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Frequently Asked Questions About GRAS for Substances Intended for Use in Human or Animal Food: Guidance for Industry

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
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Frequently Asked Questions About GRAS for Substances Intended for Use in Human or Animal Food: Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This list of frequently asked questions (FAQ) is intended to be a convenient place to find answers to common questions about the food substance classification known as "generally recognized as safe" or "GRAS." This FAQ addresses common questions about the regulatory process and regulatory considerations regarding whether the use of a substance in human or animal food is GRAS.

Our Center for Food Safety and Applied Nutrition (CFSAN) provides additional information about GRAS substances intended for use in human food on CFSAN's Web site entitled "Generally Recognized as Safe (GRAS)." Our Center for Veterinary Medicine (CVM) provides additional information about GRAS substances intended for use in animal food on CVM's Web site entitled "Generally Recognized as Safe (GRAS) Notification Program." To contact CFSAN or CVM to obtain more information about whether the intended use of a substance in human food or animal food is GRAS, see section III.

This guidance updates and replaces a previous guidance, entitled "Frequently Asked Questions About GRAS," that CFSAN issued in December 2004. This updated guidance refers to the provisions of a final rule that we published on August 17, 2016 (81 Fed. Reg. 54960) and addresses substances used in human food as well as substances used in animal food. This guidance also includes an editorial change, relative to the guidance issued on October 17, 2016, to clarify the response to Question 14.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

[1] This guidance has been jointly prepared by the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition and the Division of Animal Feeds in the Office of Surveillance and Compliance in the Center for Veterinary Medicine at the U.S. Food and Drug Administration.

The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Frequently Asked Questions

1. What does "GRAS" mean?

"GRAS" is an acronym for the phrase “Generally Recognized as Safe.” Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.[2] Sections 201(s) and 409 were enacted in 1958 as part of the Food Additives Amendment to the FD&C Act. FDA has several lists of substances that are used in food on the basis of the GRAS provision (see Question 15).

2. What are the criteria for eligibility for classification as GRAS?

Under section 201(s) of the FD&C Act, and FDA's implementing regulations in Title 21 of the Code of Federal Regulations (21 CFR), the use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food. Table 1 provides regulatory citations for key regulations implementing the GRAS provisions of the FD&C Act for substances intended for use in human food. Table 2 provides regulatory citations for key regulations implementing the GRAS provisions of the FD&C Act for substances intended for use in animal food.

Table 1.—Key Regulatory Text Regarding Whether the Intended Use of a Substance in Human Food is GRAS

Regulatory Citation	Regulatory Text
21 CFR 170.3(f)	Common use in food means a substantial history of consumption of a substance for food use by a significant number of consumers.
21 CFR 170.3(h)	Scientific procedures include the application of scientific data (including, as appropriate, data from human, animal, analytical, or other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance under the conditions of its intended use.
21 CFR 170.30	Eligibility for Classification as Generally Recognized as Safe (GRAS)

[2] For example, substances whose use meets the definition of a pesticide, a dietary ingredient of a dietary supplement, a color additive, a new animal drug, or a substance used in accordance with a sanction or approval granted prior to September 6, 1958, are excepted from the definition of food additive.

Regulatory Citation	Regulatory Text
21 CFR 170.30(a)	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 directly or indirectly added to food. 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. General recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use (see § 170.3(i)).
21 CFR 170.30(b)	General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. General recognition of safety through scientific procedures shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.
21 CFR 170.30(c)(1)	(1) General recognition of safety through experience based on common use in food prior to January 1, 1958, may be achieved without the quantity or quality of scientific procedures required for approval of a food additive. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.
21 CFR 170.30(c)(2)	(c)(2) A substance used in food prior to January 1, 1958, may be generally recognized as safe through experience based on its common use in food when that use occurred exclusively or primarily outside of the United States if the information about the experience establishes that the substance is safe under the conditions of its intended use within the meaning of section 201(u) of the FD&C Act (see also § 170.3(i)). Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance. The information used to document and to corroborate the history and circumstances of use of the substance must be generally available; that is, it must be widely available in the country in which the history of use has occurred and readily available to interested qualified experts in the United States. A person who concludes that a use of a substance is GRAS through experience based on its common use in food outside of the United States should notify FDA of that view in accordance with subpart E of this part.

Table 2.—Key Regulatory Text Regarding Whether the Intended Use of a Substance in Food for Animals is GRAS

Regulatory Citation	Regulatory Text
21 CFR 570.3(f)	Common use in food means a substantial history of consumption of a substance by a significant number of animals of the species to which the substance is intended to be fed (and, for food-producing animals fed with such substance, also means a substantial history of consumption by humans consuming human foods derived from those food-producing animals), prior to January 1, 1958.
21 CFR 570.3(h)	Scientific procedures include the application of scientific data (including, as appropriate, data from human, animal, analytical, or other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance under the conditions of its intended use.
21 CFR 570.30	Eligibility for Classification as Generally Recognized as Safe (GRAS)
21 CFR 570.30(a)	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 directly or indirectly added to food. 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. General recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful to either the target animal or to humans consuming human food derived from food-producing animals under the conditions of its intended use (see § 570.3(i)).
21 CFR 570.30(b)	General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. General recognition of safety through scientific procedures shall address safety for both the target animal and for humans consuming human food derived from food-producing animals and shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.
21 CFR 570.30(c)(1)	(c)(1) General recognition of safety through experience based on common use in food prior to January 1, 1958, shall address safety for both the target animal and for humans consuming human food derived from food-producing animals and may be achieved without the quantity or quality of scientific procedures required for approval of a food additive. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance in the same animal species prior to January 1, 1958, and shall ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.

