

areas extending upward from 700 feet or more above ground level are published in Paragraph 6005 of FAA Order 7400.9B dated July 18, 1994, and effective September 16, 1994, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations that need frequent and routine amendments to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth

* * * * *

ASW TX E5 La Grange, TX [New]

Fayette Regional Air Center, TX
(Lat. 29°54'31" N., long. 096°56'59" W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Fayette Regional Air Center.

* * * * *

Issued in Fort Worth, TX on November 18, 1994.

Helen Fabian Parke,
Manager, Air Traffic Division Southwest Region.

[FR Doc. 94-29799 Filed 12-2-94; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 94-ASW-16]

Proposed Establishment of Class E Airspace; Ozona, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish Class E airspace extending upward from 700 feet above ground level (AGL) at Ozona Municipal Airport, Ozona, TX. The development of a Global Positioning System (GPS) standard instrument approach procedure (SIAP) to Runway (RWY) 16 has made this proposal necessary. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Ozona Municipal Airport, Ozona, TX.

DATES: Comments must be received on or before January 20, 1995.

ADDRESSES: Send comments on the proposal in triplicate to Manager, System Management Branch, Air Traffic Division, Federal Aviation Administration, Southwest Region, Docket No. 94-ASW-16, Fort Worth, TX 76193-0530.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, Southwest Region, 2601 Meacham Boulevard, Fort Worth, TX, between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the System Management Branch, Air Traffic Division, Federal Aviation Administration, Southwest Region, 2601 Meacham Boulevard, Fort Worth, TX.

FOR FURTHER INFORMATION CONTACT: Donald J. Day, System Management Branch, Air Traffic Division, Federal Aviation Administration, Fort Worth, TX 76193-0530; telephone: (817) 222-5593.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis

supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify the airspace docket number and be submitted in triplicate to the address listed under the caption ADDRESSES. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit, with those comments, a self-addressed, stamped, postcard containing the following statement: "Comments to Airspace Docket No. 94-ASW-16." The postcard will be date and time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel, Federal Aviation Administration, Southwest Region, 2601 Meacham Boulevard, Fort Worth, TX, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, System Management Branch, Department of Transportation, Fort Worth, TX 76193-0530. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A that describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace, controlled airspace extending upward from 700 feet AGL, at Ozona Municipal Airport, Ozona, TX. The development of a GPS RWY 16 SIAP has made this proposal necessary. The intended effect of this proposal is to provide adequate Class E airspace for aircraft executing the GPS RWY 16 SIAP at Ozona Municipal Airport, Ozona, TX.

The coordinates for this airspace docket are based on North American Datum 83. Designated Class E airspace areas extending upward from 700 feet or more above ground level are published in Paragraph 6005 of FAA Order 7400.9B dated July 18, 1994, and effective September 16, 1994, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations that need frequent and routine amendments to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, *Airspace Designations and Reporting Points*, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth

* * * * *

ASW TX E5 Ozona, TX [New]

Ozona, Ozona Municipal Airport, TX
(Lat. 30°44'06" N., long. 101°12'10" W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Ozona Municipal Airport.

* * * * *

Issued in Fort Worth, TX on November 18, 1994.

Helen Fabian Parke,
Manager, Air Traffic Division, Southwest Region.

[FR Doc. 94-29797 Filed 12-2-94; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 94-ANM-23]

Proposed Amendment to Class E Airspace; Wenatchee, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to amend the Wenatchee, Washington, Class E airspace. This action would provide controlled airspace for a new instrument approach procedure at the Wenatchee, Pangborn Memorial Airport, Washington. Controlled airspace extending upward from 700 feet above ground level (AGL) is needed for aircraft executing the approach. The area would be depicted on aeronautical charts to provide a reference for pilots operating under Visual Flight Rules (VFR).

DATES: Comments must be received on or before December 30, 1994.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, System Management Branch, ANM-530, Federal Aviation Administration, Docket No. 94-ANM-23, 1601 Lind Avenue SW., Renton, Washington 98055-4056.

The official docket may be examined at the same address.

An informal docket may also be examined during normal business hours at the address listed above.

FOR FURTHER INFORMATION CONTACT: Ted Melland, ANM-536, Federal Aviation Administration, Docket No. 94-ANM-23, 1601 Lind Avenue SW., Renton, Washington 98055-4056, Telephone: (206) 227-2536.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments

are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made:

"Comments to Airspace Docket No. 94-ANM-23." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination at the address listed above both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-230, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-3484.

Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend Class E airspace at Wenatchee, Washington, to provide controlled airspace for a new instrument approach procedure at the Pangborn Memorial Airport. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9B, dated July 18, 1994, and effective September 16, 1994, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p.389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9B, Airspace Designations and Reporting Points, dated July 18, 1994, and effective September 16, 1994, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth

* * * * *

ANM WA E5 Wenatchee, WA [Revised]

Wenatchee, Pangborn Memorial Airport, WA (Lat. 47°23'55" N, long. 120°12'24" W)
Wenatchee, VOR/DME
(Lat. 47°23'58" N, long. 120°12'39" W)

That airspace extending upward from 700 feet above the surface within 4.3 miles each side of the 299° radial from the Wenatchee VOR/DME to 13.4 miles northwest of the VOR/DME to 21 miles southeast of the VOR/DME, excluding that portion within the Moses Lake, Grant County, and Quincy Airport, WA, Class E airspace areas; that airspace extending upward from 1,200 feet

above the surface bounded by a line beginning at:

Lat. 47°36'00" N, long. 120°43'00" W;
To lat. 47°36'00" N, long. 119°39'30" W;
To lat. 47°07'00" N, long. 119°39'30" W;
To lat. 47°07'00" N, long. 120°43'00" W;
To the point of beginning. Excluding that portion within the Moses Lake, Grant County Airport, WA, Class E airspace area.

* * * * *

Issued in Seattle, Washington, November 16, 1994.

Temple H. Johnson, Jr.,

Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 94-29818 Filed 12-2-94; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 83G-0277]

α -Amylase Enzyme Preparation; Affirmation of GRAS Status as Direct Human Food Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Tentative final rule.

SUMMARY: The Food and Drug Administration (FDA) is tentatively affirming that α -amylase enzyme preparation derived from *Bacillus stearothermophilus* is generally recognized as safe (GRAS) for use in the processing of starch to make maltodextrins and nutritive carbohydrate sweeteners.

DATES: Written comments by February 3, 1995.

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

FOR FURTHER INFORMATION CONTACT: Vincent E. Zenger, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3105.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), CPC International Inc., International Plaza, Englewood Cliffs, NJ 07632, submitted a petition (GRASP 3G0284) requesting that α -amylase enzyme from *B. stearothermophilus* used in the production of nutritive saccharides from

starch be affirmed as GRAS as a direct human food ingredient. The petition includes information about the identity of, and manufacturing processes for, α -amylase enzyme preparations derived from *B. stearothermophilus*; information about the history of human food use of α -amylase derived from *B. stearothermophilus*; final reports and published articles of safety studies with α -amylase enzyme preparation derived from *B. stearothermophilus*; and published literature with respect to α -amylase and bacterial α -amylase preparations. FDA published a notice of the filing of this petition in the Federal Register of September 21, 1983 (48 FR 43096). FDA gave interested persons an opportunity to submit comments to the Dockets Management Branch (address above). FDA did not receive any comments in response to that notice.

In the filing notice the agency gave notice that the petition had requested that α -amylase enzyme derived from *B. stearothermophilus* be affirmed as GRAS for use in production of sweeteners from starch. However, the petition requested, and the agency evaluated, the use of this enzyme preparation in the production of nutritive saccharides (which includes maltodextrins as well as nutritive carbohydrate sweeteners). The end products of the α -amylase hydrolysis of starch are maltodextrins, which are not sweet and are not used as sweeteners in food, as well as nutritive carbohydrate sweeteners. Maltodextrins may be used as a food ingredient or used as a raw material in the manufacture of nutritive carbohydrate sweeteners, for example, glucose syrups. Therefore, FDA finds that the phrase "production of maltodextrins and nutritive carbohydrate sweeteners from starch" is a more accurate description of the petitioned food use of α -amylase enzyme preparation. FDA is publishing this document as a tentative final rule to afford interested persons the opportunity to comment on this change. To avoid confusion between α -amylase, the enzyme, and α -amylase, the enzyme preparation (in which α -amylase is the principal active component, but which also contains other components derived from the production organism or the fermentation media), this document will use the term " α -amylase" to refer to the former and " α -amylase enzyme preparation" to refer to the latter.

II. Standards for GRAS Affirmation

Pursuant to § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of

substances. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation but ordinarily is to be based upon generally available data and information concerning its pre-1958 use (§ 170.30(c)).

