protected area"; and by removing the words "the protected area" both times they appear and adding in their place the words "a protected area".

Done in Washington, DC, this 23rd day of January 1992.

Robert Melland,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 92-2012 Filed 1-27-92; 8:45 am]

BILLING CODE 3410-34-M

7 CFR Part 319

[Docket No. 91-176]

Importation of Pummelo from Israel

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Fruits and Vegetables regulations to allow the importation of pummelo from Israel, subject to completion of the Animal and Plant Health Inspection Service prescribed cold treatment for the Mediterranean fruit fly. We believe this action is warranted because there appears to be no significant pest risk associated with the importation of pummelo from Israel under these circumstances.

EFFECTIVE DATE: January 23, 1992.

FOR FURTHER INFORMATION CONTACT: James Petit de Mange, Operations Officer, Port Operations Staff, PPQ, APHIS, USDA, room 632, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-8645.

SUPPLEMENTARY INFORMATION: The Fruits and Vegetables regulations in 7 CFR 319.56 *et seq.* (referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States to prevent the introduction and dissemination of injurious insects that are new to or not widely distributed within and throughout the United States.

On October 17, 1991 we published in the **Federal Register** (55 FR 52004-52005, Docket No. 91-126) a proposal to amend the regulations by allowing the importation of "pomelo" (*Citrus grandis*) from Israel, subject to completion of the Animal and Plant Health Inspection Service (APHIS) prescribed cold treatment for the Mediterranean fruit fly.

"Pomelo" and "pummelo" are both accepted common names for *Citrus grandis*. However, "pomelo" is also the Spanish word for grapefruit (*Citrus paradisi*). In order to avoid confusion, "pummelo" will be used to refer to *Citrus grandis* in this final rule.

Prior to the effective date of this final rule, the regulations in § 319.56 did not provide for the importation of pummelo from Israel. Both the Mediterranean fruit fly (*Ceratitis capitata*) and the Oriental red spider mite (*Eutetranychus orientalis*) are known to attack citrus in Israel. These are considered potentially destructive pests by APHIS, and neither is present nor widely distributed in the United States.

As explained in the proposed rule, the plant protection service of Israel requested that we consider allowing the entry of pummelo from Israel. Although both the Mediterranean fruit fly (Medfly) and the Oriental red spider mite (ORSM) are known to attack citrus in Israel, research done by the Israelis and accepted by APHIS demonstrates that the cold treatment specified in § 319.56-2d(a)(2)(i) for Medfly is also effective against the ORSM. Pest risk analyses conducted by APHIS have determined that any other injurious insects that might be carried by the pummelo would be readily detectable by a USDA inspector.

We therefore proposed to add a new § 319.56-2u to allow the importation of pummelo from Israel, subject to completion of the cold treatment in § 319.56-2d(a)(2)(i) and to all other applicable requirements of title 7 of the Code of Federal Regulations, "Subpart—Fruits and Vegetables."

Comments on the proposed rule were required to be received on or before November 18, 1991. We received one comment, from a State agency, by this date. The commenter supported the proposed rule as it addressed Medfly and ORSM, but had a reservation concerning the fungal disease mal secco (*Phoma tracheiphila*), which he said is not known to occur in the United States but is known to infect several citrus species and cultivars in many Mediterranean countries (including Israel). He was concerned that the fungus may be found in a sporulating condition on short stems which may be attached to the fruit being transported to the United States, thus entering this country. The commenter suggested that APHIS evaluate the pest introduction risk associated with this organism.

APHIS studies of scientific literature indicate that the mal secco organism causes a systemic infection in susceptible plants resulting in shedding of the leaves and eventual dieback of the infected branches. Rapid yellowing of the fruit and premature fruit fall result from the movement of the fungus through the branch toward the fruit. Dead or badly affected branches are not likely to retain fruit, and the occasional fruit which may remain on dead or badly affected branches is not of harvestable quality. The mal secco organism sporulates only after the branch has died and the fungus has invaded the bark.

The presence of healthy appearing fruit, even on affected limbs, indicates that the fungus is not yet near the fruit and definitely has not entered the stem of the fruit. Therefore, APHIS concludes that it is extremely unlikely that the fungus would be found in a sporulating condition on the stem of healthy fruit. This negligible risk does not justify a more restrictive position towards the importation of pummelo from Israel.

The commenter was also concerned that the fungus spores may be carried as contaminants on the surface of the fruit, including the calyces. APHIS recognizes that spores of the mal secco fungus (and many other organisms) may be present as surface contaminants on fruit and possibly under the calyces of fruit. The question becomes whether spore contamination is likely to result in the introduction of the organism and whether the risk justifies prohibiting or restricting fruit for spore contamination if the organism is not sporulating on the fruit. Experience and scientific evidence do not suggest that spore contamination provides a viable pathway for the introduction of fungus organisms.[1] As a result, APHIS believes that to regulate commercially harvested fruit for spore contamination is not reasonable or justified, and would result in a precedent with far reaching negative impacts.

