

80 percent safrole. Isosafrole and dihydro-safrole are derivatives of safrole, and have been used as flavors.

(ii) Food containing any added safrole, oil of sassafras, dihydro-safrole, or safrole or as a constituent of any food or extract is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 3, 1960 (25 FR 12412).

(iii) The analytical method used for detecting safrole, isosafrole and dihydro-safrole is in "Journal of the Association of Official Analytical Chemists" vol. 54, pp. 900-902 (1971).²

(7) *Monochloroacetic acid*. (i) Monochloroacetic acid is the chemical chloroacetic acid $C_2H_3ClO_2$. It is a synthetic chemical not found in natural products, and has been proposed as a preservative in alcoholic and non-alcoholic beverages. Monochloroacetic acid is permitted in food package adhesives with an accepted migration level up to 10 ppb under § 121.2520. The official methods do not detect monochloroacetic acid at the 10 ppb level.

(ii) Food containing any added or detectable level of monochloroacetic acid is deemed adulterated in violation of the act based upon trade correspondence dated December 29, 1941 (TC-377).

(iii) The analytical methods used for detecting monochloroacetic acid in food are in §§ 20.057 through 20.062 of the "Official Methods of Analysis of the Association of Official Analytical Chemists."²

(8) *Thiourea*. (i) Thiourea is the chemical thiocarbamide CH_4N_2S . It is a synthetic chemical, is not found in natural products at levels detectable by the official methodology, and has been proposed as an antimicrobial for use in dipping citrus.

(ii) Food containing any added or detectable level of thiourea is deemed to be adulterated under the act.

(iii) The analytical methods used for detecting thiourea are in §§ 20.099 through 20.100 of the "Official Methods of Analysis of the Association of Official Analytical Chemists."²

(9) *Cobaltous Salts; acetate, chloride and sulfate*. (i) Cobaltous salts are the chemicals $Co(C_2H_3O_2)_2$, $CoCl_2$ and $CoSO_4$. They have been used in fermented malt beverages as a foam stabilizer and to prevent "gushing".

(ii) Food containing any added cobaltous salts is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 12, 1966 (31 FR 8788).

(10) *NDGA (Nordihydroguaiaric acid)*. (i) Nordihydroguaiaric acid is the chemical 4,4-(2,3-dimethyltetramethylene) dipyrrocatechol $C_{26}H_{32}O_4$. It occurs naturally in the resinous exudates of certain plants. The commercial product, which is synthesized, has been used as an antioxidant in foods.

See footnote 1 previous page.

(ii) Food containing any added NDGA is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 11, 1968 (33 FR 5619).

(iii) The analytical method used for detecting NDGA in food is in § 20.0008 of the "Official Methods of Analysis of the Association of Official Analytical Chemists."²

(11) *DEPC (Diethylpyrocarbonate)*. (i) Diethylpyrocarbonate is the chemical pyrocarbonic acid diethyl ester, $C_8H_{16}O_5$. It is a synthetic chemical not found in natural products at levels detectable by available methodology and has been used as a ferment inhibitor in alcoholic and non-alcoholic beverages.

(ii) Food containing any added or detectable level of DEPC is deemed adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 2, 1972 (37 FR 15426).

(e) Substances prohibited from indirect addition to food through use in food contact surfaces:

(1) *Flectol H*. (i) Flectol H is the chemical 1,2-Dihydro-2,2,4-trimethylquinoline, polymerized ($C_{21}H_{27}N$). It is a synthetic chemical not found in natural products, and has been used as a component of food packaging adhesives.

(ii) Food containing any added or detectable level of this substance is deemed adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 7, 1967 (32 FR 5675).

(2) *4,4'-Methylenebis (2-chloroaniline)*. (i) 4,4'-Methylenebis (2-chloroaniline) has the molecular formula, $C_{12}H_8Cl_2N_2$. It is a synthetic chemical not found in natural products and has been used as a polyurethane curing agent and as a component of food packaging adhesive and polyurethane resins.

(ii) Food containing any added or detectable level of this substance is deemed adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 2, 1969 (34 FR 19073).