III. Safety Evaluation

A. Introduction Starch produced in plants exists in two main forms. The linear form is composed of α -D-glucose sugar residues bonded together with a type of linkage termed α -1,4 (Ref. 1). This linear form is commonly termed amylose. The other form of starch, termed amylopectin, is composed of amylose molecules linked together at branch points. In this form, resembling a tree-like structure, the branch points are formed by a different kind of linkage termed α -1,6. An α -amylase enzyme (1,4- α -D glucan glucanohydrolase (International Union of Biochemistry Enzyme Commission (E.C.) 3.2.1.1)) can hydrolyze, i.e., break, the α -1,4 linkages found in amylose and amylopectin (Ref. 2). Treatment with α -amylase enzyme lowers the molecular weight of the starch molecules to form molecules collectively called maltodextrins.

Certain maltodextrins may be subjected to subsequent processing. For instance, corn maltodextrins may be further hydrolyzed by another enzyme, glucoamylase, to produce glucose (also known as dextrose) which may in turn be isomerized to form high fructose corn syrups. These corn sweeteners are refined with ion exchange resins to remove impurities and are then concentrated. The processed corn sweeteners are then used in a wide variety of products in the food industry. Current technology sometimes requires the α -amylase enzyme to function at high temperatures, up to 110° C (Refs. 1 and 3). Therefore, much effort has gone into research on α -amylases from thermophilic microorganisms such as *B. stearothermophilus* (Ref. 3).

In evaluating this petition to affirm as GRAS the use of α -amylase enzyme preparation from *B. stearothermophilus* as a food ingredient, the agency considered six aspects of its manufacture and use: (1) The identity of the α -amylase enzyme component; (2) the identity and safety of the source (production) organism for the α -amylase enzyme preparation; (3) the manufacturing process of the α -amylase enzyme preparation; (4) the intended uses for the α -amylase enzyme preparation in food and exposure to residual levels of the α -amylase enzyme preparation; (5) the specifications for the formulation of the enzyme preparation; and (6) toxicological studies of the enzyme preparation.

B. The Enzyme Component

The α -amylase enzyme from *B. stearothermophilus* is extracellular (Ref. 2). That is, the enzyme is secreted by the bacteria into the surrounding media. Data and published information in the petition confirm that the petitioner's enzyme preparation from *B. stearothermophilus* functions in the hydrolysis of starch as an α -amylase (1,4- α -D glucan glucanohydrolase (E.C. 3.2.1.1)) (Refs. 4 through 7).

Published data show that the α -amylase enzyme functions at an optimum temperature of 80° C and at pH values below 6 (Ref. 7), which is consistent with previous published reports characterizing α -amylase from *B. stearothermophilus* and other thermophilic *Bacillus* species (Refs. 2 and 3).

The published data further show that the petitioner's enzyme has a molecular weight of 58 kilodaltons (kd) (Ref. 7) which is consistent with the 58 kd mass reported by Sen (Ref. 8) and within experimental error of the predicted 61 kd mass based on deoxyribonucleic acid (DNA) sequence analysis (Ref. 9).

The α -amylases are functionally divided into two categories, saccharifying α -amylases, which break approximately 40 to 60 percent of the α -1,4 linkages in a starch, and liquefying α -amylases, which break only 30 to 40 percent of the linkages in the starch (Ref. 3). The α -amylase from *B. stearothermophilus* is of the liquefying type and is very similar in protein sequence to liquefying α -amylases from other *Bacillus* species that have been commonly used in food processing (Refs. 1, 3, and 9 through 12), for example, *Bacillus amyloliquefaciens* (Ref. 1) and *Bacillus licheniformis* (see 21 CFR 184.1027).

C. The Production Organism

The source organism for this enzyme preparation is the bacterium *B. stearothermophilus*. The petition includes data to show that the strain used by the petitioner, *B. stearothermophilus* (AS-154), conforms to the description of *B. stearothermophilus* in "Bergey's Manual of Determinative Bacteriology," 8th ed. (Ref. 13), which is a standard compendium for the taxonomy of bacteria. The petition also contains data to show that this strain of *B. stearothermophilus* is an asporogenic variant and does not produce antibiotics or toxins.

Published scientific literature as well as standard textbooks on food microbiology demonstrate that *B. stearothermophilus* and its spores are widely distributed in nature and they are commonly found in fresh foods (Refs. 13 and 14). *B. stearothermophilus* is also reported to be the typical organism causing nontoxic sour spoilage in low acid foods (Ref. 14).

