

operations in the airspace over the Gulf of Mexico.

Currently, International Civil Aviation Organization (ICAO) oceanic ATC procedures are used to separate and manage aircraft operations that extend beyond the lateral boundary of the existing Gulf of Mexico High Offshore Airspace Area. Modifying the Gulf of Mexico High Offshore Airspace Area by extending the boundaries further east and south of the current location to the Houston ARTCC FIR/CTA, will allow the application of domestic ATC separation procedures over a larger area. This proposal to modify the offshore airspace area would enhance system capacity and allow for more efficient utilization of that airspace.

The Proposal

The FAA is proposing an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify the Gulf of Mexico High Offshore Airspace Area, by extending the present airspace area east and south to the Houston ARTCC FIR/CTA. The proposed modification would allow the application of domestic ATC separation procedures, in lieu of ICAO separation procedures, enhancing system capacity, and allowing for more efficient use of the airspace.

Offshore airspace area designations are published in paragraph 2003 of FAA Order 7400.9F, dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The offshore airspace area 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.

ICAO Considerations

As part of this proposal relates to navigable airspace outside the United

States, this notice is submitted in accordance with the ICAO International Standards and Recommended Practices.

The application of International Standards and Recommended Practices by the FAA, Office of Air Traffic Airspace Management, in areas outside U.S. domestic airspace is governed by the Convention on International Civil Aviation. Specifically, the FAA is governed by Article 12 and Annex 11, which pertain to the establishment of necessary air navigational facilities and services to promote the safe, orderly, and expeditious flow of civil air traffic. The purpose of the document is to ensure that civil aircraft operations on international air routes are performed under uniform conditions.

The International Standards and Recommended Practices in Annex 11 apply to airspace under the jurisdiction of a contracting state, derived from ICAO. Annex 11 provisions apply when air traffic services are provided and a contracting state accepts the responsibility of providing air traffic services over high seas or in airspace of undetermined sovereignty. A contracting state accepting this responsibility may apply the International Standards and Recommended Practices that are consistent with standards and practices utilized in its domestic jurisdiction.

In accordance with Article 3 of the Convention, state owned aircraft are exempt from the Standards and Recommended Practices of Annex 11. The United States is a contracting state to the Convention. Article 3(d) of the Convention provides that participating state aircraft will be operated in international airspace with due regard for the safety of civil aircraft.

Since this action involves, in part, the designation of navigable airspace outside the United States, the Administrator is consulting with the Secretary of State and the Secretary of Defense in accordance with the provisions of Executive Order 10854.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the FAA proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

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.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 2003 Offshore Airspace Areas

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Gulf of Mexico High [Revised]

That airspace extending upward from FL 280 to and including FL 600 bounded on the west, north, and east by a line 12 miles offshore and parallel to the Texas, Louisiana, Mississippi, Alabama, and Florida shorelines; bounded on the south from east to west by the southern boundary of the Jacksonville ARTCC, Miami Oceanic CTA/FIR; Merida UTA/FIR; Monterey UTA/UIR, Houston CTA/FIR; to the point of beginning, and that airspace extending upward from 18,000 feet MSL to and including FL 280 bounded on the west, north, and east by a line 12 miles offshore and parallel to the Texas, Louisiana, Mississippi, Alabama, and Florida shorelines bounded on the south from east to west by the southern boundary of the Jacksonville ARTCC, Miami Oceanic CTA/FIR, Houston CTA/FIR and lat. 26°00'00"N.

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Issued in Washington, DC, on November 2, 1998.

John S. Walker,

Program Director for Air Traffic Airspace Management.

[FR Doc. 98–29951 Filed 11–9–98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91, 119, 121, 125, and 135

[Docket No. FAA–1998–4458; Notice No. 98–13]

RIN 2120–AG35

Prohibition on the Transportation of Devices Designed as Chemical Oxygen Generators as Cargo in Aircraft; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); correction.

SUMMARY: This document contains a correction to the NPRM published in the **Federal Register** (63 FR 45912) on August 27, 1998. The NPRM proposes to ban, in certain domestic operations, the transportation of devices designed to chemically generate oxygen, including devices that have been discharged and newly manufactured devices that have not yet been charged for the generation of oxygen, with limited exceptions.

FOR FURTHER INFORMATION CONTACT: David L. Catey, (202) 267-8166.

Correction of Publication

In proposed rule FR Doc. 98-23010, beginning on page 45912 in the **Federal Register** issue of August 27, 1998, make the following corrections:

On page 45912, in the first column, in the heading, "[Docket No. 29318; Notice No. 98-12]", should read "[Docket No. FAA-1998-4458; Notice No. 98-13]".

