(3) The additive contains not more than 1,000 parts per million of 1,3-dichloro-2-propanol and not more than 10 parts per million epichlorohydrin. The epichlorohydrin and 1,3-dichloro-2-propanol content is determined by an analytical method entitled "The Determination of Epichlorohydrin and 1,3-Dichloro-2-Propanol in Dimethylamine-Epichlorohydrin Copolymer," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF–330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100, L St. NW., Washington, DC 20408.

(4) Heavy metals (as Pb), 2 parts per million maximum.

(5) Arsenic (as As), 2 parts per million maximum.

(c) The food additive is used as a decolorizing agent and/or flocculant in the clarification of refinery sugar liquors and juices. It is added only at the defecation/clarification stage of sugar liquor refining at a concentration not to exceed 150 parts per million of copolymer by weight of sugar solids.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to other information required by the act, adequate directions to assure use in compliance with paragraph (c) of this section.

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 2, 1984 submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto or submit additional information in support of previously filed objections and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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 regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 23, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84–8555 Filed 3–27–84; 4:04 pm]

BILLING CODE 4160–01–M

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21 CFR Parts 175 and 178

[Docket No. 82F–0055]

Indirect Food Additives: Adhesive Coatings and Components; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule; clarification.

SUMMARY: The Food and Drug Administration (FDA) is publishing additional information on a final rule published in the Federal Register of August 19, 1983 (48 FR 37615), that amended the food additive regulations to provide for the use of 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] as an antioxidant and/or stabilizer in polystyrene, rubber-modified polystyrene, and olefin polymers and as a component in adhesive formulations. The agency is providing an additional 30-day period for submitting objections or additional information in support of objections previously filed in response to the August 19, 1983 regulation.

DATE: Objections or additional information in support of previously filed objections by May 2, 1984.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas C. Brown, Center for Food Safety and Applied Nutrition (formerly Bureau of Foods) (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a final rule published in the Federal Register of August 19, 1983 (48 FR 37615), FDA provided for the use of 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] as an antioxidant and/or stabilizer in polystyrene, rubber-modified polystyrene, and olefin polymers and as a component in adhesive formulations (21 CFR 175.105(c)(5) and 178.2010(b)). That action responded to a petition (FAP 2B3592) filed by Uniroyal Chemical, Naugatuck, CT 06770.

The August 19, 1983 final rule explained that FDA believed that one of the materials used in manufacturing the additive was a carcinogenic compound but did not identify the substance because FDA had concluded that its identity was a trade secret. The final rule did discuss the rationale for regulating the additive and described the results of the agency's assessment of the risk from the constituent. Subsequently, The Natural Resources Defense Council, Inc., 122 East 42d St., New York, NY 10168; and Public Citizen's Health Research Group, 2000 P St. NW., Washington, DC 20036, filed objections to the regulation. The objections requested that the agency publish a supplemental Federal Register notice disclosing the constituent's chemical identity and discussing all other relevant health and safety issues. The objections also argued that the final regulation is illegal because it relied on the constituents theory, which the objections characterized as contrary to the Delaney clause. Finally, the objections requested an immediate stay of the regulation and an additional opportunity for objection and reserved the right to request a hearing at a later stage in the process.

Following FDA's receipt of the objections, Uniroyal informed FDA that it would waive trade secret status for the constituent at issue here. FDA is reissuing the final rule to provide the identity of the carcinogenic constituent and to respond to the request for a discussion of the health and safety issues involved. The agency is also providing an additional 30 days for the submission of objections or additional information in support of objections already filed to the final rule. FDA will act on the remaining issues raised by the objections and requests for a hearing after it has evaluated any further objections filed in response to this document. The agency is not staying the final rule because it believes that the additive is safe, and that a stay would not serve the public interest.

Although the food additive has not itself been found to induce cancer, it may contain trace amounts of dibutyltin diacetate, a carcinogenic compound, which is used in the manufacture of the additive. Residual amounts of reactants and manufacturing aids are commonly found as contaminants in all chemical products, even in highly purified reagent grade chemicals, including many food additives.

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 the data presented to FDA establish that the food additive is safe for that use. The concept of safety embodied in this requirement was explained in the legislative history of the Food Additives Amendment of 1958. "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstances." H.R. Rep. No. 2284, 85th Cong., 2d Sess. 1 (1958). This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The Delaney anticancer clause of the Food Additives Amendment of 1958 (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further that no food additive can be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to list a use of a food additive that contained or was suspected of containing minor amounts of a carcinogenic chemical, even if the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain a carcinogenic chemical but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though that color additive contains a carcinogenic constituent.