The petition contains one published pathogenicity study that demonstrated that *B. stearothermophilus* is not pathogenic (Ref. 15). The petition also contains an extensive search of the published literature from 1917 to 1992 involving over 1,700 references and citations relating to *B. stearothermophilus* concerning pathogenicity, pathogen formation, toxicology and toxins, and disease or infection. The search failed to disclose a single report that implicated *B. stearothermophilus* as the etiologic agent of a disease state in man or animals. There were no reports of any toxicity or pathogenicity associated with the presence of this organism in food.

D. The Manufacturing Process

The α -amylase enzymes of *Bacillus* are extracellular enzymes (Ref. 10). Therefore, the manufacturing procedures follow those generally used in the enzyme industry to separate and concentrate extracellular enzymes (Ref. 16). Under the method of manufacture of α -amylase enzyme preparation described in the petition, *B. stearothermophilus* is maintained as a pure culture under conditions that minimize any genetic changes and is grown in a pure culture fermentation. When fermentation is complete, the broth is clarified by treating it with calcium hydroxide, and cells are removed from the broth by filtration using a diatomaceous earth filter aid (Ref. 17). The filtered, clarified broth containing the soluble enzyme is then ultrafiltered to remove all particulate

matter. The filtrate, containing the α -amylase enzyme, is then evaporated to a concentrate of the desired enzyme potency, usually about a three-fold concentration. Sodium chloride is added to the concentrate so that the final salt concentration is 20 percent by weight of the enzyme preparation. Data submitted in the petition show that the enzyme preparation produced by this method of manufacture does not contain any viable bacterial cells.

FDA finds that the manufacturing method does not require the use of any processing materials that are not GRAS or approved food additives. Therefore, the agency concludes that the manufacturing steps will not introduce impurities into the enzyme preparation that will adversely affect the safety of the preparation.

E. Estimated Exposure Levels

The amount of the enzyme preparation used will vary based on the catalytic activity of the enzyme in any particular batch of enzyme preparation. Estimates of enzyme use level and intake are usually based on the total organic solids (TOS) content of the enzyme preparation (Ref. 18). TOS is the sum of all organic compounds present in the final enzyme preparation, excluding diluents or carriers, if added. TOS is calculated as follows: TOS percent = $100 \cdot (A+W+D)$ where A is the percent of ash, W is the percent of water, and D is the percent of diluents or carriers.

FDA's estimate of exposure to α -amylase enzyme preparation from *B. stearothermophilus* is based on the food use of maltodextrins and nutritive carbohydrate sweeteners, data for general usage of α -amylase preparations, and the relative enzymatic potency of this particular enzyme preparation compared to typical preparations. FDA calculates that the intake of typical α -amylase enzyme preparations reported as TOS is 25 milligrams (mg) TOS per person per day (TOS/person/day). The subject preparation has an enzymatic potency about six-fold higher than typical preparations; therefore, the estimated daily intake (EDI) is one-sixth of 25 mg or about 4 mg/TOS/person/day, or 67 micrograms (μ g)/kilograms (kg) body weight/day for a 60 kg person.

F. Enzyme Preparation Specifications

The petition contains data showing that the α -amylase enzyme preparation from *B. stearothermophilus* produced in this manner meets the general and additional requirements for enzyme preparations in the "Food Chemicals Codex," 3d ed. (Ref. 19).

G. Safety of Enzyme Preparation

The petition contains published animal feeding studies to support the safety of the enzyme preparation. These include a 90-day subchronic oral toxicity study in dogs and a 90-day subchronic oral toxicity study in F1 rats exposed in utero. No adverse treatment-related effects were identified in the 90-day studies (Ref. 20).

The petition also contained several unpublished, corroborative safety studies. These animal feeding studies of the α -amylase enzyme preparation included an acute oral toxicity study in rats and 14-day palatability studies in both rats and dogs. None of these studies demonstrated any adverse treatment-related effects.

Based upon the 90-day dog study, FDA estimated an acceptable daily intake (ADI) of 377 μ g/kg body weight, which is 1/1000 of the highest no-effect level (377 mg/kg body weight, which was the highest dose tested). These studies show that the ADI for the enzyme preparation (377 μ g/kg body weight/day) exceeds the EDI for uses of this enzyme preparation (67 μ g/kg body weight/day).

