authority delegated to the Commissioner of Food and Drugs, 21 CFR part 2 is amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

1. The authority citation for 21 CFR part 2 continues to read as follows:

Authority: Secs. 201, 301, 305, 402, 408, 409, 501, 502, 505, 507, 512, 601, 701, 702, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 335, 342, 346a, 348, 351, 352, 355, 357, 360b, 361, 371, 372, 374); 15 U.S.C. 402, 409.

2. Section 2.125 is amended by adding new paragraph (e)(15) to read as follows:

§ 2.125 Use of chlorofluorocarbon propellants in self-pressurized containers.

* * * * *

(e) * * *

(15) Sterile aerosol talc administered intrapleurally by thoracoscopy for human use.

* * * * *

Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12758 Filed 5–21–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 173

[Docket No. 93F–0483]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that appeared in the Federal Register of March 3, 1995 (60 FR 11899). The document amended the food additive regulations to provide for the safe use of chlorine dioxide to control the microbial population in poultry process water. The document was published with some errors. This document corrects those errors. Additionally, the agency is revising some of the discussion in the preamble for clarification. These changes are not substantive and do not affect the agency's conclusion regarding the use of chlorine dioxide in poultry process water. The codified regulation remains unchanged.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

In FR Doc. 95–5275, appearing on page 11899 in the Federal Register of Friday, March 3, 1995, the following corrections are made:

1. On page 11899, in the second column, in the first full paragraph, beginning in line 8, ''reaction of chlorine with sodium chlorite'' is corrected to read ''oxidation of sodium chlorite''; in the same paragraph, beginning in line 10, ''acidification of sodium chlorite'' is corrected to read ''disproportionation of sodium chlorite in the presence of acids (Ref. 1).''; and in the same paragraph, beginning in line 16, ''(Ref. 1).'' is corrected to read ''Ref. 1a).''

2. On page 11899, in the second column, in the second full paragraph, in line 5, ''of chlorine'' is corrected to read ''with chlorine''.

3. On page 11899, in the second column, in the fourth full paragraph, in the 4th line from the bottom, ''studies'' is corrected to read ''safety studies'' and in the 3rd line from the bottom ''petitioner were'' is corrected to read ''petitioner on poultry were''.

4. On page 11899, in the third column, in the first paragraph, in line 3, ''3 ppm'' is corrected to read ''100 ppm''.

5. On page 11899, in the third column, in the first paragraph, beginning in line 5 and ending in line 21, ''These data show that organic * * * in drinking water.)'' is corrected to read ''These data show that comparable trace levels of chloroform and dichloromethane were detected in both untreated and chlorine dioxide-treated poultry process water and that chlorine dioxide treatment did not appear to contribute to their formation.''

6. On page 11899, in the third column, in the first paragraph, in line 23, ''20'' is corrected to read ''100'', and beginning in line 24, ''no mutagenic'' is corrected to read ''negligible mutagenic''.

7. On page 11899, in the third column, in the third paragraph, beginning in line 8, ''(No chlorite or chlorate could * * * for the method used).'' is removed.

(Note: The finding of no significant residues of chlorite and chlorate was not based on chemical analysis. The agency determined that any residues of chlorite and chlorate remaining on poultry would be converted to chloride (a major component of table salt) during cooking.)

8. On page 11900, in the first column, in the first full paragraph, beginning in line 3, ''linoleic, linolenic, and arachidonic acid)'' is corrected to read ''linoleic and linolenic acid)'', and in the same paragraph, in line 11, ''levels 7 to 10 times'' is corrected to read ''levels 8 to 22 times''.

9. On page 11900, in the first column, in the second full paragraph, in line 4, ''measurable'' is corrected to read ''significant''.

10. On page 11900, in the first column, in the third full paragraph, in line 6, ''no'' is corrected to read ''negligible''.

11. On page 11900, in the third column, Ref. 1a is added to read ''1a. U.S. patent No. 4,247,531.'', and Ref. 6 is corrected to read ''6. CRC Handbook of Chemistry and Physics, 71st ed., 1990–1991, David R. Lide, Editor-in-Chief, CRC Press, Boca Raton, FL. See Table of Electrochemical Potentials (re chlorite and chlorate), sections 8–16.''

Dated: May 14, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12757 Filed 5–20–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 176

[Docket No. 92F–0313]

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 diethanolamine as a boiler water additive in paper mill boilers used in the manufacture of paper and paperboard intended for use in contact with aqueous and fatty food. This action is in response to a food additive petition filed by Betz Laboratories, Inc.

DATES: Effective May 21, 1996; written objections and requests for a hearing by June 20, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Diane E. Robertson, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of September 14, 1992 (57 FR 41944), FDA announced that a food additive petition (FAP 2B4329) had been filed by Betz Laboratories, Inc., 4636 Somerton Rd., Trevose, PA 19053–6783. The petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of diethanolamine as a boiler water additive in paper mill boilers.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it may contain minute amounts of 1,4-dioxane and ethylene oxide, which are carcinogenic impurities, resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as 1,4-dioxane and ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

II. Determination of Safety

Under the so-called ''general safety clause'' of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)),'' 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 of the act (21 U.S.C. 348(c)(3)(A)) 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 the 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).

III. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, diethanolamine, will result in exposure to no greater than 5 parts per billion (ppb) of the additive in the daily diet (3 kilograms (kg)) or an estimated daily intake (EDI) of 15 micrograms per person per day (μ/person/day) (Ref. 1) and that the cumulative dietary concentration of the additive from all regulated uses is conservatively 58 ppb in the daily diet or an EDI of 170 μ/person/day.

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that a small increase in dietary exposure is safe.

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 1,4-dioxane and ethylene oxide, carcinogenic chemicals that may be present as impurities in the additive. This risk evaluation of 1,4-dioxane and ethylene oxide has two aspects: (1) Assessment of the worst-case exposure to these 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

FDA has estimated the hypothetical worst-case exposure to 1,4-dioxane from the petitioned use of the additive in the manufacture of paper to be 0.6 part per quadrillion (ppq) of the daily diet (3 kg), or 2 picograms (pg)/person/day (Ref. 3). The agency used data from a carcinogenesis bioassay on 1,4-dioxane conducted by the National Cancer Institute (Ref. 4), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the proposed use of the additive (Ref. 4). The results of the bioassay on 1,4-dioxane demonstrated 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.

Based on the estimated worst-case exposure to 1,4-dioxane of 2 pg/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the use of the subject additive is 6.9×10^{-14}, or 6.9 in 100 trillion (Ref. 5). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to 1,4-dioxane is expected to be substantially less than the worst-case exposure, and therefore, the upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to 1,4-dioxane would result from the proposed use of the additive.

B. Ethylene Oxide

FDA has estimated the hypothetical worst-case exposure to ethylene oxide from the petitioned use of the additive in the manufacture of paper to be 0.6 ppq of the daily diet (3 kg), or 2 pg/person/day (Ref. 3). The agency used data from a carcinogenesis bioassay on ethylene oxide conducted for the Institute of Hygiene, University of Mainz, Germany to estimate the upper-bound limit of lifetime human risk from exposure to ethylene oxide resulting from the proposed use of the additive (Ref. 6). The results of the bioassay on ethylene oxide demonstrated 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 of the forestomach and carcinomas in situ of the glandular stomach.

Based on the estimated worst-case exposure to ethylene oxide of 2 pg/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the use of the subject additive is 3.7×10^{-12}, or 3.7 in 1 trillion (Ref. 5). Because of the numerous conservative assumptions used in calculating the exposure estimate, actual lifetime-averaged individual exposure to ethylene oxide is likely to be substantially less than the worst-case exposure, and therefore, the upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to ethylene oxide would result from the proposed use of the additive.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of 1,4-dioxane and ethylene oxide present as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which 1,4-dioxane and ethylene oxide 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 6.9 in 100 trillion for 1,4-dioxane and less than 3.7 in 1 trillion for ethylene oxide, respectively.

IV. Conclusion

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed use of the additive in paper mill boilers used in the manufacture of paper and paperboard products intended for use in contact with aqueous and fatty food is safe. Based on this information, the agency has also concluded that the additive will have the intended technical effect. Therefore, § 176.170 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.

V. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 20,1996, 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.

VII. References

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

1. Memorandum dated September 8, 1993, from the Chemistry Review Branch (HFS–247), to the Indirect Additives Branch (HFS–216) concerning ''FAP 2B4329 (MATS No. 654; M 2.1). Submission of 6/5/92; Betz Laboratories. Diethanolamine in papermill boilers.''

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. Memorandum dated April 28, 1994, from the Chemistry Review Branch (HFS–247) to the Indirect Additives Branch (HFS–216) concerning ''FAP 2B4329 (MATS No. 654; M 2.4): Diethanolamine. Paper mill boiler additive. Betz Laboratories-Submission of 4/8/94.''

4. ''Bioassay of 1,4-Dioxane for Possible Carcinogenicity,'' National Cancer Institute, NCI–CG–TR–80, 1978.

5. Memorandum, Report of the Quantitative Risk Assessment Committee, October 28, 1994.

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, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348, 379e).

2. Section 176.170 is amended in the table in paragraph (a)(5) by revising the entry for ''Diethanolamine'' under the heading ''Limitations'' to read as follows:

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

* * * * *

(a) * * *

(5) * * *

List of Substances	Limitations
* * *	* * * *
Diethanolamine	For use only: 1. As an adjuvant to control pulp absorbency and pitch content in the manufacture of paper and paperboard prior to the sheet-forming operation. 2. In paper mill boilers.
* * *	* * * *

* * * * *

Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12762 Filed 5–20–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 93F–0385]

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 formaldehyde, polymer with 1-naphthylenol, as a release agent, applied on the internal parts of reactors employed in the production of polyvinyl chloride and acrylic copolymers intended for food-contact applications. This action is in response to a petition filed by Compagnia Italiana di Ricerca e Sviluppo, srl (CIRS).

DATES: Effective May 21, 1996; written objections and requests for a hearing by June 20, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 18, 1993 (58 FR 60859), FDA announced that a food additive petition (FAP 3B4380) had been filed by Compagnia Italiana di Ricerca e Sviluppo, srl (CIRS), c/o AAC Consulting Group, 1730 Rhode Island Ave. NW., Washington, DC 20036. The petition proposed to amend the food additive regulations in part 178 (21 CFR part 178) to provide for the safe use of formaldehyde, polymer with 1-naphthylenol, as an antiscaling agent, applied on the internal parts of reactors employed in the production of polyvinyl chloride and acrylic copolymers intended for food-contact applications. During its review, the agency determined that the use of the additive as an antiscaling agent has essentially the same technical effect as that of a release agent. This final rule reflects this conclusion and therefore FDA is listing the additive in § 178.3860 *Release agents*.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe and that the regulations in § 178.3860 should be amended as set forth below.

FDA's review of the petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition. The Committee noted that for many years, formaldehyde has been known to be a carcinogen by the inhalation route, but it concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two drinking water studies on formaldehyde: (1) A preliminary report of a carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1); and (2) a negative study by Til et al. (1989), conducted in The Netherlands (Ref. 2). The Committee reviewed both studies and concluded that data concerning the Soffritti study reported, ''* * * were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde'' (Ref. 3). This conclusion is based on a lack of critical details in the study, questionable histopathological conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

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.

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.

Any person who will be adversely affected by this regulation may at any time on or before June 20, 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.

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. Soffritti, M., F. Maltoni, and R. Biagi, ''Formaldehyde: An Experimental Multipotential Carcinogen,'' *Toxicology and Industrial Health*, vol. 5, No. 5:699–730, 1989.

2. Til, H. P., R. A. Woutersen, V. J. Feron, V. H. M. Hollanders, H. E. Falke, and J. J. Clary, ''Two-Year Drinking Water Study of Formaldehyde in Rats,'' *Food Chemical Toxicology*, vol. 27, No. 2, pp. 77–87, 1989.

3. Memorandum of conference concerning ''formaldehyde;'' meeting of the Cancer Assessment Committee, FDA; April 24, 1991, and March 4, 1993.