reference, three other cheese spread standards to permit the optional use of nisin. Nisin is an antimicrobial agent which prevents the outgrowth of *Clostridium botulinum* spores and toxin formation in packaged cheese. This action is taken to promote honesty and fair dealing in the interest of consumers by allowing increased flexibility in product formulation.

DATES: Effective April 10, 1989; compliance may begin March 13, 1989; objections and requests for a hearing by March 10, 1989.

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

FOR FURTHER INFORMATION CONTACT: Karen L. Carson, Center for Food Safety and Applied Nuturition (HFF–414), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–485–0110.

SUPPLEMENTARY INFORMATION:

I. The Proposal

In the **Federal Register** of April 6, 1988 (53 FR 11312), FDA published a proposal based on a petition from Arthur A. Checchi, Inc., representing Aplin and Barrett, Ltd., of Trowbridge, Wiltshire, England, to amend the standards of identity for pasteurized process cheese spread (21 CFR 133.179) and, by cross-reference, pasteurized cheese spread (21 CFR 133.175), pasteurized cheese spread with fruits, vegetables, or meats (21 CFR 133.176), and pasteurized process cheese spread with fruits, vegetables, or meats (21 CFR 133.180), to provide for the optional use of nisin, an antimicrobial agent, to prevent outgrowth of *C. botulinum* spores and toxin formation in packaged cheese. A final rule affirming the generally recognized as safe (GRAS) status of nisin preparation, the ingredient in which nisin is carried, was also published in the **Federal Register** of April 6, 1988 (53 FR 11247).

Three comments, all in favor of the proposal, were received. All three comments supported the optional use of nisin as an additional safety measure that may permit variations in formulations used for pasteurized cheese spreads and pasteurized process cheese spreads. The comments agreed that the addition of nisin should not be used as a substitute for careful attention to good manufacturing practices.

After considering the comments received, the agency concludes that the proposed amendment is reasonable and that the amendment, as set out below, will promote honesty and fair dealing in the interests of consumers by allowing increased flexibility in product formulation. Accordingly, the agency is amending the standard of identity for pasteurized process cheese spread by adding paragraph (f)(11) to 21 CFR 133.179. By cross-reference to 21 CFR 133.179, the agency is also amending the standards of identity for pasteurized cheese spread (21 CFR 133.175), pasteurized cheese spread with fruits, vegetables, or meats (21 CFR 133.176), and pasteurized process cheese spread with fruits, vegetables, or meats (21 CFR 133.180) to permit the optional use of nisin.

II. Economic Impact

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that a significant impact on a substantial number of small entities would not derive from this action. FDA has not received any new information or comments that would alter its previous determination.

III. Objections

Any person who will be adversely affected by this regulation may at any time on or before March 10, 1989, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 133

Cheese, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 133 is amended as follows:

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

1. The authority citation for 21 CFR Part 133 continues to read as follows:

Authority: Secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)); 21 CFR 5.10 and 5.61.

2. Section 133.179 is amended by adding paragraph (f)(11) to read as follows:

§ 133.179 Pasteurized process cheese spread.

* * * * *

(f) * * *

(11) Nisin preparation in an amount which results in not more than 250 parts per million nisin in the food.

* * * * *

Dated: February 2, 1989.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 89–2982 Filed 2–7–89; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 178

[Docket No. 86F–0171]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of α-butyl-Ω-hydroxypoly (oxyethylene)poly(oxypropylene), minimum molecular weight 1,000, and α-lauroyl-Ω-hydroxypoly(oxyethylene), having a minimum molecular weight of 200, as components of surface lubricants used in the manufacture of metallic articles intended to contact food. This action responds to a petition filed by Reynolds Metals Co.

DATES: Effective February 8, 1989; written objections and requests for a hearing by March 10, 1989.

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

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 20, 1986 (51 FR 22566), FDA announced that a petition (FAP 6B3931) had been filed by Reynolds Metals Co., 2101 Reymet Road, Richmond, VA 23237, proposing that § 178.3910 *Surface lubricants used in the manufacture of metallic articles* (21 CFR 178.3910) be amended to provide for the safe use of α-tridecyl-Ω-hydroxypoly(oxyethylene) phosphate; α-butyl-Ω-hydroxypoly(oxyethylene)poly (oxypropylene) minimum molecular weight 1,000; and α-lauroyl-Ω-hydroxypoly(oxyethylene) in the manufacture of metallic articles intended to contact food.

FDA finds that one of the additives listed in the filing notice a α-tridecyl-Ω-hydroxypoly(oxyethylene) phosphate, is currently regulated under 21 CFR 178.3400 for the use requested in this petition. Therefore, the agency concludes that there is no need to regulate the additive under 21 CFR 178.3910, as requested by the petitioner. The agency also notes that the filing notice did not designate a minimum molecular weight of 200 for α-lauroyl-Ω-hydroxypoly(oxyethylene). This designation is being added in this final rule to better identify this additive.

