airspace within the Knoxville, IA, Class E airspace area.

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Issued in Kansas City, MO, on March 31, 1998.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 88G–0288]

Direct Food Substances Affirmed As Generally Recognized as Safe; Sheanut Oil

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that the use of sheanut oil as a direct human food ingredient is generally recognized as safe (GRAS). This action is in response to a petition filed by Fuji Oil Co., Ltd.

DATES: The regulation is effective May 27, 1998.

FOR FURTHER INFORMATION CONTACT: William J. Trotter, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3088.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), Fuji Oil Co., Ltd., 6–1, Hachiman-Cho, Minami-Ku, Osaka 542, Japan, submitted a petition (GRASP 8G0343) requesting that sheanut oil be affirmed as GRAS for use as a direct food ingredient.

FDA published a notice of filing of this petition in the **Federal Register** of September 30, 1988 (53 FR 38347), and gave interested parties an opportunity to submit comments to the agency. FDA received three comments in response to that notice. These comments are discussed in section VIII of this document.

II. Standards for GRAS Affirmation

Under § 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, through experience based on common use in food (§ 170.30(a)). 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obtain approval of a food additive and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)).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, but ordinarily is to be based upon generally available data and information concerning the pre-1958 history of use of the food ingredient (§ 170.30(c)(1)). In evaluating this petition, the agency reviewed information and data on the history of sheanut oil use and on published and unpublished safety studies for sheanut oil.

III. Identity and Specification

Sheanut oil is produced from sheanuts derived from the Shea tree *Butyrospermum parkii* and is composed mainly of triglycerides containing an oleic acid moiety at the 2-position and saturated fatty acids, usually stearic or palmitic acids, at the 1- and 3-positions. It meets the following specifications, which are consistent with those for other food-grade oils as described in the Food Chemicals Codex (Ref. 1):

1. Saponification value—185 to 195,
2. Iodine value—28 to 43,
3. Unsaponifiable matter—not to exceed 1.5 percent,
4. Free fatty acids—less than 0.1 percent (as oleic acid),
5. Peroxide value—less than 10 milliequivalents/equivalent (meq/eq),
6. Heavy metals—less than 0.1 part per million (ppm) each of lead and copper.

The petitioner adequately referenced methods of analyses for these specifications.

IV. Manufacturing Process

Sheanut oil is refined by various processes, which may involve different sequences of manufacturing steps and solvents that are in common use in the fat and oil industry. The crude oil must be refined to remove excessive unsaponifiable material. Standard refining techniques, e.g., decolorization by passage through bleaching clay and steam distillation to remove odoriferous impurities, are employed to purify further the oil.

V. Proposed Use in Food

The intended use for sheanut oil is as a component of a mixture of oils used as cocoa butter substitutes. The agency has calculated a mean estimated daily intake (EDI) of 2.2 gram/person/day (g/p/d) for sheanut oil in confections and candies (2+ year olds). The EDI for consumers at the 90th percentile level is 4.4 g/p/d. The EDI for children from 2 to 5 years old is 1.8 g/p/d at the mean and 4.3 g/p/d at the 90th percentile level.

VI. Common Use in Food Before 1958

The petitioner provided several published articles that document that sheanut oil has a history of common use in food prior to 1958. Sheanut oil has been used in Africa for food purposes since the 1800's (Ref. 2). It has also been used in Europe as a cooking oil and as a cocoa butter substitute, as well as for making margarine (Ref. 3 through 7). In addition, in a comment submitted in support of the petition, Loders Croklaan, Inc.,[1] of Berwyn, PA, presented information that documents use of sheanut oil in England for more than 50 years; among the uses of sheanut oil documented in this comment were as a pastry fat, a cooking oil, a cocoa butter substitute, and for making margarine. The comment provided copies of formulations from England that showed that some cooking fats in 1948 contained between 5 and 7 percent sheanut oil and that a pastry margarine known as ''flex,'' marketed between 1954 and 1958, contained between 80 and 91 percent sheanut oil.[2]

VII. Safety Information

The evidence documenting common use of sheanut oil in food reflects no known adverse effects. The absence of documented adverse effects from food use of sheanut oil is corroborated by several animal feeding studies, by information regarding the components of sheanut oil, and its similarity in

[1] In a comment submitted to the agency, Loders Croklaan, Inc., also requested that all safety data and other information concerning sheanut oil contained in its Food Master File (FMF) No. 253 be incorporated into Fuji's petition. Consequently, the information contained in FMF No. 253 was made available for public display under the same docket no. 88G–0288 with the Fuji petition.

[2] In addition, in its comment Loders Croklaan, Inc., quoted official United Kingdom statistics for sheanuts imported into the United Kingdom as averaging 6,000 metric tons per year between 1948 and 1957.

composition to other GRAS fats and oils.

Specifically, sheanut oil is composed principally of triglycerides containing oleic acid in the 2-position and the saturated fatty acids, usually stearic and palmitic acids, in the 1- and 3-positions. The components of these triglycerides, glycerol, and oleic, stearic, and palmitic acids, as well as other fatty acids found as minor components, are naturally found as part of lipids and lipoproteins of both plants and animals; they are also the same fatty acids and glycerol components found in a broad range of edible fats and oils that are GRAS. The synthesis and metabolism of these substances are well understood and are documented in biochemistry textbooks (for example, Ref. 8).

In addition, the agency has determined that sheanut oil has an overall composition that conforms to that of other edible oils in terms of its total glyceride content, fractions of tri-, di- and monoglycerides, and unsaponifiable matter (Ref. 9). Thus, sheanut oil is similar in chemical composition to commonly used GRAS fats and oils, such as cocoa butter, cottonseed oil, soybean oil, corn oil, and palm oil.

Further, the agency evaluated four corroborative animal studies on the safety of sheanut oil. Three of these studies, which are published (Ref. 10 through 12), establish that sheanut oil has absorbability comparable to that as the other tested GRAS oils and fats. These studies also establish that the growth rates for the subject animals were comparable to those for animals fed other GRAS oils and fats. The fourth study, which is unpublished, is a 104-week toxicity/carcinogenicity study of sheanut oil and other oils in rats. The results of this 104-week study demonstrate that there is no carcinogenic potential for sheanut oil (Ref. 13).

VIII. Response to Comments

In response to the published notice, FDA received three comments from the law offices of Freeman, Wasserman & Schneider on behalf of Loders Croklaan, Inc., of Berwyn, PA.

As discussed previously, the first comment requested that FDA incorporate the safety data and other information on sheanut oil submitted by Loders Croklaan, Inc., and contained in FMF No. 253. The comment asserted that, in addition to the fact that sheanut oil has been used as part of the human diet for a considerable period of time prior to 1958 in countries outside the United States, the safety data also establish that sheanut oil is safe for human consumption.

The second comment, also submitted in support of the petition, was intended to: (1) Provide independent documentation of the history of use of sheanut oil in food prior to 1958 (discussed in section VI of this document), (2) provide safety data for sheanut oil (discussed in section VII of this document), and (3) suggest modifications to the proposed specifications of sheanut oil. These suggested modifications are consistent with the fact that sheanut oil can be made by different processes that involve various sequences of processing steps and various solvents. The comment asserted that certain changes, discussed as follows, should be made to the specifications proposed by the petitioner.

First, the comment stated that the refined oil produced by Loders Croklaan, Inc.'s process, which has an iodine value typically between 33 and 43, allows for a greater percentage of 2-oleoyl-1,3-distearin (SOS). The comment pointed out that an oil composed entirely of SOS would have an iodine value of 25 and, therefore, recommended a specification for an iodine value between 25 and 43. Second, the comment stated that, if a specification for residual solvent is included, it should reflect the possible varieties of recrystallizing and precipitating solvents typically used in the fat and oil industry, instead of specifications for hexane and ethanol only, which the petitioner uses in its process. Third, the comment stated that the proposed specifications for specific gravity and refractive index reflect only the petitioner's oil product and that if these specifications are to be included in a regulation, the comment suggested that broader ranges be used to reflect industry-wide standards rather than the petitioner's specific product.

The agency agrees that sheanut oil may be refined using a variety of solvents and procedures commonly used in the fats and oils industry. The agency believes that sheanut oil produced by standard processing of sheanuts, including further refining to remove excessive unsaponifiable material, should be the food ingredient to be affirmed as GRAS and that the specifications for sheanut oil should encompass all of the typical sheanut oils produced under good manufacturing practices.

The agency agrees with the comment that the range given for iodine value should be modified. However, the agency has calculated a theoretical iodine value for pure SOS of 28.6 and, therefore, believes that a specification range of 28 to 43 would encompass all likely refined sheanut oils (Ref. 14). With regard to residual solvents, the agency agrees with the comment that the specifications for solvents should not be limited to those used by the petitioner (Ref. 14). The agency notes that solvents other than those used by the petitioner are used in the fats and oils industry, and further notes that any residual solvent that becomes or may reasonably be expected to become a functional component of sheanut oil must be GRAS or a food additive approved for use in the manufacture of food fats and oils. Therefore, the agency believes that no specification for solvents is necessary. Similarly, the agency does not believe that specifications for specific gravity and refractive index are necessary in a regulation in order to ensure a safe product; this would be consistent with specifications for other food-grade oils as described in the Food Chemicals Codex (Ref. 1).

The third comment was a reiteration of Loders Croklaan, Inc.'s position regarding specifications for sheanut oil, which have been discussed previously, together with the agency's response.

IX. Conclusions

The petitioner has provided evidence that demonstrates that sheanut oil was in common use in food prior to 1958; this information is published and is corroborated by other information from separate published sources, including information submitted in a comment. There are no reports of adverse effects from such food use of sheanut oil. As provided for under § 170.30(a)(2), FDA has determined that this information provides an adequate basis upon which to conclude that the use of sheanut oil is GRAS among experts qualified by scientific training and experience to evaluate the safety of substances used in food.

This evidence of common use in food prior to 1958 without any reported adverse effects is further corroborated by information regarding the components of sheanut oil, the similarity of sheanut oil to other oils that are GRAS, and the results of four animal feeding studies, three of which are published. Therefore, the agency is affirming the use of sheanut oil as GRAS in accordance with 21 CFR 184.1(b)(3) in the following food categories at levels not to exceed current good manufacturing practice, except that the ingredient may not be used in a standardized food unless permitted by the standard of identity: Confections and frostings as defined in § 170.3(n)(9)

(21 CFR 170.3(n)(9)), coatings of soft candy as defined in § 170.3(n)(38), and sweet sauces and toppings as defined in § 170.3(n)(43).

X. Environmental Effects

The agency has determined under 21 CFR 25.32(f) 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.

XI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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). According to Executive Order 12866, a regulatory action is ''economically significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is considered ''significant'' under Executive Order 12866 if it raises novel legal or policy issues. The agency finds that this rule is neither an economically significant nor a significant regulatory action as defined by Executive Order 12866. In addition, it has been determined that this final rule is not a major rule for the purpose of congressional review.

The primary benefit of this action is to remove uncertainty about the regulatory status of the petitioned substance. No compliance costs are associated with this final rule because no new activity is required, and no current or future activity is prohibited by this rule.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic impact of their regulations on small businesses and other small entities. No compliance costs are associated with this final rule because no new activity is required, and no current or future activity is prohibited. Therefore, this final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, under the Regulatory Flexibility Act, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

XII. Effective Date

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. Thus, no delay in the effective date is required by the Administrative Procedure Act (5 U.S.C. 553(d)). Therefore, the rule will be effective immediately (5 U.S.C. 553(d)(1)).

XIII. 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. *Food Chemicals Codex*, National Research Council, National Academy Press, Washington, DC, 4th ed., 1996.

2. ''Shea,'' *The Oxford English Dictionary*, The Clarendon Press, Oxford, p. 648, 1933.

3. Hefter, G., *Technologie der Fette und Ole*, Julius Springer, Berlin, pp. 688–693, 1908.

4. Jamieson, G. S., *Vegetable Fats and Oils*, Reinhold Publishing Corp., New York, p. 63, 1943.

5. Schwitzer, M. K., *Margarine and Other Food Fats*, Leonard Hill [Books], Ltd., London, p. 40, 1956.

6. Commonwealth Economic Committee, *Vegetables Oils and Oilseeds*, Royal Stationary Office, London, pp. 130–131, 1952.

7. Anderson, J. A. C., and P. N. Williams, *Margarine*, Pergamon Press, Oxford, 2d revised ed., p. 34, 1965.

8. Lehninger, A. L., *Principles of Biochemistry*, Worth Publishers, Inc., New York, NY, 1982.

9. Memorandum from M. DiNovi, FDA to L. Lin, FDA, January 9, 1989.

10. Thomasson, H. J., ''The Biological Value of Oils and Fats: I. Growth and Food Intake on Feeding with Natural Oils and Fats,'' *Journal of Nutrition 56*, pp. 455–468, 1955.

11. Thomasson, H. J., ''The Biological Value of Oils and Fats: IV. The Rate of Intestinal Absorption,'' *Journal of Nutrition 59*, pp. 343–352, 1956.

12. Sawadogo, K. A., and J. A. Bezard, ''Triglyceride Structure of Adipose Tissue of Rats Fed a Diet Based on Shea Butter,'' *Oleagineux 37*, pp. 247–253, 1982.

13. Memorandum of C. Johnson, FDA to K. Ekelman, FDA, May 18, 1995.

14. Memorandum of M. DiNovi, FDA to L. Lin, FDA, February 21, 1989.

List of Subjects in 21 CFR Part 184

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

2. Section 184.1702 is added to read as follows:

§ 184.1702 Sheanut oil.

(a) Sheanut oil is produced from sheanuts derived from the Shea tree *Butyrospermum parkii* and is composed principally of triglycerides containing an oleic acid moiety at the 2-position and saturated fatty acids, usually stearic or palmitic acids, at the 1- and 3-positions.

(b) The ingredient meets the following specifications when tested using any appropriate validated methodology:

(1) Saponification value of 185 to 195,

(2) Iodine value of 28 to 43,

(3) Unsaponifiable matter not to exceed 1.5 percent,

(4) Free fatty acids not more than 0.1 percent as oleic acid,

(5) Peroxide value not more than 10 milliequivalents/equivalent (meq/eq),

(6) Lead not more than 0.1 part per million (ppm),

(7) Copper not more than 0.1 ppm.

(c) In accordance with § 184.1(b)(3), the ingredient is used in the following food categories at levels not to exceed current good manufacturing practice, except that the ingredient may not be used in a standardized food unless permitted by the standard of identity: Confections and frostings as defined in § 170.3(n)(9) of this chapter, coatings of soft candy as defined in § 170.3(n)(38) of this chapter, and sweet sauces and toppings as defined in § 170.3(n)(43) of this chapter.

Dated: May 13, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

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