Interested persons may on or before October 24, 1973, file with the Hearing Clerk, Food and Drug Administration, Rm. 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: July 19, 1973.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.73-15216 Filed 7-25-73; 8:46 am]

[21 CFR Part 121]

REMOVAL OF CERTAIN SUBSTANCES FROM THE GRAS LIST REVIEW

Notice of Withdrawal of Proposal

In the FEDERAL REGISTER of April 13, 1973 (38 FR 9310), the Commissioner of

Food and Drugs proposed to delete 52 substances from the current GRAS review and to delist these same substances from § 121.101 (21 CFR 121.101). The basis for this proposed deletion and delisting was the absence of reported use or production of the substances during 1970. The use and production survey of the industry was conducted by the National Academy of Sciences, through its Food Protection Committee of the National Research Council, under contract with the Food and Drug Administration.

One hundred and eighty comments were received in response to the proposal. Eighty-seven of these comments indicated usage of the GRAS substances in animal feeds, 37 in nutrient pharmaceutical preparations, 18 in indirect food ingredients, and 38 in direct human food use.

In the direct human use category, the comments reported the use of 43 of the 52 GRAS substances listed in the proposal. These comments gave numerous reasons for not participating in the NAS Survey, including non-solicitation by NAS. Although most of the comments were in agreement with the intent of the proposal, each requested specific exceptions.

As a result of the above comments, the Commissioner recognizes that there is sufficient commercial interest in these GRAS food substances to retain them in the current GRAS review. Accordingly, notice is hereby given that the 52 substances as published in the FEDERAL REGISTER on April 13, 1973 (38 FR 9310), will remain in § 121.101 (21 CFR 121.101), pending the results of this review.

Dated: July 19, 1973.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.73-15222 Filed 7-25-73; 8:45 am]

[21 CFR Part 121]

CAROB BEAN GUM

Proposed Transfer From GRAS List to Food Additive Regulation for Direct Human Food Use and Affirmation of GRAS Status as Indirect Human Food Ingredient

The Food and Drug Administration is conducting a comprehensive study of direct human food ingredients classified as generally recognized as safe (GRAS) or subject to a prior sanction. Pursuant to this review, the safety of carob bean gum has been evaluated. In accordance with the provisions of §§ 121.40 and 121.41, the Commissioner of Food and Drugs proposes to affirm the GRAS status of this ingredient for indirect human food use and to transfer the ingredient to a food additive regulation for direct human food use. The Commissioner also proposes to establish a new § 121.105, under which all indirect human food ingredients affirmed as GRAS will be listed.

As the review of GRAS and prior-sanctioned direct human food ingredients progresses, these ingredients will be

PROPOSED RULES

proposed for inclusion in new § 121.104 *Substances added directly to human food affirmed as generally recognized as safe (GRAS)*, proposed new § 121.108 *Substances prohibited from use in food*, Subpart D as direct human food additives, Subpart E as prior sanctions, or Subpart H as interim human food additives. Because § 121.101 is not limited to direct human food ingredients, and has been regarded also as the basis of GRAS determinations for indirect food ingredient use, in or on food contact surfaces, and for use in pet food and animal feed, the Commissioner has concluded that when an ingredient listed in § 121.101 is affirmed for direct human food use it will be retained in § 121.101 with the explanation that it has been affirmed as GRAS and cross-referenced to the applicable paragraph in new § 121.104. Similarly, where it is affirmed as GRAS for indirect human food use and transferred to a food additive regulation for direct use, the same explanation will be provided, along with appropriate exceptions. This latter procedure is proposed with respect to carob bean gum.

Many of the substances published as GRAS § 121.101, or used on a determination that they are GRAS without publication in § 121.101, were approved by the United States Department of Agriculture for food packaging or processing use in meat or poultry, or were approved by the Food and Drug Administration for food packaging or processing pursuant to correspondence, regulations, informal announcements, or in other ways, prior to 1958. Thus, many of these ingredients are subject to specific prior sanctions for indirect human food use in addition to GRAS status. No comprehensive list of such prior sanctions exists. To the extent that one of these substances is affirmed as GRAS, the fact that it may also be subject to a prior sanction is largely of historical interest, and has no regulatory significance. To the extent that one of these substances is not affirmed as GRAS, any restrictions or limitations imposed upon its use could in any event also be imposed on the prior-sanctioned uses under the adulteration provisions of the act as provided in § 121.2000, published in the FEDERAL REGISTER of May 15, 1973 (38 FR 12738).