IV. Conclusions

The petition requested affirmation of GRAS status of α -amylase preparation from *B. stearothermophilus* based on its similarity to other α -amylase enzyme preparations that have a history of common use in food prior to 1958. The petition cites data that report that α -amylase enzyme preparation from *B. subtilis* has been used commercially since 1929, when it was used in the manufacture of chocolate syrup to reduce its viscosity (Ref. 21). The petition stated that bacterial α -amylase enzyme preparations were first described in the preparation of corn sweeteners in 1962, but that common use of these enzymes by major food processors did not occur until some time later. The petition also stated that today, corn sweeteners prepared with bacterial amylase enzyme preparations are used in nearly all commercially prepared foods.

The agency evaluated the petition using the criteria of § 170.30(c) and concluded that although α -amylase enzyme preparations have had a long history of use before 1958, the data provided no evidence for history of use of α -amylase enzyme preparation from *B. stearothermophilus*, and that based on the data in the petition, this preparation is not eligible for GRAS affirmation based on history of common use in food. However, the agency has also evaluated the petition using the

criteria of § 170.30(b) and concludes that α -amylase enzyme preparation from *B. stearothermophilus* is eligible for GRAS affirmation based on scientific procedures.

The agency has evaluated the information in the petition along with other available information and concludes, based on evaluation of published information, corroborated by unpublished data and information, that use of the α -amylase enzyme preparation derived by fermentation from *B. stearothermophilus* to hydrolyze starch to produce maltodextrins and nutritive carbohydrate sweeteners is GRAS. Furthermore, the data show no basis for a potential risk from any use of this α -amylase preparation that can be anticipated. Therefore, the agency is tentatively affirming that the use of the enzyme is GRAS with no limits other than current good manufacturing conditions in accordance with 21 CFR 184.1(b)(1).

The agency further finds that because the principal active ingredient of the α -amylase enzyme preparation is safe and because expected impurities in the α -amylase enzyme preparation do not provide any basis for a safety concern that the general and additional requirements given for enzyme preparations in the "Food Chemicals Codex," 3d ed. (1981), pp. 107-110, are adequate for defining minimum criteria for a food-grade α -amylase enzyme preparation derived from *B. stearothermophilus*.

V. Environmental Effects

The agency has determined under 21 CFR 25.24(b)(7) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the tentative final rule under Executive Order 12866, and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this tentative final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the tentative final rule is not a significant

regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because no current activity is prohibited by this tentative final rule, the compliance cost to firms is zero. Because no increase in the health risks faced by consumers will result from this tentative final rule, total costs are also zero. Potential benefits include the wider use of this enzyme because of reduced uncertainty concerning its GRAS status, and any resources saved by eliminating the need to prepare further petitions to affirm the GRAS status of this enzyme for this use. The agency certifies, therefore, that the tentative final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

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. MacAllister, R. V., "Manufacture of High Fructose Corn Syrup Using Immobilized Glucose Isomerase," in "Immobilized Enzymes for Food Processing," W. H. Pitcher, Jr., editor, CRC Press, Inc., Boca Raton, FL, pp. 81-111, 1980.
2. Vihinen, M. and P. Mantsala, "Microbial Amylolytic Enzymes," *CRC Critical Reviews in Biochemistry and Molecular Biology*, 24:329-418, 1989.
3. Tomazic, S. J. and A. M. Klivanov, "Mechanisms of Irreversible Thermal Inactivation of *Bacillus* α -Amylases," *Journal of Biological Chemistry*, 263:3086-3091, 1988.
4. Tamuri, M. et al., "Heat and Acid Stable α -Amylase Enzymes and Processes for Producing the Same," U.S. Patent No. 4,284,722, 1981.
5. Brumm, P. J. and W. M. Teague, "Effect of Additives on the Thermostability of *Bacillus stearothermophilus* α -Amylase," *Biotechnology Letters*, 11:541-544, 1989.
6. Henderson, W. E. and W. M. Teague, "A Kinetic Model of *Bacillus stearothermophilus* α -Amylase under Process Conditions," *Starch/Stärke*, 40:412-418, 1988.
7. Brumm, P. J. et al., "Purification and Properties of a New Commercial, Thermostable *Bacillus stearothermophilus* α -Amylase," *Food Biotechnology*, 2:67-80, 1988.
8. Sen, S. and P. Oriol, "Multiple Amylase Genes in Two Strains of *Bacillus stearothermophilus*," *Gene*, 76:137-144, 1989.
9. Ihara, H. et al., "Complete Nucleotide Sequence of a Thermophilic α -Amylase

Gene: Homology between Prokaryotic and Eukaryotic α -Amylases at the Active Sites," *Journal of Biochemistry*, 98:95-103, 1985.