Since that decision, FDA has approved the use of three such color additives, D&C Green No. 5 (47 FR 24278; June 4, 1982) and D&C Red No. 6 and D&C Red No. 7 (47 FR 57681; December 28, 1982), on the same basis. FDA fully explained the scientific, legal, and policy underpinnings for those decisions in the advance notice of proposed rulemaking on a policy for regulating carcinogenic chemicals in food and color additives, which was published in the **Federal Register** of April 2, 1982 (47 FR 14464). In brief, the agency believes that the Delaney anticancer clause is not triggered unless the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer but that contains a carcinogenic constituent may properly be evaluated under the general safety clause of the statute, using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, —— F.2d —— (Nos. 82-3544/3759) (6th Cir. February 23, 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which, as explained above, contains a carcinogenic chemical but has not itself been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

Because 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl) propionate] has not been shown to cause cancer, the anticancer clause does not apply to it. FDA has evaluated the safety of this additive under the general safety clause, using risk assessment procedures to estimate the upper bound limit of risk presented by the carcinogenic chemical that may be present as an impurity in the additive, and has concluded that the additive is safe under the proposed conditions of use.

The risk assessment procedures used are similar to the methods used to examine the risk associated with the presence of minor carcinogenic impurities in D&C Green No. 6 (47 FR 14138; April 2, 1982), D&C Green No. 5 (47 FR 24278; June 4, 1982), and D&C Red No. 6 and D&C Red No. 7 (47 FR 57681; December 28, 1982). This risk evaluation of a carcinogenic constituent consists of two parts: (1) Assessment of the probable exposure to the constituent 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.

FDA estimated the potential exposure to dibutyltin diacetate from extraction studies, taking into account what fraction of the daily diet might be packaged in materials containing 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate]. FDA used data from the National Cancer Institute (NCI) carcinogenicity bioassays in which dibutyltin diacetate was administered in the diet of rats and mice to estimate the upper level of human risk from exposure to dibutyltin diacetate stemming from the proposed use of 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate]. The results of the NCI bioassay on dibutyltin diacetate indicated compound-related increases in the incidence of hepatocellular adenomas in male and female mice. (The rat study was negative.) These particular lesions, while not frank malignancies, are considered by the agency to be precursors to carcinomas and, therefore, indicative of the carcinogenicity of dibutyltin diacetate.

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiment to the very low doses encountered under the proposed conditions of use. 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. FDA estimates that the upper limit individual lifetime risk from potential exposure to dibutyltin diacetate at the level considered to be a conservative estimated daily intake is 7×10^{-8} or less than 1 in 10 million. Because of numerous conservatisms in the exposure estimate, lifetime-averaged individual exposure to dibutyltin diaceatte is expected to be substantially less than the estimated daily intake, and therefore the calculated upper bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to dibutyltin diacetate that results from the use of 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxphenyl)propionate].

The agency has calculated an estimated daily intake of 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxphenyl)propionate] based on considerations such as migration of the additive under maximum intended use conditions into food stimulants and estimates of the probable fraction of the daily diet that packaging containing the additive may contact. The estimated daily intake for 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxphenyl)propionate] under the intended use conditions is 0.6 milligram per day (mg/day) for a 60-kilogram (kg) person (0.2 part per million (ppm) in the daily diet).

The petitioner (Uniroyal Chemical Co., Naugatuck, CT 06770) has submitted the results of several studies to demonstrate that there is a reasonable certainty of no harm from the intended use of 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl]-propionate].

These studies include an acute oral toxicity study in rats, a range-finding study (14-day maximum tolerated dose feeding study in dogs), an Ames-type mutagenicity test, and 90-day (subchronic) feeding studies in rats and dogs. The subchronic rat study included an in utero phase. The acute oral toxicity in rats is greater than 10 grams per kilogram body weight. No adverse effects were observed in the range-finding study at feeding levels of 15 percent or less. The mutagenicity test was negative. No tissue abnormalities or other compound-related adverse effects were observed in either the dog or rat subchronic feeding studies over the range of doses tested.

For the level of dietary exposure (0.2 ppm) estimated for 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate], the agency ordinarily requires, at a minimum, a subchronic toxicology study in a rodent with in utero exposure and a subchronic toxicology study in a nonrodent (Refs. 1 and 2). The toxicology studies submitted by the petitioner, therefore, satisfy the agency toxicology testing requirements for this indirect food additive. The data from the submitted toxicology studies indicate no need for additional toxicology studies. In particular, the toxicology information gives no reason to suspect 2,2'-oxamidobis[ethyl 3-(3,5,-di-*tert*-butyl-4-hydroxyphenyl)propionate] to be a carcinogen.