Accordingly, the Commissioner has concluded that regulations based upon the review of GRAS and prior-sanctioned indirect human food ingredients will initially be proposed on the assumption that no prior sanction exists. Because prior-sanctioned status constitutes an exemption from section 409 of the act, it should be construed narrowly, and the burden of coming forward with evidence of the sanction properly rests upon the person who asserts it. In the event that any person responds to a proposed regulation with proof of a valid prior sanction, a final regulation will be issued under Subpart E, "Substances for which prior sanctions have been granted," as well as under any other applicable sections of the regulations. In this way, all possible uses of the ingredient will be fully covered. Any regulation promul-

gated pursuant to this review will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure to submit proof of an applicable prior sanction in response to any proposed regulation will also constitute a waiver of the right to assert such sanction at any later point in time. Any proposed regulation will also be construed as a proposal under Subpart E in the event that a prior sanction is asserted in comments submitted on it. This procedure is necessary because of the unavailability of any comprehensive list of prior sanctions.

Carob bean gum (locust bean gum) has been listed in § 121.101(d) (7), published in the FEDERAL REGISTER of November 20, 1959 (24 FR 9368), as GRAS as a stabilizer and in § 121.101(h) and (i) as GRAS for food contact surfaces. Carob bean, locust bean, and St. John's bread are also individually listed as GRAS in § 121.101(e) (2) as natural flavoring substances, as published in the FEDERAL REGISTER of January 19, 1960 (25 FR 404). These numerous listings, as well as the published literature, have caused a great deal of misunderstanding about the status of these substances. Carob bean gum, or its synonym locust bean gum, has been used in U.S. food production since 1925. It consists of the endosperm of the carob (locust) bean seed and usually the seed coat and germ. Carob bean, locust bean, and St. John's bread are all synonyms for the whole bean consisting of pod, pulp, and seed and can be compared to a whole string bean. The dried gum has been used as a stabilizer and thickener in foods and as a coating for food packaging containers. The whole bean is eaten as a green vegetable and also dried and ground for a multitude of human and animal food and food ingredient uses. This notice covers only the food ingredient uses of the gum, obtained from the carob (locust) bean seed, when used in human food. Food ingredient uses of the whole bean will be evaluated at a later date.

Carob bean gum (known also as locust bean gum) has been the subject of a search of the scientific literature from 1920 to the present. The parameters used in the search were chosen to discover any articles that considered (1) the chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) any reported carcinogenicity, teratogenicity or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 165 abstracts on carob (locust) bean gum were reviewed and 11 particularly pertinent reports from the literature survey have been summarized in a Scientific Literature Review.

A representative cross-section of food manufacturers was surveyed to determine the specific foods in which the carob bean gum was used and at what levels. Available surveys of consumer consumption were obtained and combined with the production information

to obtain an estimate of the consumer exposure to carob bean gum. The total carob (locust) bean gum used in food in 1970 is reported to be about twice the amount used in 1960.

The Scientific Literature Review shows, among other studies, the following information as summarized in the report of the Select Committee on GRAS Substances:

Two Chick experiments are pertinent. In the first, 10 one-day-old Arbor Acres chicks were fed a stock diet; another comparable group was fed the stock diet plus a 2 percent cellulose supplement; and a third, comparable group was fed a 2 percent carob bean gum supplement. The third group showed a 30 percent depressed feed intake after three weeks, with a corresponding decrease in weight as compared to the cellulose-fed group. Each chick consumed about 340 mg. of carob bean gum per day, or in excess of 2 g per kg per day. The degree of nitrogen retention and metabolizable energy content were about the same as in the cellulose group, although the fat absorption was about 8 percent higher.

In the second test, similar groups of chicks were fed stock diets supplemented with 0.25, 0.5, 1.0, and 2.0 percent of carob bean gum. After three weeks, the chicks fed at the 2 percent level showed a 27 percent growth depression as compared to the controls, while those at the lower levels of supplement showed an average 6 percent growth depression. However, the authors provided no data on food intakes in this experiment. Others working with carob bean pods have shown that tannins depress appetite and growth. In addition, carob beans contain trypsin inhibitors which are known to have growth-inhibiting properties. Since tannins and trypsin inhibitors could be naturally present in the carob bean gum used in the chick studies, either or both could have accounted for the growth depression reported. From the data given, it is not possible to ascribe depression in growth to toxicity of the gum.