Based on the rationale set forth in the proposal and in this document, we are adopting the provisions of the proposal as a final rule without change.

Effective Date

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**. Immediate implementation of this rule is necessary to provide relief to those persons who are adversely affected by restrictions we no longer find warranted. The shipping season for pummelos from Israel is in progress. Making this rule effective immediately will allow interested producers and others in the marketing chain to benefit during this year's shipping season. Therefore, the Administrator of APHIS has determined that this rule should be effective upon signature.

[1] Information concerning the scientific evidence may be obtained from the individual listed under "FOR FURTHER INFORMATION CONTACT."

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

We are changing the regulations to allow the importation of pummelo from Israel, subject to completion of an APHIS-prescribed cold treatment for the Medfly and the ORSM. Embassy officials anticipate that initial annual pummelo shipments from Israel to the United States will average between 200 and 300 metric tons and increase to approximately 1,000 metric tons within several years. The initial retail value of Israeli pummelo shipments will range from approximately $373,600 to $747,000. As Israel increases annual exports, the total retail value of pummelo shipments to the United States will be expected to increase to between $1.5 million and $2.1 million.

In the United States, pummelos represent an extremely small portion of the domestic citrus industry. There are only a handful of commercial pummelo producers in the United States—approximately two to three in Florida, with some additional production occurring in California. Current estimates indicate that there are fewer than 1,000 pummelo trees in the United States. Domestic producers grow pummelo as a small part of large-scale citrus operations, and it is expected that they will continue to grow pummelo at the same rate. Thus domestic production of pummelo is not expected to be affected by increased imports from Israel.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR, subpart V.)

List of Subjects in 7 CFR Part 319

Agricultural commodities, Fruit, Imports, Plant diseases, Plant pests, Plants (Agriculture), Quarantine, Transportation.

PART 319—FOREIGN QUARANTINE NOTICES

Accordingly, we are amending 7 CFR part 319 as follows:

1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151–167; 7 CFR 2.17, 2.51, and 371.2(c), unless otherwise noted.

2. In Subpart—Fruits and Vegetables, a new § 319.56–2u is added to read as follows:

§ 319.56–2u Conditions governing the entry of pummelo from Israel.

Pummelo from Israel may be imported into the United States only if cold treated in accordance with § 319.56–2d(a)(2)(i) of this subpart and if all other applicable requirements of this subpart are met. Entry is limited to North Atlantic ports north of and including Baltimore, MD, if treatment is to be completed in the United States. Entry may be through any port if treatment has been completed prior to arrival in the United States.

Done in Washington, DC, this 23rd day of January 1992.

Robert Melland,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 92–2014 Filed 1–27–92; 8:45 am]

BILLING CODE 3410–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 89F–0451]

Indirect Food Additives: Paper and Paperboard Components

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 12-hydroxystearic acid-polyethylene glycol block copolymers as surfactants for dispersions of polyacrylamide retention and drainage aids used in the manufacture of paper and paperboard. This action responds to a petition filed by ICI Americas, Inc.

DATES: Effective January 28, 1992. Written objections and requests for a hearing by February 27, 1992.

ADDRESSES: 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: Daniel N. Harrison, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFF–335), 200 C Street SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 17, 1989 (54 FR 47828), FDA announced that a petition (FAP OB4179) had been filed by ICI Americas, Inc., Concord Pike and Murphy Rd., Wilmington, DE 19803, proposing that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended to provide for the safe use of polyethylene glycol (MW 1500–4000)/poly (12-hydroxystearic acid) copolymers as surfactants for dispersions of polyacrylamide retention and drainage aids used in the manufacture of paper and paperboard intended to contact aqueous and fatty foods.

The filing notice proposed that the molecular weight of the polyethylene glycol reactant be 1500 to 4000. FDA concludes, however, that it is unnecessary to specify an upper molecular weight range for the polyethylene glycol reactant because the safety of the additive prepared using polyethylene glycol with an average molecular weight of 1500 has been established by this petition and copolymers prepared using polyethylene glycol with higher average molecular weights are generally known, based on agency experience, to be less toxic than lower molecular weight compounds. Therefore, in this regulation, the agency is only specifying 1500 as the minimum molecular weight for the polyethylene glycol components. FDA also has determined that the additive is best described by the nomenclature 12-

hydroxystearic acid-polyethylene glycol block copolymers. The agency is therefore using this name for the additive in the regulation.