10. Suominen, I. et al., "Extracellular Production of Cloned α -Amylase by *Escherichia coli*," *Gene*, 61:165-176, 1987.

11. Tsukamoto, A. et al., "Nucleotide Sequence of the Maltohexaose-Producing Amylase Gene from an Alkalophilic *Bacillus* sp. No. 707 and Structural Similarity to Liquefying Type α -Amylases," *Biochemical and Biophysical Research Communications*, 151:25-31, 1988.

12. Satoh, H. et al., "Evidence for Movement of the α -Amylase Gene into Two Phylogenetically Distant *Bacillus stearothermophilus* Strains," *Journal of Bacteriology*, 170:1034-1040, 1988.

13. "Bergey's Manual of Determinative Bacteriology," 8th ed., Williams and Wilkins Co., Baltimore, p. 1135, 1975.

14. Ito, K. A., "Thermophilic Organisms in Food Spoilage: Flat-Sour Aerobes," *Journal of Food Protection*, 44:157-163, 1981.

15. Sattar, S. A. et al., "Hazard Inherent in Microbial Tracers: Reduction of Risk by the Use of *Bacillus stearothermophilus* Spores in Aerobiology," *Applied Microbiology*, 23:1053-1059, 1972.

16. Frost, G. M. and D. A. Moss, "Production of Enzymes by Fermentation," in "Biotechnology, Vol. 7A, Enzyme Technology," H. J. Rehm and G. Reed, editors, J. F. Kennedy, Vol. editor, VCH, New York, pp.72-76, 1987.

17. Brummer, W. and G. Gunzer, "Laboratory Techniques of Enzyme Recovery," in "Biotechnology, Vol. 7A, Enzyme Technology," H. J. Rehm and G. Reed, editors, J. F. Kennedy, Vol. editor, VCH, New York, pp. 217-219 and 273, 1987.

18. "The 1978 Enzyme Survey Summarized Data," National Research Council/National Academy of Sciences, Washington, DC; U.S. Department of Commerce, National Technical Information Service PB81-216897, 1981, pp. i-iii.

19. Monograph on Enzyme Preparations, in "Food Chemicals Codex," 3d ed., National Academy Press, Washington, DC, pp. 107-110, 1981.

20. MacKenzie, K. M. and S. R. W. Petsel, "Subchronic Toxicity Studies in Dogs and In Utero Rats Fed Diets Containing *Bacillus stearothermophilus* α -Amylase from a Natural or Recombinant DNA Host," *Food and Chemical Toxicology*, 27:599-606, 1989.

21. Reed, T., "Enzymes in Food Processing," Academic Press, New York, p. 406, 1966.

VIII. Comments

FDA is publishing this document as a tentative final rule to afford interested persons the opportunity to comment on the use of the enzyme preparations in the production of maltodextrins, which was not discussed in the filing notice.

Interested persons may, on or before February 3, 1995, submit to the Dockets Management Branch (address above) written comments regarding this tentative final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

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, it is proposed that 21 CFR part 184 be amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE1.

The authority citation for 21 CFR Part 184 continues to read as follows:

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

2. New § 184.1012 is added to subpart B to read as follows:

§ 184.1012 α -Amylase enzyme preparation from *Bacillus stearothermophilus*.

(a) α -Amylase enzyme preparation is obtained from the culture filtrate that results from a pure culture fermentation of a nonpathogenic and nontoxicogenic strain of *Bacillus stearothermophilus*. Its characterizing enzyme activity is α -amylase (1,4- α -D glucan glucanohydrolase (E. C. 3.2.1.1)).

(b) The ingredient meets the general and additional requirements for enzyme preparations in the "Food Chemicals Codex," 3d ed. (1981), pp. 107-110, which is incorporated by reference in accordance with 5 U.S.C. 552(a). Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., Suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practices. The affirmation of this ingredient as GRAS as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in § 170.3(o)(9) of this chapter, in the hydrolysis of edible starch to produce maltodextrins and nutritive carbohydrate sweeteners.

(2) The ingredient is used at levels not to exceed current good manufacturing practices.