A 10 percent dietary supplement of carob bean gum does not significantly affect the growth of rats. Three groups of 8 rats averaging 44 g each were fed for 28 days on a stock diet, stock diet plus 1 percent cholesterol, and stock diet plus 1 percent cholesterol and 10 percent carob bean gum. Differences in weight gain among the three groups were not significant and no adverse effects were reported. While feed consumption was not reported, it is estimated that a 44-g rat would consume no less than 10 g per day of the 10 percent carob bean gum diet, which would be equivalent to 1 g of the gum per day. For a 44-g rat this intake rate would be about 23 g per kg per day.

Oral LD₅₀ in the rat is reported to be greater than 5 g per kg for multiple doses, and greater than 10 g per kg for a single dose.

Clinical observations of 16 human infants showed no untoward effects from feeding a 1 percent carob-bean gum powder, called "Nestargel," for an unstated period of time. The substance was apparently not changed by the saliva and gastric juice.

The fate of carob bean gum in the gastrointestinal tract of adults was followed by means of x-rays and stool examination. Eight adults were fed barium suspensions followed by "two heaping teaspoonfuls" of a gum preparation called "Vacuosa." The colloidal gel from the breakup of the "Vacuosa" pellets mixed thoroughly with the fecal masses in the colon. The carob bean gum did not disintegrate into the gelatinous state until it reached the large bowel. There was no evidence of interference with normal digestion. Actual body load of carob bean gum was not reported; but assuming 15 g per two tea-

PROPOSED RULES

20043

spoonfuls, the gum must have been administered at a level of about 280 mg per kg.

Beyond these studies, there is no detailed information relating to the absorption, digestion, metabolism, or excretion of carob bean gum in man or animals.

Mutagenic tests on rats and mice using three different methods gave negative results. There was no measurable mutagenic response of alteration in the recombination frequency for *Saccharomyces cerevisiae* in either the host-mediated assay at levels as high as 5 g per kg or the associated in vitro tests. No adverse effects were observed on either metaphase chromosomes from rat bone marrow or anaphase chromosomes from in vitro cultures of human lung cells at any of the doses or time periods tried. No significant adverse responses were noted in the dominant lethal gene test on rats.

Teratologic tests on four species of animals were negative. Ora intubation of up to 1.3 g per kg of body weight of carob beans gum in anhydrous corn oil to pregnant rats for 10 consecutive days, or up to 1.0 g per kg to pregnant hamsters for 5 consecutive days, produced no clearly discernible effect on nidation or on maters or feta surviva. The frequency of abnormalities in either soft or skeletal tissues of the test animals was comparable to that occurring spontaneously in the sham-treated controls. In mice, no untoward teratogenic or maternal effects were noted at a level of 280 mg per kg for 10 consecutive days. At 1.3 g per kg, 5 out of 21 dams died. The surviving dams produced normal litters. In pregnant rabbits, no untoward effects were noted at a level of 198 mg per kg for 13 consecutive days, but at 910 mg per kg, a majority of the dams died. The surviving dams produced normal litters.

No evidence of carcinogenic or allergenic activity of carob bean gum has been found in the literature surveyed.

All of the available safety information on carob bean gum has been carefully evaluated by qualified scientists of the Select Committee on GRAS Substances selected by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB). It is the opinion of the Select Committee that: "The available information contains no evidence demonstrating that carob bean gum constitutes a hazard to the public when used in the manner and quantity now practiced. However, it is not possible to determine, without additional data, whether a significant increase in consumption would constitute a dietary hazard."

Based upon his own evaluation of all available information, the Commissioner concurs with this conclusion. In addition the Commissioner concludes that continued safe use of carob (locust) bean gum will require food additive regulation of the ingredient to preserve present levels of use. The levels of use adopted in this proposal, for various categories of food, are those reported to the National Academy of Sciences in their Survey of food manufacturers. The Commissioner further concludes that indirect human food use of carob (locust) bean gum, as a food contact surface in packaging, does not contribute significantly to the carob bean gum content of the packaged food and should thus be affirmed as GRAS for this purpose.

Neither of these proposed actions affects the present use of carob (locust) bean gum for pet food or animal feed or the present uses of carob bean meal and

powder, when made from the whole carob bean pod with seed, or carob bean as a raw agricultural commodity.