FDA, in its evaluation of the safety of 12-hydroxystearic acid-polyethylene glycol block copolymers, reviewed the safety of the additive, including impurities that might be present in the additive. The agency is not aware of any data that show that the additive, 12-hydroxystearic acid-polyethylene glycol block copolymers, is a cancer-causing chemical. However, ethylene oxide and 1,4-dioxane, which could be present as impurities in the polyethylene glycol, have been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as ethylene oxide and 1,4-dioxane, 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," a food additive cannot be approved for a particular use unless a fair evaluation of the data establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "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 circumstance." (H. Rept. 2284, 85th Cong., 2d Sess. 4 (1958).) This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409(c)(3)(A) of the act) provides further that no food additive shall 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 approve a use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though 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 it contains a carcinogenic constituent. Since that decision, FDA has approved the use of other color additives and food additives on the same basis.

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*, 728 F. 2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical, but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of the Petitioned Use

FDA estimates that the petitioned use of 12-hydroxystearic acid-polyethylene glycol block copolymers will result in extremely low levels of exposure to this additive. The agency calculated the estimated daily intake of 12-hydroxystearic acid-polyethylene glycol block copolymers based on several factors, including the migration of the additive under the most severe intended use conditions and the probable concentration of the additive in the daily diet from food-contact articles. The estimated daily intake for the additive is no greater than 39 micrograms per person per day.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2), and the agency has not required such testing in this case. On the basis of available acute toxicity data and the low level of exposure to the 12-hydroxystearic acid-polyethylene glycol block copolymers, the agency concludes that there is an adequate margin of safety for the proposed use of this additive.

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 chemicals, ethylene oxide and 1,4-dioxane, that may be present as impurities in the additive. Based on this evaluation, the agency has concluded that the additive is safe under the proposed conditions of use.

The risk assessment procedures that FDA used in this evaluation are similar to the methods that the agency has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food and color additives that contain carcinogenic impurities (see e.g., 49 FR 13018 at 13019, April 2, 1984). This risk evaluation of the 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. 1,4-Dioxane

Based on the fraction of the daily diet that may be in contact with surfaces containing the additive and assuming that 1,4-dioxane is present in the finished polymer, FDA estimated the hypothetical worst-case exposure to 1,4-dioxane from the use of the additive to be no greater than 19 picograms (pg) per person per day (Ref. 3). The agency used data from a carcinogenesis bioassay conducted by the National Cancer Institute (Ref. 4) to estimate the upper-bound level of lifetime human risk from the proposed use of the additive. The results of the bioassay on 1,4-dioxane indicated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

The Center for Food Safety and Applied Nutrition's Cancer Assessment Committee (the committee) reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on 1,4-dioxane. The committee further concluded that the 1,4-dioxane bioassay provided the appropriate basis on which to calculate an estimate of the upper-bound level of lifetime risk from potential exposure to 1,4-dioxane stemming from the proposed use of the additive.

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. For this reason, the estimate can be used with confidence to determine, to a reasonable certainty, whether any harm will result from the proposed conditions and levels of use of the food additives.

Based on a worst-case exposure of 19 pg per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from the potential exposure to 1,4-dioxane from the use of the subject additive is 6.7×10^{-13}, or 6.7 in 10 trillion (Ref. 5). Because of numerous conservatisms in the exposure estimate, actual lifetime averaged exposure to 1,4-dioxane is expected to be substantially less than the estimated daily intake and, therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to 1,4-dioxane that might result from the proposed use of the additive.

B. Ethylene Oxide

Based on the fraction of the daily diet that may be in contact with surfaces containing the additive and assuming that ethylene oxide is present at the limit of detection (Ref. 3), FDA estimated the hypothetical worst-case exposure to ethylene oxide from the use of the additive to be no greater than 7.5 pg per person per day. The agency used data from a carcinogenesis bioassay on ethylene oxide performed by the Institute of Hygiene, University of Mainz, Germany (Ref. 6) to estimate the upper-bound level of lifetime human risk from the proposed use of the additive. The results of the bioassay on ethylene oxide indicated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas in situ of the forestomach and carcinoma in situ of the glandular stomach.

The committee reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on ethylene oxide. The committee further concluded that the ethylene oxide bioassay provided the appropriate basis on which to calculate an estimate of the upper-bound level of lifetime risk from potential exposure to ethylene oxide stemming from the proposed use of the additive.

Based on a worst-case exposure of 7.5 pg per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from the potential exposure to ethylene oxide from the use of the subject additive is 1.5×10^{-11}, or 1.5 in 100 billion (Ref. 5). Because of numerous conservatisms in the exposure estimate, actual lifetime averaged individual daily exposure to ethylene oxide is expected to be substantially less than the estimated daily intake, and therefore the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to ethylene oxide that might result from the proposed use of the additive.