The level at which exposure to a food additive can be considered safe is called the acceptable daily intake. The acceptable daily intake is determined by first establishing a highest no-adverse-effect level for each of the required subchronic animal feeding studies, by applying a safety factor of 1000 to each of these no-adverse-effect levels, and by selecting the study that leads to the lower level. In both subchronic studies, the highest no-adverse-effect level was the highest level at which the additive was fed: 500 milligram per kilogram per day (mg/kg/day) for dogs and 2000 mg/kg/day for rats. A safety factor of 1000 is applied to these studies yielding 0.5 mg/kg/day for dogs and 2 mg/kg/day for rats. The study yielding the lower level is the dog study. Therefore, the agency has established the acceptable daily intake for humans as 0.5 mg/kg/day or 30 mg/day for a 60 kg person. This acceptable daily intake is 50 times greater than estimated daily intake of 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxphenyl)propionate].

FDA applied a thousandfold safety factor rather than the hundredfold safety factor set forth in 21 CFR 170.22 because the agency's calculation is based on subchronic studies. It has been the agency's general practice to apply a thousandfold safety factor when subchronic studies are relied upon to support safety, and when lifetime studies are neither required nor available (Ref. 2).

The agency has considered whether a specification is necessary to control the amount of dibutyltin diacetate that might migrate to food. The agency finds that a specification is not necessary for the following reasons: (1) The upper limit lifetime risk resulting from exposure to dibutyltin diacetate is very low; (2) use of the 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] is limited to 0.5 percent or less of a formulation, except for use of the additive in adhesives, where migration to food is expected to be much less than migration from the regulated polymeric food-contact surfaces; and (3) when used in accordance with current good manufacturing practice, it is likely that dibutyltin diacetate will be used in the manufacture of this additive in amounts consistent with those reviewed by the agency.

FDA has reviewed the available toxicity data and its exposure calculation for the additive, and it has determined that the risk posed by exposure to dibutyltin diacetate is very low. The agency has therefore concluded that the proposed use of the food additive 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] is safe.

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 (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection. Among the documents that the agency has relied upon are Refs. 3 through 15.

References 1 and 2 have been placed on display in the Dockets Management Branch (address above) and may be reviewed in that office between 9 a.m. and 4 p.m., Monday through Friday. The remaining references can be inspected at the Center for Food Safety and Applied Nutrition (address above) by making an appointment with the information contact person.

References

1. Carr, G. M., "Carcinogen Testing Programs," *in* "Food Safety: Where Are We?" Committee on Agriculture, Nutrition, and Forestry, United States Senate, July 1979, p. 59.

2. Kokoski, C. I., "Regulatory Food Additive Toxicology" presented at the "Second International Conference on Safety Evaluation and Regulation of Chemicals," October 24, 1983, Cambridge, MA.

3. Food Additive Petition (FAP 2B3592), Uniroyal Chemical Co., submission, dated October 15, 1981.

4. Memo from Food Additive and Animal Drug Chemistry Evaluation Branch to Petitions Control Branch, dated November 23, 1981, concerning FAP 2B3592 submission, dated October 15, 1981, "2,2'-Oxamidobis[Ethyl 3-(3,5-di-*tert*-Butyl-4-Hydroxyphenyl)Propionate] for Use as an Antioxidant in Plastics."

5. Memorandum from Food Additive and Animal Drug Chemistry Evaluation Branch to Petitions Control Branch, dated February 16, 1982, concerning FAP 2B3592 "Recalculation of EDI for 2,2-Oxamidobis [Ethyl 3-(3,5-di-*tert*-Butyl-4-Hydroxyphenyl)Propionate]."

6. Memorandum from Food Additive Evaluation Branch to Petitions Control Branch, dated February 26, 1982, concerning FAP 2B3592 "2,2'-Oxamidobis[Ethyl 3-(3,5-di-*tert*-Butyl-4-Hydroxyphenyl)Propionate) for Use as an Antioxidant in Plastics."

7. FAP 2B3592 submission, dated May 7, 1982.

8. Memorandum from Food Additive and Animal Drug Chemistry Evaluation Branch to Petitions Control Branch, dated June 7, 1982, concerning FAP 2B3592 submission, dated May 7, 1982 "High Density Polyethylene (HDPE) Extraction Data."

9. FAP 2B3592 submission, dated April 12, 1983.

10. FAP 2B3592 submission, dated April 19, 1983.

11. Memorandum from Food Additive and Animal Drug Chemistry Evaluation Branch to Petitions Control Branch, dated May 13, 1983, concerning FAP 2B3592 submissions, dated April 12, 1983 and April 19, 1983.

12. Memorandum of conference, Bureau of Foods' Cancer Assessment Committee, dated October 18, 1979, concerning "Dibutyltin Diacetate."

13. Memorandum from Executive Secretary of the Bureau of Foods' Cancer Assessment Committee to Food Additive Evaluation Branch, dated May 23, 1983, concerning "Estimation of a Safe Dose for Dibutyltin Diacetate."