Copies of the Scientific Literature Review on carob bean gum and the report of the FASEB Committee are available for review at the office of the Hearing Clerk, Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20852, and may be purchased from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22151.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic

Act (secs. 201(s), 409(d), 701(a), 52 Stat. 1055, 72 Stat. 1784, 1787; 21 U.S.C. 321 (s), 348(d), 371(a)), and under authority delegated to him (21 CFR 2.120), the Commissioner proposes that Part 121 be amended as follows:

1. By amending § 121.101(d) (7) to add the explanation "food additive regulation § 121.1251; affirmed as GRAS § 121.105 (f) (1)" after "Carob bean gum (locust bean gum)" to read as follows:

§ 121.101 Substances that are generally recognized as safe.

(d) . . .

Product	Tolerance	Limitations, restrictions or explanations
(7) STABILIZERS
Carob bean gum (locust bean gum).	. . .	Food additive regulation § 121.1251; affirmed as GRAS § 121.105(f)(1).

2. By adding to Subpart B a new section, as follows:

§ 121.105 Substances in food contact surfaces affirmed as generally recognized as safe (GRAS).

(a) The indirect human food ingredients listed in this section have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS), for the purposes and under the conditions prescribed.

(b) This section does not authorize direct addition of any food ingredient to a food. It authorizes only the use of these ingredients as indirect ingredients of food, through migration from their immediate wrapper, container, or other food contact surface. Any migration or use levels included in this section represent maximum levels under current good manufacturing practice.

(c) The listing of a food ingredient in this section does not authorize the use of such substance for the purpose of adding the ingredients to the food through extraction from the food contact surface.

(d) The listing of a food ingredient in this section does not authorize the use of such substance in a manner that may lead to deception of the consumer or to any other violation of the act.

(e) If the Commissioner of Food and Drugs is aware of any prior sanction for use of an ingredient under conditions different from those proposed to be affirmed as GRAS, he will concurrently propose a separate regulation covering such use of the ingredient under Subpart E of this part. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such

an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under Subpart E, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(f) The following indirect human food ingredients have been affirmed as GRAS:

(1) *Carob (locust) bean gum*. (i) Carob bean gum (also called locust bean gum) is the material obtained from the ground endosperm of the seed of the *Ceratonia siliqua* (Linne), a leguminous evergreen tree.

(ii) The ingredient meets specifications of the Food Chemicals Codex 2nd Ed. (1972).¹

(iii) The ingredient is used or intended for use as a constituent of food packaging containers and thus may only become a component of food through migration from this surface.

(iv) The ingredient migrates to the packaged or wrapped food at levels not to exceed good manufacturing practices.

3. By adding to Subpart D a new section as follows:

121.1251 Carob bean gum (locust bean gum).

The food additive carob bean gum may be safely used in food in accordance with the following conditions:

(a) Carob bean gum (locust bean gum) is the material obtained from the ground endosperm of the seed of the *Ceratonia siliqua* (Linne), a leguminous evergreen tree.

(b) The additive meets specifications of the Food Chemicals Codex 2nd Ed. (1972).¹

(c) The additive is used at not to exceed the following maximum levels:

¹ Copies may be obtained from: National Academy of Sciences 2101 Constitution Ave., N.W. Washington, D.C. 20037.

PROPOSED RULES

MAXIMUM USAGE LEVELS

Food	Permitted Percent	Function
Baked goods and baking mixes, § 121.10(1)-----	0.15	Flavoring agent, § 121.1(m)(11); stabilizer and thickener, § 121.1(m)(20)
Beverages and beverage bases, nonalcoholic, § 121.10(2)	0.25	Flavoring agent, § 121.1(m)(11); stabilizer and thickener, § 121.1(m)(20)
Cheeses, § 121.10(3)	0.75	Stabilizer and thickener, § 121.1(m)(20)
Cheeses, § 121.10(4)	0.40	Stabilizer and thickener, § 121.1(m)(20)
Cebollitas, patties, and fillings, § 121.10(22)	0.50	Flavoring agent, § 121.1(m)(11); stabilizer and thickener, § 121.1(m)(20)
All other food categories-----		

(d) The label and labeling of the additive and any intermediate mix of the additive for use in finished food shall bear, in addition to the other labeling required by the act:

- (1) The name of the additive;
- (2) A statement of the concentration of the additive in any intermediate mix; and
- (3) Adequate information to assure that the final food product complies with the limitations prescribed in paragraph (c) of this section.

The Commissioner hereby gives notice that he is unaware of any prior sanction for the use of this ingredient in food under conditions different from those proposed above. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal. The regulation proposed above will constitute a determination that excluded uses would result in adulteration of the food in violation of section 402 of the act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on such a sanction at any later time. This notice also constitutes a proposal to establish a regulation under Subpart B, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to this proposal.