Dated: November 22, 1994.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 94-29731 Filed 12-2-94; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[EE-81-88]

RIN 1545-AN55

Deductions for Transfers of Property

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of hearing.

SUMMARY: This document contains proposed amendments to the regulations to eliminate the special rule that requires an employer to deduct and withhold income tax as a prerequisite for claiming a deduction for property transferred to an employee in connection with the performance of services. Under the existing regulation, employers have been denied a deduction for failure to withhold even where the employee has reported the income and paid the tax. The proposed amendments will provide guidance on substantiating deductions for property transferred in connection with the performance of services. The proposed amendments will affect employers and other service recipients who transfer property for services.

DATES: Written comments and requests for a public hearing must be received by February 3, 1995.

ADDRESSES: Send comments and requests for a public hearing to: Internal Revenue Service, POB 7604, Ben Franklin Station, Attn: CC:DOM:CORP:T:R (EE-81-88), room 5228, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:T:R (EE-81-88), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Charles T. Deliee, telephone 202-622-6060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the

Office of Management and Budget for review in accordance with the Paperwork Reduction Act (44 U.S.C. 3504(h)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, PC:FP, Washington, DC 20224.

The collection of information is in §§ 1.6041-1 and 1.6041-2 of the Regulations. This information is required by the IRS to ensure the proper matching of income recognized by service providers with deductions claimed by service recipients. The likely respondents are individuals, farms, business or other for-profit institutions, nonprofit institutions, and small businesses or organizations.

The burden for the reporting requirement contained in §§ 1.6041-1 and 1.6041-2 is reflected in the burden for Forms W-2 and 1099.

Overview

This document contains proposed amendments to the Income Tax Regulations (26 CFR Part 1) under section 83(h) of the Internal Revenue Code of 1986 (Code). The proposed regulations eliminate the requirement to deduct and withhold income tax as a prerequisite for claiming a deduction.

Under section 83(h) of the Code, in the case of a transfer of property to which section 83(a) applies, the person for whom services were provided may deduct an amount equal to the amount included in the service provider's gross income. In light of the difficulty that a service recipient may have in demonstrating that an amount has actually been included in the service provider's gross income, the general rule in existing § 1.83-6(a)(1) permits the deduction for the amount "includible" in the service provider's gross income. Thus, the deduction may be allowed to the service recipient even if the service provider does not properly report the includible amount. Where the service provider is an employee of the service recipient, however, the special rule in § 1.83-6(a)(2) provides that a deduction may be claimed only if the service recipient (employer) deducts and withholds income tax in accordance with section 3402. The special rule was designed to ensure that the service recipient's deduction is in fact offset by a corresponding inclusion in the service provider's gross income. The special rule is limited to employer-employee situations because in other situations

there is no underlying withholding requirement upon which the deduction could be conditioned.

Taxpayers have expressed concern that it is often difficult to satisfy the prerequisite that employers must deduct and withhold income tax from payments in kind as a condition for claiming a deduction. The proposed amendments to the section 83 regulations would address this concern by eliminating this prerequisite, while still ensuring consistent treatment between service recipients and service providers as required by the statute. In addition, because the deduction no longer would be conditioned on withholding, there no longer would be a need to have different rules for those who receive services from employees and those who receive services from others.

Under the proposed amendments, the existing general rule and special rule would be replaced by a revised general rule that more closely follows the statutory language of section 83(h). The service recipient would be allowed a deduction for the amount "included" in the service provider's gross income. For this purpose, the amount included means the amount reported on an original or amended return or included in gross income as a result of an IRS audit of the service provider.

Because of the potential difficulty of demonstrating actual inclusion by the service provider, a special rule would provide that, if the service recipient timely complies with applicable Form W-2 or 1099 reporting requirements under section 6041 (or 6041A), as appropriate, with respect to the amount includible in income by the service provider, the service provider will be deemed to have included the amount in gross income for this purpose. Thus, the proposed amendments would allow the deduction without requiring the service recipient to demonstrate actual inclusion by the service provider. If a transfer met the requirements for exemption from reporting for payments aggregating less than \$600 in any taxable year, or was eligible for any other reporting exemption, no reporting would be required in order for the service recipient to rely on the deemed inclusion rule.

In order to allow service recipients to take advantage of the deemed inclusion rule with respect to property transfers to all service providers, the proposed amendments would permit service recipients to use the special rule also in the case of transfers to corporate service providers. To that end, service recipients would be permitted, solely for purposes of this rule, to treat the