14. Memorandum from Food Additive Evaluation Branch to Petitions Control Branch, dated May 24, 1983, concerning "Risk Assessment for Dibutyltin Diacetate Found as a Constituent Catalyst in the Antioxidant/Stabilizer 2,2'-Oxamidobis[Ethyl 3-(3,5-di-*tert*-Butyl 4-Hydroxyphenyl)Propionate]."

15. Memorandum from Food Additive and Animal Drug Chemistry Evaluation Branch to Petitions Control Branch, dated July 7, 1983, concerning FAP 2B3592 "Memorandum for the Record."

List of Subjects

21 CFR Part 175

Adhesives, Food additives, Food packaging.

21 CFR Part 178

Food additives, Food packaging.

For convenience, FDA is republishing in its entirety the final regulation that appeared in the **Federal Register** of August 19, 1983. This clarification of the final rule does not amend the regulation in any way.

This clarification of the final rule is issued under the Federal Food, Drug, and Cosmetic Act.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES COATINGS AND COMPONENTS

1. Part 175 is amended in § 175.105(c)(5) by alphabetically inserting a new item in the list of substances, to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
2,2'-Oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] (CAS Reg. No. 70331-94-1).	
* * * * *	

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

2. Part 178 is amended in § 178.2010(b) by alphabetically inserting a new item in the list of substances, to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * * * *	
2,2'-Oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] (CAS Reg. No. 70331-94-1).	For use only: 1. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene complying with § 177.1640 of this chapter. 2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, and 1.3. 3. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, 3.4, 3.5, and 4.0 that contact food types I, II, IV-B, VI, VII-B and VIII described in Table 1 of § 176.170(c) of this chapter. 4. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, and 4.0 that contact food types III, IV-A, V, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter; except that olefin copolymers complying with items 3.1 and 3.2 where the majority of polymer units are derived from propylene may contain the additive at levels not to exceed 0.5 percent by weight. 5. At levels not to exceed 0.1 percent by weight of olefin polymers complying with item 3.4 of § 177.1520(c) of this chapter, that contact food types III, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter; except that olefin copolymers complying with item 3.4 where the majority of the polymer units are derived from propylene may contain the additive at levels not to exceed 0.5 percent by weight.
* * * * *	

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Any person who will be adversely affected by the regulation may at any time on or before May 2, 1984, submit to the Dockets Management Branch (address above) written objections or additional information in support of previously filed objections and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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 regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: March 23, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-8557 Filed 3-27-84; 4:04 pm]

BILLING CODE 4160-01-M

21 CFR Part 176

[Docket No. 82F-0087]

Indirect Food Additives; Paper and Paperboard Components; Components of Paper and Paperboard in Contact with Aqueous and Fatty Foods

AGENCY: Food and Drug Administration.

ACTION: Final rule; clarification.

SUMMARY: The Food and Drug Administration (FDA) is publishing additional information on a final rule published in the **Federal Register** of August 19, 1983 (48 FR 37617), that amended the food additive regulations by removing the upper viscosity limit of a currently regulated retention aid. The retention aid is polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting adipic acid with diethylenetriamine to form a basic polyamide and further reacting the polyamide with an epichlorohydrin and dimethylamine mixture. The agency is providing an additional 30-day period for submitting objections or additional information in support of objections already filed in response to this regulation.

DATE: Objections or additional information in support of previously filed objections by May 2, 1984.

ADDRESS: Written objections or additional information in support of previously filed objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John L. Herrman, Center for Food Safety and Applied Nutrition (formerly Bureau of Foods) (HFF-334), Food and Drug

Administration, 200 C St. SW., Washington, DC 20204, 202–472–5740.

SUPPLEMENTARY INFORMATION: FDA published a final rule in the **Federal Register** of August 19, 1983 (48 FR 37617), that amended the food additive regulations (21 CFR 176.170) by removing the upper viscosity limit of a currently regulated retention aid. The retention aid is polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting adipic acid with diethylenetriamine to form a basic polyamide and further reacting the polyamide with an epichlorohydrin and dimethylamine mixture. That action responded to a petition (FAP 2B3622) filed by Sandoz Colors and Chemicals, East Hanover, NJ 07936.

The preamble to the regulation explained that the agency had evaluated data in the petition and had concluded that the proposed use of the substance was safe, and that the food additive regulations should be amended as requested in the petition. The document did not discuss the specific nature of the data evaluated.

Subsequently, The Natural Resources Defense Council, Inc., 122 East 42d St., New York, NY 10168; and Public Citizen's Health Research Group, 2000 P St. NW., Washington, DC 20036, filed objections to the regulation. The objections argued that the agency did not provide adequate information about the additive and the basis for FDA's decision to approve it. The objections stressed that the preamble to the **Federal Register** document did not disclose that the agency's action involved consideration of whether the Delaney anticancer clause might apply to the additive. According to the objections, omission of such an explanation foreclosed interested persons from effectively commenting on or objecting to the regulation. The objections requested FDA to publish a supplemental **Federal Register** notice discussing the factual and legal bases for the decision. The objections also argued that the final regulation is illegal because it relies on the constituents theory, which the objections characterize as contrary to the Delaney anticancer clause. Finally, the objections requested an immediate stay of the regulation and an additional opportunity for objection, and they reserved the right to request a hearing at a later stage in the process.