In the **ADDRESSES** section on page 45912, in the first column, in the fifth line, the docket number "FAA-98-29318", should read "FAA-1998-4458".

In the Comments Invited section on page 45912, in the second column, last paragraph, first line, "Docket No. 29318", should read "Docket No. FAA-1998-4458".

Issued in Washington, DC on November 4, 1998.

Donald P. Byrne,

Assistant Chief Counsel.

[FR Doc. 98-30088 Filed 11-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98P-0683]

Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to authorize the use, on food labels and in food labeling, of health claims on the association between soy protein and reduced risk of coronary heart disease (CHD). FDA is proposing this action in response to a petition filed by Protein Technologies International, Inc. (the

petitioner). The agency has tentatively concluded that, based on the totality of publicly available scientific evidence, soy protein included in a diet low in saturated fat and cholesterol may reduce the risk of CHD.

DATES: Written comments by January 25, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Susan M. Pilch, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4500.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535). This new law amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the most notable aspects of the 1990 amendments was that they provided procedures whereby FDA is to regulate health claims on food labels and in food labeling.

In the **Federal Register** of January 6, 1993 (58 FR 2478), FDA issued a final rule that implemented the health claim provisions of the act (hereinafter referred to as the 1993 health claims final rule). In that final rule, FDA adopted § 101.14 (21 CFR 101.14), which sets out the rules for the authorization and use of health claims. Additionally, § 101.70 (21 CFR 101.70) establishes a process for petitioning the agency to authorize health claims about a substance-disease relationship (§ 101.70(a)) and sets out the types of information that any such petition must include (§ 101.70(d)). These regulations became effective on May 8, 1993.

In response to the 1990 amendments, FDA also conducted an extensive review of the evidence on the 10 substance-disease relationships listed in the 1990 amendments. As a result of its review, FDA has authorized claims for 8 of these 10 relationships, one of which focused on the relationship between dietary saturated fat and cholesterol and reduced risk of CHD. CHD is the most common, most frequently reported, and most serious form of cardiovascular disease (CVD) (58 FR 2739, January 6, 1993). Further, while the agency denied the use on food labeling of health claims relating dietary fiber to reduced risk of CVD (58 FR 2552), it authorized a health claim relating diets low in saturated fat

and cholesterol and high in fruits, vegetables, and grain products that contain dietary fiber (particularly soluble fiber) to a reduced risk of CHD.

In the proposed rule entitled "Health Claims and Label Statements; Lipids and Cardiovascular Disease" (56 FR 60727, November 27, 1991), FDA set out the criteria for evaluating evidence on diet and CVD relationships. The agency focused on those aspects of the dietary lipid and CVD relationship for which the strongest scientific evidence and agreement existed. FDA noted that, because of the public health importance of CHD, identification of "modifiable" risk factors for CHD had been the subject of considerable research and public policy attention. The agency also noted that there is general agreement that elevated blood cholesterol levels are one of the major "modifiable" risk factors in the development of CHD. FDA cited Federal Government and other reviews that concluded that there is substantial epidemiologic and clinical evidence that high blood levels of total and low density lipoprotein (LDL) cholesterol are a cause of atherosclerosis and represent major contributors to CHD. Further, factors that decrease total blood cholesterol and LDL-cholesterol will also decrease the risk of CHD. FDA concluded that it is generally accepted that blood total and LDL-cholesterol levels are major risk factors for CHD, and that dietary factors affecting blood cholesterol levels affect the risk of CHD. High intakes of dietary saturated fat and, to a lesser degree, of dietary cholesterol are consistently associated with elevated blood cholesterol levels. FDA concluded that the publicly available data supported an association between diets low in saturated fat and cholesterol and reduced risk of CHD (58 FR 2739 at 2751).

Based on its review using the stated criteria, and on its consideration of comments received in response to the proposed rule entitled "Health Claims; Dietary Fiber and Cardiovascular Disease" (56 FR 60582), FDA concluded that the publicly available scientific information supported an association between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products (i.e., foods that are low in saturated fat and cholesterol and that are good sources of dietary fiber) and reduced risk of heart disease (58 FR 2552 at 2572). In the 1993 dietary fiber and CVD final rule, in response to a comment regarding the apparent hypocholesterolemic properties of specific food fibers, FDA again articulated its criteria for evaluating diet and CHD relationships (58 FR 2552 at 2567). FDA agreed that