estimated the potential daily intakes of the four impurities to be 13, 10, 5.4, and 10 nanograms/p/d, respectively (Ref. 1). The additive may also contain small amounts of carcinogenic impurities (PCDD's).

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 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 (PCDD's) that may be present as impurities in the additive. This risk evaluation of PCDD's 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. PCDD's

FDA has estimated the worst-case exposure to PCDD's from the petitioned use of the additive as discussed below. Because little is known about the toxicity of PCDD's 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 PCDD's 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 PCDD present as an impurity gives the total exposure to PCDD's in terms of a total equivalent EDI for TCDD of 1.4×10^{-4} 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 C. I. Pigment Yellow 138 as a food contact colorant for polymers. 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 (C. I. Pigment Yellow 138) as a colorant in food-contact polymers.

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 actual conditions of the use of the additive as colorant in polymers. 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 16×10^{-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 9×10^{-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 PCDD's present in the additive in terms of a total equivalent EDI for TCDD of 1.4×10^{-4} pg/p/d, FDA estimates that the upper-bound limit of risk of cancer would be 2.1×10^{-11} 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 PCDD's 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 PCDD'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 PCDD's as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because low levels of PCDD'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 small 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 2.1 in 100 billion for PCDD's.

III. Conclusion

FDA has evaluated data in the petition and other relevant material and concludes that the proposed use of the additive as a colorant in food-contact polymers is safe. Based on this information, the agency has also concluded that the additive will have the intended technical effect. Therefore, § 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 21 CFR 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. Memoranda from the Chemistry Review Branch (HFS–247) to the Indirect Additives Branch (HFS–216) concerning FAP 3B4383—BASF Corp.—exposure to the food additive and its component (polychlorinated dibenzo-*p*-dioxins, PCDD's) dated January 21, 1994, April 19, 1994, and March 10, 1995.

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 Integrated 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 of the Center for Food Safety and Applied Nutrition, FDA, ''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 of the Center for Food Safety and Applied Nutrition, FDA, ''Estimation of upper-bound lifetime risk from polychlorinated dibenzo-*p*-dioxins in C. I. Pigment Yellow 138,'' May 24, 1994.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before February 26, 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 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 paragraph (e) in the table by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
4,5,6,7-Tetrachloro-2-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinolinyl]-1H-isoindole-1,3(2H)-dione (C. I. Pigment Yellow 138, CAS Reg. No.30125–47–4).	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 C through H, as described in Table 2 of § 176.170(c) of this chapter; provided further that the finished articles shall not be filled at temperatures exceeding 158 °F (70 °C).
* * *	* * * *

Dated: January 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–1144 Filed 1–24–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

28 CFR Part 49

[AG Order No. 2005–96]

RIN 1105–AA37

Use and Examination of Materials Submitted Pursuant to the Antitrust Civil Process Act

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This rule finalizes changes made by an interim rule published on August 25, 1995 at 60 FR 44276 to a Department of Justice regulation concerning the use and examination of materials submitted pursuant to the Antitrust Civil Process Act (''ACPA'' or ''Act''). The interim rule added references to ''answers to interrogatories'' and ''transcripts of oral testimony'' as types of material subject to the provisions of the ACPA and also added references to ''agents'' of the Department of Justice having the authority to use and copy such materials. These changes were necessary to conform the language of the regulation to the current provisions of the Act. The interim rule also made minor changes to the spelling and capitalization of certain words used in the regulation for purposes of conformity with the Act and internal consistency.

DATES: This Final Rule is effective January 25, 1996.

FOR FURTHER INFORMATION CONTACT: Howard Blumenthal, Assistant Chief, Legal Policy Section, Antitrust Division, Room 3121, Main Justice Building, 10th & Pennsylvania Avenue NW., Washington, DC 20530; telephone (202) 514–2513.

SUPPLEMENTARY INFORMATION: Congress enacted the ACPA, Pub. L. No. 87–664 (codified at 15 U.S.C. 1311–14, as amended), in 1962 to provide the Antitrust Division (''Division'') of the Department of Justice with the authority to issue civil investigative demands (''CIDs''), a type of pre-complaint compulsory process. CIDs enable the Division to gather information concerning possible civil violations of the antitrust laws before filing lawsuits, which often permits the Department of Justice to determine that no antitrust violation has occurred without resort to litigation. Thus, the use of CIDs will frequently save the Department of Justice, the parties being investigated, and the federal court system time and money through the avoidance of unnecessary litigation or the streamlining of any litigation that does result from an investigation.

The CID authority provided to the Division in 1962 was relatively narrow. The only type of information that the Division could acquire by CID was documentary material. Without the consent of the person who produced such material, access to CID information in the possession of the Division was generally limited to officers, members, or employees of the Department of Justice.

The Division's CID authority was expanded by the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (''HSR Act''), Pub. L. No. 94–435. In addition to producing documentary material, CID recipients could now be required to answer in writing written interrogatories and to give oral testimony. In the Antitrust Procedural Improvements Act of 1980 (''APIA''), Pub. L. No. 96–349, Congress clarified that CID information in the possession of the Division could be disclosed to and used by agents of the Department of Justice (for example, expert witnesses or independent contractors) as well as by officers and employees.

The ACPA requires the Attorney General to promulgate regulations setting forth the manner in which CID materials in the possession of the Division will be made available for official use by the Department of Justice, and to prescribe the terms and conditions under which such materials may be examined by the persons who produced them to the Division. The Attorney General promulgated 28 CFR part 49 in 1963 to comply with this requirement. However, this regulation was not amended to reflect the changes to the Act made by the HSR Act in 1976 or the APIA in 1980. The purpose of this order is to make final an interim rule published on August 25, 1995 at 60 FR 44276, which amended the pre-existing regulation to conform with the current provisions of the ACPA.

The rule now being finalized differs from the pre-existing regulation in two main respects. First, references in the pre-existing regulation to the use and examination of documentary material in the possession of the Division were expanded, where and as appropriate, to also refer to answers to interrogatories and transcripts of oral testimony to take into account the additional types of information that can be acquired under the ACPA as amended by the HSR Act. Second, references to the use and copying of CID information by officers and employees of the Department of Justice were expanded to also include agents of the Department of Justice to reflect the change to the Act made by the APIA. The rule now being finalized also differs from the pre-existing regulation in several technical respects.