This clarification of the final rule responds to the request for supplemental information about the reasons for FDA's decision and provides an additional 30 days for the submission of objections or additional information in support of objections that have already been filed. FDA will act on the remaining issues raised by the objections and requests for a hearing after it has evaluated any further objections or other information filed in response to this document. The agency is not staying the regulation because FDA believes that the additive is safe, and that a stay would not serve the public interest.

In evaluating Sandoz's petition, FDA considered data bearing on the safety of the additive, including the safety of the various constituents of the additive. The polyamide-epichlorohydrin water-soluble thermosetting resins that constitute the food additive have not been found to induce cancer. However, the resins may contain trace amounts of a carcinogenic compound, epichlorohydrin which is used in the manufacture of the additive.

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 the data presented to FDA establish that the additive is safe for that use. The concept of safety embodied in this requirement was explained in the legislative history of the Food Additives Amendment of 1958. "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstances." H.R. Rep. No. 2284, 85th Cong., 2d Sess. 1 (1958). This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The Delaney anticancer clause of the Food Additives Amendment of 1958 (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further that no food additive can be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to list a use of a food additive that contained or was suspected of containing minor amounts of a carcinogenic chemical, even if the additive as a whole has not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of food additives that contain a carcinogenic chemical but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though the color additive contains a carcinogenic constituent. Since that decision, FDA has approved the use of three such color additives, D&C Green No. 5 (47 FR 24278; June 4, 1982) and D&C Red No. 6 and D&C Red No. 7 (47 FR 57681; December 28, 1982), on the same basis. FDA fully explained the scientific, legal, and policy underpinnings for those decisions in the advance notice of proposed rulemaking on a policy for regulating carcinogenic chemicals in food and color additives, which was published in the **Federal Register** of April 2, 1982 (47 FR 14464). In brief, the agency believes that the Delaney anticancer clause is not triggered unless the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer but that contains a carcinogenic constituent may properly be evaluated under the general safety clause of the statute, using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott* v. *FDA*, —— F.2d —— (Nos. 82–3544/3759) (6th Cir. February 23, 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which, as explained above, contains a carcinogenic chemical but has not itself been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

The agency calculated the upper bound limit of lifetime risk of cancer resulting from exposure to epichlorohydrin from the previously regulated uses of polyamide-epichlorohydrin water-soluble copolymer resins to be no more than 1.3×10^{-5}. Removing the upper viscosity limit for the polymer allows for a higher molecular weight copolymer, which is more efficient as a retention aid for paper and paperboard. FDA concludes that a higher molecular weight copolymer is not likely to contain any more epichlorohydrin monomer than the copolymer resin with the lower viscosity. The upper bound risk estimate for the lower viscosity resin was based on the conservative assumption that all uncoated paper was treated with the resin. Therefore, FDA concludes that the decision to allow a higher viscosity resin

would not increase the exposure to epichlorohydrin monomer from that previously assumed.

The agency has not performed a risk estimate for all food exposure to epichlorohydrin because it does not have, nor could it reasonably obtain, adequate, reliable data on the total dietary exposure to epichlorohydrin from other regulated additives. Nonetheless, in this specific situation, despite its inability to cumulate exposure to the carcinogenic constituent, FDA still finds the use of polyamide-epichlorohydrin is safe. FDA has reached this conclusion for the following reasons: (1) The exposure to epichlorohydrin from the use of this retention aid is so small that it will not contribute significantly to the level of epichlorohydrin in the diet. (2) The agency regards the upper-bound limit of risk calculated for exposure to epichlorohydrin from use of polyamide-epichlorohydrin to be sufficiently low to assure safe use of this additive even with additional exposure to epichlorohydrin from other products. (3) The food additive regulation at issue does not approve a new additive; it merely changes the conditions of use of an already approved additive and does so in such a way as not to increase exposure to epichlorohydrin. Thus, the agency concludes that there is a reasonable certainty that no harm will result from the proposed removal of the upper viscosity limit.

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 (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection. Among the documents that the agency has relied upon are the following:

1. FAP 3B2856, Exhibit B, Appendix II, April 11, 1972.

2. FAP 3B2856, Exhibit B, August 9, 1973.

3. Memorandum: Organic and Additives Chemistry Branch to Petitions Control Branch; August 21, 1973; FAP 3B2856.

4. Memorandum: Food Additive and Animal Drug Chemistry Evaluation Branch to Petitions Control Branch; November 29, 1982; FAP 2B3622 estimated daily intake for epichlorohydrin.

