

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 184

[Docket No. 99P-5332]

## Substances Affirmed as Generally Recognized as Safe: Menhaden Oil

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulation on menhaden oil which has been affirmed as generally recognized as safe (GRAS) as a direct human food ingredient with specific limitations. FDA is proposing to reallocate the uses of menhaden oil in food that currently are established in FDA's regulations. This proposal responds to a citizen petition on menhaden oil from the National Fish Meal and Oil Association (NFMOA).

**DATES:** Submit written or electronic comments by [*insert date 75 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202-418-3103.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of June 5, 1997 (62 FR 30751), FDA published a final rule to affirm that menhaden oil is GRAS for use as a direct human food ingredient with specific limitations (hereinafter referred to as the June 1997 final rule). FDA published the June 1997 final rule in response to a GRAS petition (GRASP 6G0316) submitted by the NFMOA. FDA concluded in the June 1997 final rule that, based on scientific procedures (including published and other information), the use of menhaden oil as a direct human food ingredient is safe, provided that the combined daily intake of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) from menhaden oil does not exceed 3.0 grams per person per day (g/p/d).

Affirming the GRAS status of menhaden oil with specific limitations (§ 184.1(b)(2) (21 CFR 184.1(b)(2))) was necessary because of the agency's concerns over possible adverse effects of fish oils on bleeding time (the time taken for bleeding from a standardized skin wound to cease), glycemic control, and low-density lipoprotein cholesterol. These issues were discussed fully in the June 1997 final rule.

## II. The Citizen Petition

The NFMOA has submitted a citizen petition (Docket No. 99P-5332) under 21 CFR 10.20 and 10.30 requesting that the agency amend § 184.1472 *Menhaden oil* (21 CFR 184.1472) by reallocating the uses of menhaden oil in food, while maintaining the total daily intake of EPA and DHA from menhaden oil at a level not exceeding 3.0 g/p/d. The maximum limit of 3.0 g/p/d on the total daily intake of EPA and DHA has been considered a reasonable safeguard against the possible adverse effects stated above and to date no new information available has caused the agency to alter this limit. The reallocation is performed by: (1) Reducing the maximum levels of use of menhaden oil in some of the currently listed food categories; (2) adding additional food categories along with assigning maximum levels of use in these new categories; and (3) eliminating the listing of subcategories, for example, cookies and crackers, breads and rolls, fruit pies and

custard pies, and cakes, and including them under broader food categories, i.e., baked goods and baking mixes.

Table 1 shows the current maximum levels of use of menhaden oil in the currently listed food categories as established in § 184.1472(a)(3).

TABLE 1.—CURRENT MAXIMUM LEVELS OF USE OF MENHADEN OIL

Category of food <sup>1</sup>	Current maximum level of use in food (as served)
Cookies and crackers (1) .....	5.0 percent
Breads and rolls (white and dark) (1) .....	1.0 percent
Fruit pies and custard pies (1) .....	7.0 percent
Cakes (1) .....	10.0 percent
Cereals (4) .....	4.0 percent
Fats and oils (12), but not in infant formula .....	20.0 percent
Yogurt (31) .....	4.0 percent
Cheese products (5) .....	5.0 percent
Frozen dairy products (20) .....	5.0 percent
Meat products (29) .....	10.0 percent
Egg products (11) .....	5.0 percent
Fish products (13) .....	20.0 percent
Condiments (8) .....	5.0 percent
Soup mixes (40) .....	3.0 percent
Snack foods (37) .....	5.0 percent
Nut products (32) .....	5.0 percent
Gravies and sauces (24) .....	5.0 percent

<sup>1</sup>The number in parenthesis following each food category is the paragraph listing of that food category in § 170.3(n) (21 CFR 170.3(n)).

Table 2 shows the new maximum levels of use of menhaden oil in the currently listed food categories plus new food categories, as proposed by the NFMOA.

TABLE 2.—NEW MAXIMUM LEVELS OF USE OF MENHADEN OIL

Category of food <sup>1</sup>	Proposed maximum level of use
Baked goods and baking mixes (1) .....	5.0 percent
Cereals (4) .....	4.0 percent
Cheese products (5) .....	5.0 percent
Condiments (8) .....	5.0 percent
Egg products (11) .....	5.0 percent
Fats and oils (12), but not in infant formula .....	12.0 percent
Fish products (13) .....	5.0 percent
Frozen dairy desserts (20) .....	5.0 percent
Gravies and sauces (24) .....	5.0 percent
Meat products (29) .....	5.0 percent
Milk products (31) .....	5.0 percent
Nut products (32) .....	5.0 percent
Snack foods (37) .....	5.0 percent
Soup mixes (40) .....	3.0 percent
Nonalcoholic beverages (3) .....	0.5 percent
Chewing gum (6) .....	3.0 percent
Confections and frostings (9) .....	5.0 percent
Dairy product analogs (10) .....	5.0 percent
Gelatins and puddings (22) .....	1.0 percent
Pastas (23) .....	2.0 percent
Hard candy (25) .....	10.0 percent
Jams and jellies (28) .....	7.0 percent
Plant protein products (33) .....	5.0 percent
Poultry products (34) .....	3.0 percent
Processed fruit juices (35) .....	1.0 percent
Processed vegetable juices (36) .....	1.0 percent
Soft candy (38) .....	4.0 percent
White granulated sugar (41) .....	4.0 percent

TABLE 2.—NEW MAXIMUM LEVELS OF USE OF MENHADEN OIL—Continued

Category of food <sup>1</sup>	Proposed maximum level of use
Sugar substitutes (42) .....	10.0 percent
Sweet sauces, toppings, and syrups (43) .....	5.0 percent

<sup>1</sup>The number in parenthesis following each food category is the paragraph listing of that food category in § 170.3(n).

As shown in table 1, the currently listed food categories include several subcategories, such as cookies and crackers, breads and rolls, fruit pies and custard pies, and cakes. These items are subcategories of baked goods and baking mixes as described under § 170.3(n)(1). The proposed reallocation (in table 2) does not list any subcategory, but rather includes the food category baked goods and baking mixes, which would include all of these items. Also, the currently listed food categories include another subcategory, i.e., yogurt, a subcategory of milk product as described under § 170.3(n)(31). Similarly, the proposed reallocation does not list yogurt, but rather includes the food category milk products, which would include yogurt.

Although each food category in the proposed reallocation (table 2) is associated with a paragraph in § 170.3(n), menhaden oil may not be added to all foods included in that paragraph, unless such food is listed in table 2. For example, § 170.3(n)(23) includes grain products and pastas, but menhaden oil only could be added to pastas (not grain products) under this proposed reallocation in table 2. In other words, only the food categories that are listed in table 2 are those that the NFMOA is requesting for the amendment of the regulation on menhaden oil.

The NFMOA has provided exposure analyses that contain estimates of EPA and DHA intake from menhaden oil for the revised uses of the currently listed food categories and the proposed uses of the new food categories. The NFMOA states that the estimated daily exposure to EPA and DHA from those uses of menhaden oil is 2.7 g/p/d. The NFMOA concludes that menhaden oil is GRAS for the revised uses of the currently listed food categories and the proposed uses of the new food categories, because the total daily intake of EPA and DHA from those uses of menhaden oil would not exceed 3.0 g/p/d, consistent with the June 1997 final rule.

### **III. Proposed Action**

Based on information in the citizen petition and other relevant material, FDA tentatively has determined that the GRAS status of menhaden oil with specific limitations remains unchanged if uses of menhaden oil in food are reallocated, because the total daily intake of EPA and DHA from menhaden oil from the revised uses of the currently listed food categories and the proposed uses of the new food categories would not exceed 3.0 g/p/d. Because not all foods in the marketplace within those food categories in table 2 would contain menhaden oil that substitutes for other edible fat or oil, and because not all foods that a consumer chooses daily would be those with menhaden oil used as a substitute oil, the actual total daily intake of EPA and DHA from menhaden oil for an average person should be significantly below 3.0 g/p/d. Further, because the total daily intake of EPA and DHA from menhaden oil based on the uses proposed in this rulemaking would not exceed 3.0 g/p/d, and the agency is not aware of any new data and information that would prompt the agency to change the upper limit of safety of 3.0 g/p/d, FDA intends to rely on its safety determination from its prior GRAS affirmation for finding these uses safe. Therefore, the agency is proposing to amend the regulation on menhaden oil to reallocate its use in food.

### **IV. Environmental Impact**

The agency carefully has considered the potential environmental effects of this action. FDA tentatively 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.

## V. Analysis of Economic Impacts

### A. Preliminary Regulatory Impact Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation also is considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

FDA is proposing to amend its regulation on menhaden oil, which the agency believes is GRAS with specific limitations. This proposed rule would reallocate the uses of menhaden oil in food, without causing the combined daily intake of EPA and DHA from menhaden oil to exceed 3.0 g/p/d.

The main benefit of this proposed rule would be the expansion of the potential uses of menhaden oil as proposed in table 2. Firms choosing to use menhaden oil would bear labeling and other costs. Because these costs are voluntary, they will be borne only if doing so is anticipated to be advantageous to the firm.

FDA proposes to reduce maximum use levels of menhaden oil for pies, cakes, fats, oils, fish products, and meat products. The potential compliance costs of this proposed rule would be borne by firms making products that now use menhaden oil at levels below the current maximum but above the proposed maximum. The proposed rule would force them to either reformulate their products or cease production. Although the potential cost of both reformulation and ceasing production may be large, FDA does not know of any products that would be forced to bear these

costs. Using menhaden oil in pies, cakes, fats, oils, fish products, and meat products at the current maximum levels leads to products with undesirable flavors. Based on both market observations and taste, FDA assumes that no products currently contain levels of menhaden oil above the proposed maximum levels and thus there are no costs associated with reformulation or ceasing production based on this proposal. We request comments on this assumption.

### *B. Initial Regulatory Flexibility Analysis*

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

FDA is proposing to amend the GRAS affirmation for menhaden oil by establishing new maximum levels of use. The use of the menhaden oil by any small business is voluntary and is undertaken only if anticipated to be advantageous to the small business. Small businesses would only bear a compliance cost if, as stated above, they make products that are below the current maximum but above the proposed maximum levels of use. The proposed rule would force them to either reformulate their products or cease production. Although the potential cost of both reformulation and ceasing production to small businesses may be large, FDA does not know of any small businesses that would be forced to bear these costs. Using menhaden oil in pies, cakes, fats, oils, fish products, and meat products at the current maximum levels leads to products with undesirable flavors. Based on both market observations and taste, FDA assumes that no products currently contain levels of menhaden oil above the proposed maximum levels and thus there are no costs associated with reformulation or ceasing production based on this proposal. The agency therefore tentatively concludes that the new maximum levels proposed would not impose significant costs on a substantial number of small entities. The agency requests comments from small businesses on this assumption. Based on the assumption that no small businesses make products that would be affected by reducing the maximum levels of menhaden oil in pies, cakes, fats, oils,

fish products, and meat products, FDA finds that this proposed rule would not have a significant economic impact on a substantial number of small entities.

### *C. Unfunded Mandates*

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a “Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The current inflation-adjusted statutory threshold is \$110 million. FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995.

## **VI. Paperwork Reduction Act of 1995**

This proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## **VII. Federalism Impact**

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has tentatively determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The agency invites comments on its tentative conclusion that the proposed rule does not contain policies that have federalism implications as defined in the order, and consequently, a federalism summary impact statement is not required.

## **VIII. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposed rule by *[insert date 75 days after date of publication in the*

**Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 184**

Food additives, Food ingredients.

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 SAFE**

1. The authority citation for 21 CFR part 184 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348, 371.

2. Section 184.1472 is amended by revising paragraph (a)(3) to read as follows:

**§ 184.1472 Menhaden oil.**

(a) \* \* \*

(3) In accordance with § 184.1(b)(2), the ingredient may be used in food only within the following specific limitations:

Category of food	Maximum level of use in food (as served)
Baked goods, baking mixes, § 170.3(n)(1) of this chapter. ....	5.0 percent
Cereals, § 170.3(n)(4) of this chapter. ....	4.0 percent
Cheese products, § 170.3(n)(5) of this chapter. ....	5.0 percent
Chewing gum, § 170.3(n)(6) of this chapter. ....	3.0 percent
Condiments, § 170.3(n)(8) of this chapter. ....	5.0 percent
Confections, frostings, § 170.3(n)(9) of this chapter. ....	5.0 percent
Dairy product analogs, § 170.3(n)(10) of this chapter. ....	5.0 percent
Egg products, § 170.3(n)(11) of this chapter. ....	5.0 percent
Fats, oils, § 170.3(n)(12) of this chapter, but not in infant formula. ....	12.0 percent
Fish products, § 170.3(n)(13) of this chapter. ....	5.0 percent
Frozen dairy desserts, § 170.3(n)(20) of this chapter. ....	5.0 percent
Gelatins, puddings, § 170.3(n)(22) of this chapter. ....	1.0 percent
Gravies, sauces, § 170.3(n)(24) of this chapter. ....	5.0 percent

Category of food	Maximum level of use in food (as served)
Hard candy, § 170.3(n)(25) of this chapter. ....	10.0 percent
Jams, jellies, § 170.3(n)(28) of this chapter. ....	7.0 percent
Meat products, § 170.3(n)(29) of this chapter. ....	5.0 percent
Milk products, § 170.3(n)(31) of this chapter. ....	5.0 percent
Nonalcoholic beverages, § 170.3(n)(3) of this chapter. ....	0.5 percent
Nut products, § 170.3(n)(32) of this chapter. ....	5.0 percent
Pastas, § 170.3(n)(23) of this chapter. ....	2.0 percent
Plant protein products, § 170.3(n)(33) of this chapter. ....	5.0 percent
Poultry products, § 170.3(n)(34) of this chapter. ....	3.0 percent
Processed fruit juices, § 170.3(n)(35) of this chapter. ....	1.0 percent
Processed vegetable juices, § 170.3(n)(36) of this chapter. ....	1.0 percent
Snack foods, § 170.3(n)(37) of this chapter. ....	5.0 percent
Soft candy, § 170.3(n)(38) of this chapter. ....	4.0 percent
Soup mixes, § 170.3(n)(40) of this chapter. ....	3.0 percent
Sugar substitutes, § 170.3(n)(42) of this chapter. ....	10.0 percent
Sweet sauces, toppings, syrups, § 170.3(n)(43) of this chapter. ....	5.0 percent
White granulated sugar, § 170.3(n)(41) of this chapter. ....	4.0 percent

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Dated: January 11, 2002.

**L. Robert Lake,**

*Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.*

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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