III. Need for Specifications and Conclusion on Safety

The agency has also considered whether specifications are necessary to control the amount of 1,4-dioxane and ethylene oxide in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which ethylene oxide and 1,4-dioxane may be expected to remain as impurities following production of the additive, the agency would not expect these impurities to become components of food at other than extremely low levels; and (2) the upper-bound limit of lifetime risk from exposure to either of these impurities, even under worst-case assumptions, is very low, 1.5 in 100 billion.

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed food additive use is safe and that the regulations 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 (address above) 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. Objections

Any person who will be adversely affected by this regulation may at any time on or before February 27, 1992 file with the Dockets Management Branch (address above) written objections thereto.

Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Carr, G.M., "Carcinogen Testing Programs," in *Food Safety: Where Are We?*, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, p. 59, July 1979.
2. Kokoski, C.J., "Regulatory Food Additive Toxicology," in *Chemical Safety Regulation and Compliance*, edited by Homburger, F., J.K. Marquis, and S. Karger, New York, NY, pp. 24–33, 1985.
3. Memorandum from the Food and Color Additives Review Section to the Indirect Additives Branch, dated May 18, 1990.
4. "Bioassay of 1,4-dioxane for Possible Carcinogenicity," National Cancer Institute, NCI–CG–TR–80, 1978.
5. Memorandum from the Quantitative Risk Assessment Committee, dated April 11, 1991, Re: FAP OB4179.
6. Dunkelberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide upon Intragastric Administration to Rats," *British Journal of Cancer*, 46:924, 1982.

List of Subjects in 21 CFR Part 176

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 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR Part 176 continues to read as follows:

Authority: Secs. 201, 402, 406, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348, 376).

2. Section 176.170 is amended in paragraph (a)(5) by alphabetically adding a new entry to read as follows:

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

* * * * *

(a) * * *

(5) * * *

List of substances	Limitations
* * * * *	
12-Hydroxystearic acid-polyethylene glycol block copolymers (CAS Reg. No. 70142-34-6) produced by the reaction of polyethylene glycol (minimum molecular weight 1500) with 12-hydroxystearic acid.	For use only as a surfactant for dispersions of polyacrylamide retention and drainage aids employed prior to the sheet forming operation in the manufacture of paper and paperboard.
* * * * *	

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Dated: January 21, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-1990 Filed 1-27-92; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 177

[Docket No. 89F-0171]

Indirect Food Additives; Poly(Phenyleneterephthalamide) Resins

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of poly(phenyleneterephthalamide) resins and various adjuvants used in the resin production, when used in repeated contact with food. The additive is the subject of a petition filed by E.I. du Pont de Nemours & Co.

DATES: Effective January 28, 1992; written objections and requests for a hearing by February 27, 1992.

ADDRESSES: 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: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 6, 1989 (54 FR 24264), FDA announced that a food additive petition (FAP 8B4101) had been filed by E.I. du Pont de Nemours & Co., 1007 Market St., Wilmington, DE 19898, proposing that the food additive regulations be amended for the safe use of poly(p-phenyleneterephthalamide) resins intended to produce articles for repeated use in the processing and handling of food. The filing notice announced that the processing and finishing of the resins may include the following optional adjuvant substances:

Diundecylphthalate
Mono-and dipotassium salts of lauryl phosphate
o-Phenylphenol
Poly(oxyethylene/oxypropylene)monobutylether
Polyethylene glycol mono(nonylphenyl)ether
Polyvinylmethyl ether
Poly(oxyethylene) sorbitol monolaurate tetraoleate
Poly(oxyethylene) sorbitol hexaoleate
4,4'-Butylidenebis(6-*tert*-butyl-*m*-cresol)

To be consistent with current acceptable nomenclature, polyethylene glycol mono(nonylphenyl)ether has been changed to read poly(oxyethylene) mono(nonylphenyl)ether and poly(p-phenyleneterephthalamide) resin has been changed to read poly(phenyleneterephthalamide) resin.

I. The Additive

FDA has reviewed the safety of these additives, as well as the starting materials. Four of the additives reviewed, poly(oxyethylene/oxypropylene)monobutylether, poly(oxyethylene) mono(nonylphenyl)ether, poly(oxyethylene) sorbitol monolaurate tetraoleate, and poly(oxyethylene) sorbitol hexaoleate may contain minute amounts of ethylene oxide and 1,4-dioxane as impurities from their production. These chemical impurities have been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as ethylene oxide and 1,4-dioxane, are commonly found as contaminants in chemical products, including some food additives.

II. Prior Action

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 establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "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. Rept. 2284, 85th Cong., 2d Sess. 4 (1958). This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer, or Delaney clause, of the food additive amendment (section 409(c)(3)(A) of the act) provides further that no food additive shall 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 approve a use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though the additive as a whole had not been shown to cause cancer. The agency now believes, however, that development 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 it contains a carcinogenic constituent. Since that decision, FDA has approved the use of other color additives and food additives on the same basis. 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