5. Memorandum: Color and Cosmetics Evaluation Branch to Marcia Van Gemert, November 29, 1982; Risk estimation for epichlorohydrin.

6. Memorandum: Food Additives Evaluation Branch to Petitions Control Branch; December 16, 1982; FAP 2B3622.

7. Memorandum: Associate Director for Compliance, Bureau of Foods to Associate Commissioner for Regulatory Affairs, May 9, 1983; Amendment to § 176.170; FAP 2B3622.

List of Subjects in 21 CFR Part 176

Food additives; Food packaging; Paper and paperboard.

For convenience, FDA is republishing in its entirety the final regulation that appeared in the **Federal Register** of August 19, 1983. This clarification of the final rule does not amend the regulation in any way.

This clarification of the final rule is issued under the Federal Food, Drug, and Cosmetic Act.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods

* * * * *

(a) * * *

(5) * * *

List of substances	Limitations
* * * * *	
Polyamide-epichlorohydrin water-soluble thermosetting resins [CAS Reg. No. 68583-79-9] prepared by reacting adipic acid with diethylenetriamine to form a basic polyamide and further reacting the polyamide with an epichlorohydrin and dimethylamine mixture such that the finished resins have a nitrogen content of 17.0 to 18.0 percent on a dry basis, and that a 30-percent-by-weight aqueous solution has a minimum viscosity of 350 centipoises at 20° C, as determined by a Brookfield viscometer using a No. 3 spindle at 30 r.p.m. (or equivalent method).	For use only under the following conditions: 1. As a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard and limited to use at a level not to exceed 0.12 percent by weight of dry paper or paperboard. 2. The finished paper or paperboard will be used in contact with food only of the types identified in paragraph (c) of this section, table 1, under types I and IV–B and under conditions of use described in paragraph (c) of this section, table 2, conditions of use F and G.
* * * * *	

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 2, 1984, submit to the Dockets Management Branch (address above), written objections thereto or submit additional information in support of previously filed objections and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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 regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 23, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-8556 Filed 3-27-84; 4:01 pm]

BILLING CODE 4160-01-M

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Parts 1601, 1610, 1611, and 1626

Provisional Revisions Necessitated by Reorganization of Field Office Structure

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: The Equal Employment Opportunity Commission has recently approved a reorganization of its field office structure which will enable it to more efficiently administer and enforce the employment discrimination statutes for which it is responsible. There will now be three types of field office instead of two. This document amends the Commission's regulations to reflect this change.

DATES: This Final Rule is effective on April 1, 1984.

FOR FURTHER INFORMATION CONTACT: The Office of Legal Counsel, Legal Services, Nicholas M. Inzeo (634–6592) or Thomas J. Schlageter (634–6592).

List of Subjects

7 CFR Part 1601

Administrative practice and procedure.

7 CFR Part 1610

Freedom of information.

7 CFR Part 1611

Privacy.

7 CFR Part 1626

Administrative practice and procedure.

For the Commission.

Clarence Thomas,

Chairman, Equal Employment Opportunity Commission.

PART 1601—PROCEDURAL REGULATIONS

§ 1601.5 [Amended]

1. Section 1601.5 is amended by adding the following after the fourth sentence:

* * * The term "local office" shall mean an EEOC office with responsibility over a part of the United States within a district fixed by the Commission as a particular sub-unit of a district. The term "local director" shall refer to that person designated as the Commission's chief officer for the local office. * * *

2. Section 1601.5 is amended by adding "and local" after "area" in the next to the last sentence.

§ 1601.8 [Amended]

3. Section 1601.8 is amended by removing "district or area" and replacing it with "district, area or local".

4. Section 1601.8 is amended by removing "district" in the last sentence and replacing it with "field".

§§ 1601.10, 1601.14, 1601.20 and 1601.28 [Amended]

5. Sections 1601.10, 1601.14(b), 1601.20(a) and 1601.28(c) are amended by adding "Local Directors," after "Area Directors" wherever it appears.

§§ 1601.19 and 1601.24 [Amended]

6. Sections 1601.19(g) and 1601.24(b) are amended by adding "or Local Directors" after "Area Directors" wherever it appears.

§ 1601.21 [Amended]

7. The introductory paragraph of § 1601.21(d) is amended by adding "or Local Directors" after "Area Directors" in the first sentence.

8. The introductory paragraph of § 1601.21(d) is amended by substituting "Each" for "Such" in the next to the last sentence.

9. The introductory paragraph of § 1601.21(d) is amended by substituting "each Area Director and each Local Director" for "and each Area Director" in the last sentence.