FDA has reviewed the safety of the two remaining additives and the starting materials used to manufacture these additives, as well as the byproducts associated with the manufacturing process. Although the additives themselves have not been found to cause cancer, they have been found to contain minute amounts of unreacted ethylene oxide and 1,4-dioxane as byproduct impurities which are carried through the reaction process. Ethylene oxide and 1,4-dioxane have been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as these chemicals, are commonly found as contaminants in chemical products including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) 21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data 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 of 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 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 carcinogenic chemicals 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 carcinogenic impurities 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 United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use

The agency estimated the daily intake of the petitioned use of the additives, α-butyl-Ω-hydroxypoly(oxyethylene) poly(oxypropylene), minimum molecular weight 1,000, and α-lauroyl-Ω-hydroxypoly(oxyethylene), minimum molecular weight of 200 (common name—polyethylene glycol-200 monolaurate), on the basis of several factors, including projected migration of the additives under the most severe conditions of use and the probable concentration of the additives in the daily diet from food-contact articles. The agency estimated that the daily intake of the two additives would be 0.18 milligram per person per day and 0.033 milligram per person per day, respectively.

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 level (Refs. 1 and 2), and the agency has not required such testing here. However, the agency has reviewed available acute oral toxicity studies on α-lauroyl-Ω-hydroxypoly(oxyethylene) and acute oral toxicity studies and subchronic studies in the rat and dog on α-butyl-Ω-hydroxypoly(oxyethylene)poly (oxyprophylene). No adverse effects were reported in these studies.

Because these two additives have not been shown to cause cancer, the anticancer clause does not apply to them. However, FDA has evaluted the safety of these additives under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper bound limit of risk presented by the carcinogenic chemicals ethylene oxide and 1,4-dioxane that may be present as impurities in the additives. Based on this evaluation, the agency has concluded that the additives are 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 (e.g., 49 FR 13018, 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 additives, and assuming

that 1,4-dioxane is present at the limit of detection in the additives (Ref. 3), FDA estimated the hypothetical worst case exposure to 1,4-dioxane from the use of these two additives to be 2.1 nanograms per person per day. The agency used data from a carcinogenesis bioassay on 1,4-dioxane conducted for the National Cancer Institute (Ref. 4) to estimate the upper bound level of lifetime human risk from the proposed use of the additives. 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 an upper bound level of lifetime risk from potential exposure to 1,4-dioxane stemming from the proposed use of these two additives could be calculated from the bioassay.

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 2.1 nanograms 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 these two additives is 8×10^{-11} or less than 1 in 12 billion (Ref. 5). Because of numerous conservatisms in the exposure estimate, lifetime averaged individual 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 additives and assuming that ethylene oxide is present at the limit of detection in the additives (Ref. 3), FDA estimated the hypothetical worst case exposure to ethylene oxide from the use of these two additives to be 1.8 nanograms per person per day. The agency used data from a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, Federal Republic of Germany (Ref. 6) to estimate the upper bound level of lifetime human risk from the proposed use of the additives. 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 carcinoma 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 an upper bound level of human risk from potential exposure to ethylene oxide stemming from the proposed use of these two additives could be calculated from the bioassay.

Based on a worst case exposure of 1.8 nanograms 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 these two additives is 3×10^{-9} or less than 1 in 330 million (Ref. 5). Because of numerous conservatisms in the exposure estimate, lifetime averaged individual 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 these two additives.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of ethylene oxide and 1,4-dioxane in the additives. 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 additives, the agency would not expect these impurities to become components of food at other than extremely small levels; and (2) the upper bound limit of lifetime risk from exposure to these impurities, even under worst case assumptions, is very low, less than 1 in 12 billion for 1,4-dioxane and less than 1 in 330 million for ethylene oxide.

D. Conclusion on Safety

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed use of these additives in lubricants used in the production of metallic articles for food-contact is safe, and that 21 CFR 178.3910(a)(2) should be amended to provide for the safe use of α-Buty1-Ω-hydroxypoly(oxyethylene) poly(oxypropylene) (CAS Reg. No. 9038–95–3) and α-Lauroyl-Ω-hydroxypoly (oxyethylene) (CAS Reg. No. 9004–81–3).

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.

III. 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., "Carcinogenicity Testing Programs," *in* "Food Safety: Where Are We?" Committee on Agriculture, Nutrition, and Forestry, United States Senate, p. 59, July 1979.

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 June 4, 1987, from the Food Chemistry Branch to the Indirect Additives Branch.

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

5. Memorandum dated September 25, 1986, from the Quantitative Risk Assessment Committee of the Center for Food Safety and Applied Nutrition.

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

IV. Objections

Any person who will be adversely affected by this regulation may at any time on or before March 10, 1989, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 178 is amended as follows:

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

1. The authority citation for 21 CFR Part 178 continues to read as follows:

Authority: Sec. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 178.3910 is amended in paragraph (a)(2) by alphabetically adding two new entries in the table to read as follows:

§ 178.3910 Surface lubricants used in the manufacture of metallic articles.

* * * * *

(a) * * *

(2) * * *

List of substances	Limitations
* * * * *	
α-Butyl-Ω-hydroxypoly (oxyethylene)-poly (oxypropylene) (CAS Reg. No. 9038-95-3) produced by random condensation of a 1:1 mixture by weight of ethylene oxide and propylene oxide with butanol and having a minimum molecular weight of 1,000.	
* * * * *	
α-Lauroyl-Ω-hydroxypoly (oxyethylene) (CAS Reg. No. 9004-81-3) having a minimum molecular weight of 200.	
* * * * *	

* * * * *

Dated: February 2, 1989.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 89–2981 Filed 2–7–89; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 178

[Docket No. 87F–0150]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of dimethyl succinate polymer with 4-hydroxy-2,2,6,6-tetramethyl-1-piperidineethanol as a stabilizer for olefin polymers and ethylene-vinyl acetate copolymers complying with 21 CFR 177.1520 and 21 CFR 177.1350, respectively. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective February 8, 1989; written objections and requests for a hearing by March 10, 1989.

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: 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 May 20, 1987 (52 FR 18958), FDA announced that a food additive petition (FAP 7B3991) had been filed by Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY 10532, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of dimethyl succinate polymer with 4-hydroxy-2,2,6,6-tetramethyl-1-piperidineethanol as a stabilizer for olefin polymers and ethylene-vinyl acetate copolymers complying with 21 CFR 177.1520 and 21 CFR 177.1350, respectively.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that the regulations should be amended in 21 CFR 178.2010(b) 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.

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 March 10, 1989 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that

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

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, Part 178 is amended as follows:

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

1. The authority citation for 21 CFR Part 178 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 178.2010 is amended in paragraph (b) by revising the entry for "Dimethyl succinate polymer with 4-hydroxy-2,2,6,6-tetramethyl-1-piperidineethanol (CAS Reg. No. 65447–77–0)" in the table under the heading "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * * * *	
Dimethyl succinate polymer with 4-hydroxy-2,2,6,6-tetramethyl-1-piperidineethanol (CAS Reg. No. 65447-77-0).	For use only: 1. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520 of this chapter and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.3 percent by weight of ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.
* * * * *	

Dated: January 27, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–2927 Filed 2–7–89; 8:45 am]

BILLING CODE 4160-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–3513–7; FL–019]

Approval and Promulgation of Implementation Plans; Florida Stack Height Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this action, EPA is approving revisions to the Florida state implementation plan (SIP) submitted to EPA on July 1, 1986. Florida has revised its SIP to include regulations for good engineering practice stack height. These regulations are equivalent to EPA requirements promulgated at Part 51 of Chapter I, Title 40 of the Code of Federal Regulations.

EFFECTIVE DATE: This action will be effective on April 10, 1989, unless notice is received within 30 days that adverse or critical comments will be submitted.

ADDRESSES: Copies of the materials submitted by Florida may be examined during normal business hours at the following locations:

Public Information Reference Unit, Library Systems Branch, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460

Air Programs Branch, Environmental Protection Agency, Region IV, 345 Courtland Street NE., Atlanta, Georgia 30365

Bureau of Air Quality Management, Twin Towers Office Building, 2600 Blair Stone Road, Tallahassee, Florida 32301

FOR FURTHER INFORMATION CONTACT: Beverly T. Hudson, EPA Region IV, Air Programs Branch at above listed address, telephone (404) 347–2864 or FTS 257–2864.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 8, 1985 (50 FR 27892), EPA published final regulations to implement section 123 of the Clean Air Act (CAA), which regulates the manner in which dispersion of pollutants from a source may be considered in setting emission limitations. Pursuant to these regulations and the Clean Air Act Amendments of 1977, all states were required to (1) review and revise, as necessary, their state implementation plans (SIPs) to include provisions that limit stack height credit and dispersion techniques in accordance with the revised regulations, and (2) review all existing emission limitations to determine whether these limitations have been affected by stack height credits above GEP or any other dispersion techniques. For any limitations so affected, states were to prepare revised limitations consistent with their revised SIPs. All SIP revisions and revised emission limits were to be submitted to EPA within nine months of promulgation.

Subsequently, EPA issued detailed guidance on carrying out the necessary reviews. For the review of emission limitations, states were to prepare inventories of stacks greater than 65 meters in height and sources with emissions of sulfur dioxide (SO_2) in excess of 5000 tons per year. These limits correspond to the *de minimis* GEP stack height and the *de minimis* SO_2 emission exemption from prohibited dispersion techniques. These sources were then to be subjected to detailed review for conformance with the revised regulations. State submissions were to contain an evaluation of each stack and source in the inventory.

On July 1 and November 19, 1986, the Florida Department of Environmental Regulation submitted SIP revisions for good engineering practice stack height. Since the State formally revised its SIP, public hearings on these stack height rules were held on March 26 and August 20, 1986.

Florida's regulations limit the amount of stack height or dispersion credit (dispersion techniques) a source can claim in the process of establishing its emission limitation. Dispersion techniques include the use of stack heights greater than 65 meters and use of other techniques to increase the dispersion of emissions rather than continuously reducing emissions from a source. These regulations do not limit the physical stack height of any source,