

traffic flow and reduce pilot/controller workload.

The FAA has determined that this 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 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).

Adoption of the Amendment

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

PART 71—[AMENDED]

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

* * * * *

V-514 [New]

From Mission Bay, CA; INT Mission Bay 091° and Julian, CA, 185° radials; Julian; Thermal, CA; Twentynine Palms, CA; INT Twentynine Palms 043° and Goffs, CA 200° radials; Goffs, INT Goffs 033° and Boulder City, NV, 165° radials; Boulder City.

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Issued in Washington, DC, on October 24, 1995.

Harold W. Becker,
 Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 95-27349 Filed 11-2-95; 8:45 am]

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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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is 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. This action is based on a petition requesting such affirmation.

DATES: Effective November 3, 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 in 21 CFR part 184, effective November 3, 1995.

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. Introduction

In the Federal Register of September 21, 1983 (48 FR 43096), FDA announced that a petition (GRASP 3G0284) had been filed by CPC International, Inc., International Plaza, Englewood Cliffs, NJ 07632, requesting that α-amylase enzyme from *B. stearothermophilus* used in the production of sweeteners from starch be affirmed as GRAS as a direct human food ingredient.

In a tentative final rule published in the Federal Register of December 5, 1994 (59 FR 62366), FDA announced its tentative decision to affirm as GRAS the use of this enzyme preparation to produce maltodextrins, as well as nutritive carbohydrate sweeteners from starch. The agency published a tentative final rule before proceeding to final action because 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 found that the phrase “production of maltodextrins and nutritive carbohydrate sweeteners from starch” was a more accurate description of the petitioned use of the α-amylase enzyme preparation. FDA published the tentative final rule to afford interested persons the opportunity to comment on this change. FDA did not receive any comments in response to this tentative final rule. Therefore, the agency concludes that the tentative final rule should be issued as a final rule.

II. Environmental Impact

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.

III. Analysis of Impacts

FDA has examined the impacts of the 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the 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 final rule, the compliance cost to firms is zero. Because no increase in the health risks faced by consumers will result from this 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. Thus the agency certifies that the 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.

IV. Effective Date

As this rule recognizes an exemption from the food additive definition in the Federal Food, Drug, and Cosmetic Act, and from the approval requirements applicable to food additives, no delay in effective date is required by the Administrative Procedure Act (5 U.S.C. 553(d)). The rule will therefore be effective immediately (5 U.S.C. 553(d)(1)).

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, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. 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) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or 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: October 19, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Chapter I and Parts 1, 7, 9, 14, 20 and 64

RIN 1024-AC37

General Provisions, Definitions: Change in Organizational Title From Regional Director to Field Director

AGENCY: National Park Service, Interior.
ACTION: Final rule.

SUMMARY: The National Park Service (NPS) is amending the General Provisions Definition of "Regional Director" to reflect a new organizational structure. With the recent reorganization of the NPS eliminating existing geographic regions (effective May 15, 1995), the term Regional Director is no longer an agency job position. The duties and responsibilities of these positions have been assumed by Field Directors. This amendment to the definition will replace the term Regional Director with Field Director wherever it appears in 36 CFR parts 1-199, as well as eliminate all reference to the former geographic regions.

This change is necessary because the terms Region and Regional Director are no longer recognized in the NPS reorganizational structure. Certain responsibilities and delegations of authority associated with the former Regional Directors are now assumed by the positions identified by the term Field Director. Publication of this change is also a requirement of the Federal Register Act (44 U.S.C. Chapter 15).

EFFECTIVE DATE: This rule is effective November 3, 1995.

ADDRESSES: Comments should be addressed to: Dennis Burnett, National Park Service, Ranger Activities Division, P.O. Box 37127, Washington, D.C. 20013-7127.

FOR FURTHER INFORMATION CONTACT: Dennis Burnett, Ranger Activities Division, at the above address. Telephone (202) 208-4874.

SUPPLEMENTARY INFORMATION:

Background

The National Park System of the United States comprises 368 areas covering over 80 million acres in 49 States, the District of Columbia, American Samoa, Guam, Puerto Rico, Saipan and the Virgin Islands. These areas of national significance justify special recognition and protection in accordance with various acts of Congress.

In an Act signed on August 25, 1916, Congress established in the Department of the Interior the National Park Service to provide cohesive administration of those federal parklands under the Department of the Interior's jurisdiction. This new agency assumed the responsibility for the management of 29 park units that had previously been designated by Congress. An Executive Order in 1933 transferred 63 national monuments and military sites from the Forest Service and the War Department to the NPS. With this rapid increase in the number of units entering the system, the NPS determined that an expanded management system was necessary to properly administer the parks.

In August of 1937, the NPS initiated the geographical concept of Regional Offices administered by Regional Directors by establishing four (4) Regional Offices: Region One in Richmond, VA; Region Two in Omaha, NE; Region Three in Santa Fe, NM; and Region Four in San Francisco. These four original regional offices provided assistance in the management and administration of the parks in their regions from 1937 until 1955 when Region Five was established in Philadelphia, PA. National Capital Parks became Region Six on January 22, 1962. Also in 1962, Region One was renamed Southeast Region and on January 9, 1972, the headquarters moved from Richmond to Atlanta, GA. A seventh regional office, Northwest Region, was added on December 30, 1969, in Seattle, WA. Region Eight, North Atlantic Region, was established on January 6, 1974, in Boston, MA. Region Nine, Rocky Mountain Region, was established on November 30, 1973, in Denver, CO. The tenth and final region,