§ 1601.28 [Amended]

10. Section 1601.28(a)(2) is amended by adding "the Local Director" after "the Area Director".

11. Section 1601.28(a)(3) is amended by inserting "Local Director;" after "Area Director" in the first sentence.

12. Section 1601.28(c) is amended by inserting "Local Directors," after "Area Directors".

PART 1610—AVAILABILITY OF RECORDS

§ 1610.4 [Amended]

13. Section 1610.4(b) is amended by removing "district and area" and replacing it with "district, area and local."

14. Section 1610.4(c) is amended by removing "District and Area" and replacing it with "District, Area and Local."

15. Section 1610.4(c) is amended by removing "Area" after "Buffalo", "El Paso," "Fresno," "Greensboro," "Greenville," "Minneapolis," "Oakland," "San Diego" and "San Jose" and replacing it with "Local."

16. Section 1610.4(c) is amended by substituting the below listed addresses for the following offices:

§ 1610.4 Public reference facilities and current index.

* * * * *

(c) * * *

Atlanta * * *, Citizens Trust Bank Building, 10th Floor, 75 Piedmont Avenue, NE., Atlanta, Georgia 30335

Baltimore * * *, 109 Market Place, Suite 4000, Baltimore, Maryland 21202

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Boston * * *, J. F. Kennedy Federal Bldg., Room 409B, Boston, Massachusetts 02203

Buffalo * * *, 210 Franklin Street, Room 503, Buffalo, New York 14202

Charlotte * * *, 1301 East Morehead Street, Charlotte, North Carolina 28204

Chicago * * *, Federal Building, Room 930A, 536 South Clark Street, Chicago, Illinois 60605

* * * * *

Cleveland * * *, 1 Playhouse Square, 1375 Euclid Avenue, Cleveland, Ohio 44115

Dallas * * *, 1900 Pacific Building, 13th Floor, Dallas, Texas 75201

* * * * *

El Paso * * *, 1st National Building, Suite 1112, 109 North Oregon Street, El Paso, Texas 79903

* * * * *

Greensboro * * *, Post Office Building, 324 West Market Street, Room B27, Post Office Box 3363, Greensboro, North Carolina 27402

Greenville * * *, Bankers Trust Building, 7 North Laurens Street, Suite 1001, Greenville, South Carolina 29601

Houston * * *, 405 Main street, 6th Floor, Houston, Texas 77002

Indianapolis * * *, Federal Building, Room 456, 46 East Ohio Street, Indianapolis, Indiana 46205

Jackson * * *, New Federal Building, 100 West Capitol Street, Suite 721, Jackson, Mississippi 39269

Kansas City * * *, 911 Walnut Street, 10th Floor, Kansas City, Missouri 64106

Little Rock * * *, Savers Building, Room 621, 320 West Capitol Avenue, Little Rock, Arkansas 72201

* * * * *

Louisville * * *, U.S. Post Office and Courthouse, 601 West Broadway, Room 104, Louisville Kentucky 40202

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Milwaukee * * *, Henry S. Reuss Federal Plaza, Suite 800, 310 West Wisconsin Avenue, Milwaukee, Wisconsin 53203

Minneapolis * * *, Federal Building, Room 178, 110 South 4th Street, Minneapolis, Minnesota 55401

Nashville * * *, Parkway Towers, Suite 1820, Nashville, Tennessee 37219

Newark * * *, Military Park Building, 3d Floor, Newark, New Jersey 07102

* * * * *

New York * * *, 90 Church Street, Room 1501, New York, New York, 10007

Norfolk * * *, Federal Building, Room 412, 200 Granby Mall, Norfolk, Virginia 23510

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Oklahoma City * * *, 50 Penn Place, Suite 504, Oklahoma City, Oklahoma 73118

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Phoenix * * *, 135 North Second Avenue, 4th Floor, Phoenix, Arizona 85003

* * * * *

Raleigh * * *, Professional Bldg., Suite 500, 127 W. Hargett, Raleigh, North Carolina 27601

* * * * *

San Francisco * * *, 10 United Nations Plaza, 4th Floor, San Francisco, California 94102

* * * * *

St. Louis * * *, 625 North Euclid Street, 5th Floor, St. Louis, Missouri 63108

* * * * *

§ 1610.7 [Amended]

17. Section 1610.7(a) is amended by removing "district or area" from the first sentence and replacing it with "district, area of local office."

18. Section 1610.7(a)(1)–(3) is amended by removing "district or area" and replacing it with "district, area or local" wherever it appears.

PART 1611—PRIVACY ACT REGULATIONS

§ 1611.3 [Amended]

19. Section 1611.3(b)(1) is amended by removing "District or Area" and replacing it with "District, Area or Local," and by removing "29 CFR 1610.21(b)" and replacing it with "29 CFR 1610.4(c)."