Interested persons may, on or before October 24, 1973, file with the Hearing Clerk, Food and Drug Administration, Rm. 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: July 19, 1973.

A. M. SCHMIDT,
Commissioner of Food and Drugs.
[FR Doc. 73-15215 Filed 7-25-73; 8:45 am]

[21 CFR Part 121]

FOOD CATEGORIES AND FOOD INGREDIENT FUNCTIONS

Proposed Designation

The Food and Drug Administration is conducting a study of the direct human food ingredients classified as generally

recognized as safe (GRAS) or subject to a prior sanction. As this study progresses, the Commissioner of Food and Drugs will publish in the FEDERAL REGISTER, appropriate proposals to (1) affirm GRAS status, (2) publish a prior sanction, (3) establish an interim food additive regulation, (4) establish a permanent food additive regulation, or (5) eliminate food use of the ingredient under review. The Commissioner is proposing regulations in this issue of the FEDERAL REGISTER with respect to the first ingredients subject to this review.

In regulation as published since 1958 under the Food Additives Amendment, it has frequently been appropriate to designate broad food categories in which an ingredient may properly be used, and to state the functional purpose for which the ingredient may be used. To date, no standardized definitions of the food categories or functional descriptions have been adopted.

In conducting the industry survey of production and use of GRAS and prior-sanctioned food substances, under contract with the Food and Drug Administration, for use in the review of the safety of these ingredients, the National Academy of Sciences developed standardized food categories. Food categories of a similar type were also used by the United States Department of Agriculture and the Market Research Corporation of America (MRCA), in their respective surveys, to determine the sizes of servings used by consumers and the frequency of consumption of specific foods.

The Commissioner has concluded that the food categories adopted by the National Academy of Sciences (NAS) represent a valid and useful method of dividing food products into general classes of related products. Where tolerances or limitations are established for the use of direct human food ingredients, and there is significant variation with respect to appropriate tolerances or limitations for one or more specific food categories, this method of classification will permit designation of the foods to be covered without requiring a detailed list of each of the individual products included. In many instances, tolerances or limitations may be imposed uniformly for all foods. It may also be necessary to impose, with relatively few exceptions, tolerances or limitations for specific food categories at levels higher or lower than the general rule. It is the Commissioner's intent to utilize the broadest possible approach, in the interests of simplification, wherever justified by the available safety data and information.

It is appropriate that the same food classification system developed by the NAS for its production and consumption survey should also be utilized by the Food and Drug Administration in imposing tolerances and limitations for use of specific ingredients. NAS Survey data was accumulated using these food categories, and they are consequently of great assistance in determining whatever tolerances and limitations are justified. The same classification system, already cross-indexed to the MRCA and USDA consumption data, also provides an immediate reference to consumption patterns on which those tolerances and limitations are in part based.

The proposal set out below contains a general description of each food category, without attempting to list in detail all the products within it. Wherever any question arises with respect to the proper classification of a specific food product which might reasonably fall within two or more categories, proper classification will be determined by referring to the more detailed and specific classification lists established by the MRCA and cross-indexed to NAS food categories, as contained in the final NAS report to the Food and Drug Administration. The Final Report of the NAS is now available from the National Technical Information Service (NTIS), in accordance with the notice on this matter published in this issue of the FEDERAL REGISTER. Accordingly, the Commissioner is incorporating this specific classification list, by reference, into this proposed regulation, for purposes of resolving close questions with respect to proper classification.

The NAS also found it necessary to establish a similar classification system with respect to the technical functions performed by the various specific ingredients directly added to human food. These functional effects are contained in the final NAS report to the Food and Drug Administration and are the subject of production, use, and consumption data on the technical functions of numerous food ingredients, added to the various NAS food categories. Thus, these tables describe the specific technical purposes for which GRAS and prior-sanctioned ingredients are added to NAS food categories, and they consequently serve as an excellent reference to consumption patterns on which ingredient tolerances and limitations are in part based. Accordingly, the Commissioner is proposing to standardize the technical functional descriptions submitted by the NAS, so that regulations permitting the use of ingredients in food will accurately describe their purpose. A standardized system of classification will also assist consumers in understanding the functions performed by these ingredients in the foods they consume.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended; 21 U.S.C. 321(s), 348, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Part 121 by adding to § 121.1 the following two new paragraphs: