

This incorporation by reference of Jetstream Service Bulletin J41-53-012-41262A, Revision 1, dated October 3, 1994, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The incorporation by reference of Jetstream Service Bulletin J41-53-012, dated November 30, 1993, was approved previously by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 as of August 10, 1994 (59 FR 35247, July 11, 1994). Copies may be obtained from Jetstream Aircraft, Inc., P.O. Box 16029, Dulles International Airport, Washington, DC 20041-6029. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on July 26, 1995.

Issued in Renton, Washington, on June 2, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95-14053 Filed 6-23-95; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 81F-0105]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Epoxidized Soybean Oil

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 epoxidized soybean oil as a halogen stabilizer in brominated soybean oil. This action is in response to a petition filed by Unitech Chemical, Inc.

DATES: Effective June 26, 1995; written objections and requests for a hearing by July 26, 1995. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in new § 172.723, effective June 26, 1995.

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

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food

Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3077.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 28, 1981 (46 FR 23811), FDA announced that a food additive petition (FAP 7A3329) had been filed by Unitech Chemical, Inc., 115 West Jackson Blvd., Chicago, IL 60604. Subsequently, all rights to this petition were sold to American Chemical Service, Inc., P.O. Box 190, Griffith, IN 46319. The petition proposes that the food additive regulations be amended to provide for the safe use of epoxidized soybean oil as a halogen stabilizer at a level not to exceed 1 percent in brominated soybean oil intended for use in foods for human consumption. Brominated soybean oil is permitted in food on an interim basis under 21 CFR 180.30 (brominated vegetable oil), for use only as a stabilizer for flavoring oils used in fruit-flavored beverages in an amount not to exceed 15 parts per million in the finished beverage.

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 food additive regulations should be amended by adding new § 172.723 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 previously considered the environmental effects of this action as announced in the notice of filing for FAP 7A3329 (46 FR 23811, April 28, 1981). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required. In addition, based on information in a letter from the petitioner dated February 15, 1990, FDA prepared a new finding of no significant impact. Both the letter of February 15, 1990, and the new finding of no significant impact 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 July 26, 1995, 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 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

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, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. New § 172.723 is added to subpart H to read as follows.

§ 172.723 Epoxidized soybean oil.

Epoxidized soybean oil may be safely used in accordance with the following prescribed conditions:

(a) The additive is prepared by reacting soybean oil in toluene with hydrogen peroxide and formic acid.

(b) It meets the following specifications:

(1) Epoxidized soybean oil contains oxirane oxygen, between 7.0 and 8.0 percent, as determined by the American Oil Chemists' Society (A.O.C.S.) method Cd 9-57, "Oxirane Oxygen," reapproved 1989, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists' Society, P. O. Box 3489, Champaign, IL 61826-3489, or may be examined at the Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(2) The maximum iodine value is 3.0, as determined by A.O.C.S. method Cd 1-25, "Iodine Value of Fats and Oils Wijs Method," revised 1993, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(3) The heavy metals (as Pb) content can not be more than 10 parts per million, as determined by the "Heavy Metals Test," Food Chemicals Codex, 3d ed. (1981), p. 512, Method II (with a 2-gram sample and 20 microgram of lead ion in the control), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Box 285, Washington, DC 20055, or may be examined at the Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) The additive is used as a halogen stabilizer in brominated soybean oil at a level not to exceed 1 percent.

Dated: June 14, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95-15349 Filed 6-23-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR PART 184

[Docket No. 84G-0257]

Enzyme Preparations From Animal and Plant Sources; Affirmation of Gras Status as Direct Food Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that certain enzyme preparations derived from animal and plant sources are generally recognized as safe (GRAS) for use as direct food ingredients. This action is a partial response to a petition filed by the Ad Hoc Enzyme Technical Committee (now the Enzyme Technical Association). The following enzyme preparations derived from animal sources are affirmed as GRAS in this final rule: Catalase (bovine liver), animal lipase, pepsin, trypsin, and pancreatin (as a source of protease activity). The following enzyme preparations derived from plant sources are affirmed as GRAS in this final rule: Bromelain, ficin, and malt.

DATES: Effective June 26, 1995. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication listed in 21 CFR 184.1024(b), 184.1034(b), 184.1316(b), 184.1415(b), 184.1443a(b), 184.1583(b), 184.1595(b), and 184.1914(b), effective June 26, 1995.

FOR FURTHER INFORMATION CONTACT: Laura M. Tarantino, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3090.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Standards for GRAS Affirmation
- III. Background
 - A. Enzymes
 - B. Enzyme Nomenclature
 - C. Enzyme Preparations that are the Subject of this Document
 - 1. Introduction
 - 2. Animal-derived Enzyme Preparations
 - 3. Plant-derived Enzyme Preparations
- IV. Safety Evaluation
 - A. Pre-1958 History of Use in Food
 - B. Corroborating Evidence of Safety
 - 1. The Enzyme Component
 - 2. Enzyme Sources and Processing Aids
 - 3. Dietary Exposure
- V. Comments
- VI. Conclusions
- VII. Environmental Impact
- VIII. Economic Impact
- IX. References

I. Introduction

In accordance with the procedures described in § 170.35 (21 CFR 170.35), the Ad Hoc Enzyme Technical Committee (now the Enzyme Technical Association), c/o Miles Laboratories, Inc., 1127 Myrtle St., Elkhart, IN 46514, submitted a petition (GRASP 3G0016) requesting that the following enzyme preparations be affirmed as GRAS for use in food:

(1) Animal-derived enzyme preparations: Catalase (bovine liver); lipase, animal; pepsin; rennet; rennet, bovine; and trypsin.

(2) Plant-derived enzyme preparations: Bromelain; malt; and papain.

(3) Microbially-derived enzyme preparations: *Aspergillus niger*, var. (lipase, catalase, glucose oxidase, and carbohydrase); *Bacillus subtilis*, var. (carbohydrase and protease mixtures); *Rhizopus oryzae* (carbohydrase); and *Saccharomyces* species (carbohydrase).

FDA published a notice of filing of this petition in the **Federal Register** of April 12, 1973 (38 FR 9256), and gave interested persons an opportunity to submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. The petition was amended by notices published in the **Federal Register** of June 12, 1973 (38 FR 15471), proposing affirmation that microbially derived enzyme preparations (carbohydrase, lipase, and protease) from *A. oryzae* are GRAS for use in food; in the **Federal Register** of August 29, 1984 (49 FR 34305), proposing affirmation that the enzyme preparations ficin, obtained from species of the genus *Ficus* (fig tree), and pancreatin, obtained from bovine and porcine pancreas, are GRAS for use in food; and in the **Federal Register** of June 23, 1987 (52 FR 23607), proposing affirmation that the enzyme preparation protease from *A. niger* is GRAS for use in food. In the June 23, 1987, notice, FDA also noted the petitioner's assertion that pectinase enzyme preparation from *A. niger* and lactase enzyme preparation from *A. niger* are included under carbohydrase enzyme preparation from *A. niger*, and that invertase enzyme preparation from *Saccharomyces cerevisiae* and lactase enzyme preparation from *Kluyveromyces marxianus* are both included under carbohydrase enzyme preparation from species of the genus *Saccharomyces*. The agency further noted that, therefore, pectinase enzyme preparation from *A. niger*, lactase enzyme preparation from *A. niger*,