PART 1626—PROCEDURES—AGE DISCRIMINATION IN EMPLOYMENT ACT

§ 1626.5 [Amended]

20. Section 1626.5 is amended by removing "District or Area" in the first sentence and replacing it with "District, Area or local" and by removing "District" in the second sentence and replacing it with "District, Area and Local."

[FR Doc. 84-8613 Filed 3-30-84; 8:45 am]
BILLING CODE 6570-06-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 947

Surface Mining and Reclamation Operations Under a Federal Program for Washington

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Responses to public comments on interim final rule.

SUMMARY: The Office of Surface Mining (OSM) is responding to public comments submitted regarding the interim final rule which promulgated a Federal surface coal mining program for Washington (48 FR 7078, February 24, 1983). The Secretary of the Interior has reviewed all comments, and no changes to the interm final rule were found to be necessary. Therefore, that rule remains effective as published on February 24, 1983 (48 FR 7078).

DATES: None.

FOR FURTHER INFORMATION CONTACT: James M. Kress, Branch of Regulatory Programs, Office of Surface Mining, U.S. Department of Interior, 1951 Constitution Ave., NW., Washington, D.C. 20240. Telephone: (202) 343–5866.

SUPPLEMENTARY INFORMATION: On February 24, 1983, OSM promulgated a surface coal mining regulatory program for the State of Washington by means of an interim final rule, 48 FR 7870, pursuant to Section 504 of the Surface Mining Control and Reclamation Act (the Act), 30 U.S.C. 1254. The rule provided for a comment period of fifty days. OSM requested comments on how OSM's revisions to its permanent program rules at 30 CFR Chapter VII effected the interim final rule for Washington. The effective date of the program was to be April 25, 1983, but in response to several requests, OSM extended the comment period to April 28, 1983, and changed the affective date of the program to May 13, 1983 (48 FR 16058, April 14, 1983).

The Washington Irrigation and Development Company (WIDCO) brought suit on April 23, 1983, challenging the program, claiming principally that persons who would be required to file a permit application within two months of the effective date of the program were not given enough lead time to prepare the application. See *Washington Irrigation and Development Co.* v. *Watt, et al.*, No. C83–244T (U.S.D.C. E.D. Wash.). OSM met with the plaintiff's representatives on May 12 and 13, 1983, and the parties agreed to dismiss the action dependent upon OSM taking certain actions.

OSM published a notice in the **Federal Register** on May 13, 1983, announcing an effective date for the Washington program of May 16, 1983, and making several changes in the program rules in response both to public comments and to issues raised in the litigation. 48 FR 22292. Although OSM considered all public comments on the Washington program in its May 13, 1983, notice, it did not formally respond to all such comments because of the short period of time between the end of the extended comment period and the date of the notice. This notice, then, responds to the remaining unanswered comments on the interim final rule notice of February 24, 1983. The Secretary of the Interior has reviewed all comments, and no changes to the interim final rule were found to be necessary. Therefore, that rule remains effective as published on February 24, 1983 (48 FR 7078).

Six different persons or entities submitted comments, including comments from a prospective operator. Extensive comments were received from WIDCO. Two comments were submitted by individuals residing in King County who could be affected by operations of the prospective operator mentioned above. Weyerhaeuser Company, which owns a substantial amount of land in the State, some of which is underlain with coal, and the King County Department of Planning and Community Development, in which county a small operation is presently located and a moderate sized one is proposed, also submitted comments.

1. WIDCO took issue with the use of cross-referencing as a means of promulgating the Washington Federal Program. The company contented that the use of cross-referencing provides inadequate public notice, violates the Federal Program regulations at 30 CFR 736.12(a)(2) and the Administrative Procedure Act (5 U.S.C. 553), and causes uncertainty as to which rules comprise the program because of OSM's revision of its permanent program rules. Specifically, WIDCO stated that cross-referencing does not allow adequate consideration of differing regional conditions, that OSM has omitted certain applicable regulations from cross-referencing, and that cross-referencing does not allow for a necessary review period on amendments to permanent program rules as they affect cross-referenced Federal programs. The company urged a two step amendment process for Federal program rules: Amendment of the OSM permanent program rules followed by a separate rulemaking for a similar change to cross-referenced Federal programs.

This comment constitutes the principal grounds on which WIDCO brought suit. In settling the litigation, the parties agreed that for any proposed OSM rule revisions appearing in the **Federal Register** after the effective date of the program, OSM would follow the procedures in 30 CFR Part 736 for amending Federal programs. Further, for any proposed OSM rule revisions appearing in the **Federal Register** before the effective date of the Washington Federal program, no separate rulemaking would be necessary for amending the program if the final rule appeared in the **Federal Register** after the program effective date.

It is OSM's position that cross-referencing does provide adequate notice to the public under the Surface Mining Act and the Federal Administrative Procedure Act. It allows for adequate consideration of regional differences because changes to particular permanent program rules can be made in the cross-referencing