Regulatory Citation	Regulatory Text
21 CFR 570.30(c)(2)	(2) A substance used in food prior to January 1, 1958, may be generally recognized as safe through experience based on its common use in food when that use occurred exclusively or primarily outside of the United States if the information about the experience establishes that the substance is safe under the conditions of its intended use within the meaning of section 201(u) of the Federal Food, Drug, and Cosmetic Act (see also § 570.3(i)) for both the target animal and for humans consuming human food derived from food-producing animals. Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance. The information used to document and to corroborate the history and circumstances of use of the substance must be generally available; that is, it must be widely available in the country in which the history of use has occurred and readily available to interested qualified experts in the United States. A person who concludes that a use of a substance is GRAS through experience based on its common use in food outside of the United States should notify FDA of that view in accordance with subpart E of this part.

3. How are the criteria for eligibility for classification as GRAS similar to the criteria for FDA's approval of a food additive?

Regardless of whether the use of a substance is a food additive use or is GRAS, there must be evidence that the substance is safe under the conditions of its intended use. FDA has defined "safe" (21 CFR 170.3(i) and 21 CFR 570.3(i)) as a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use. The specific data and information that demonstrate safety depend on the characteristics of the substance, the estimated dietary exposure[3], the population that will consume the substance, and other relevant considerations.

4. How are the criteria for eligibility for classification as GRAS through scientific procedures different from the criteria for FDA's approval of a food additive?

The difference between the criteria for eligibility for classification as GRAS through scientific procedures (21 CFR 170.30(b) and 21 CFR 570.30(b)) and FDA's approval of a food additive (21 CFR 171.1 and 21 CFR 571.1) relates to who has access to the data and information and who has reviewed those data and information. For a substance to be GRAS under the conditions of its intended use, the data and information relied on to establish the safety of the use of the substance must be generally available (e.g., through publication in the scientific literature) and there must be a basis for a person to conclude that the substance is generally

[3] For a substance intended for use in animal food, the data and information address exposure to the target animal and to humans consuming human food derived from food-producing animals.

recognized, among qualified experts, to be safe under the conditions of its intended use. In contrast, for FDA's approval of a food additive privately held data and information about the substance under the conditions of its intended use are sent by the sponsor to FDA and FDA reviews those data and information to determine whether they demonstrate that the substance is safe under the conditions of its intended use.

5. If an ingredient is GRAS for one use, is it GRAS for all uses?

Not necessarily. Under section 201(s) of the FD&C Act, it is the use of a substance, rather than the substance itself, that is eligible for classification as GRAS (81 Fed. Reg. 54960 at 54963; August 17, 2016). An evaluation of the safety of the use of an ingredient includes information about the characteristics of the substance, the estimated dietary exposure under the intended conditions of use, and the population that will consume the substance. Dietary exposure to a substance depends on the food categories in which it will be used and the level of use in each of those food categories. For information about how CFSAN estimates human dietary exposure to a food substance, see CFSAN's document entitled "Estimating Dietary Intake of Substances in Food" (Ref. 1).

Some uses of a human food substance are intended for a narrowly defined population. For example, some human food substances are intended for consumption by newborn infants who consume infant formula as the sole item of the diet; in such a circumstance, there may be special considerations associated with that population but not with general use of the food substance. Likewise, some substances intended for use in animal food are intended for specific animal species (such as cattle or swine), or for a specific life stage of an animal species; a substance that is safe for use in one animal species may not be safe for use in another species or in the same species at a different stage of life.

6. Is a substance that is used to impart color eligible for classification as GRAS?

The short answer is "No." Under section 201(s) of the FD&C Act, the GRAS provision applies to the definition of a food additive. There is no corresponding provision in the definition (in section 201(t) of the FD&C Act) of a color additive.

However, under section 201(t)(1) and 21 CFR 70.3(f), the term color additive means a material that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived from a vegetable, animal, mineral, or other source, and that is capable (alone or through reaction with another substance) of imparting color when added or applied to a food; except that such term does not include any material which FDA, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring. Under 21 CFR 70.3(g), a material that otherwise meets the definition of color additive can be exempt from that definition on the basis that it is used or intended to be used solely for a purpose or purposes other than coloring, as long as the material is used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. Given the construct of section 201(t)(1) of the Act and 21 CFR 70.3(f) and (g), the use of a substance that is capable of imparting color may constitute use as both a color additive and as a food additive or GRAS substance. For example, beta-carotene is both approved for use as a color additive (21 CFR 73.95) and affirmed as GRAS for use as a nutrient in human food (21 CFR 184.1245); in some food products, beta-carotene may be safely and lawfully used for both purposes.

7. Is a substance that is used as a dietary ingredient in a human[4] dietary supplement eligible for classification as GRAS?

Under section 201(s) of the FD&C Act, a substance that is GRAS under the conditions of its intended use is excluded from the definition of a food additive. In addition, under section 201(s) of the FD&C Act the term "food additive" does not include a dietary ingredient[5] used or intended for use in a dietary supplement as defined in section 201(ff) of the FD&C Act. In other words, because dietary ingredients intended for use in dietary supplements are already excepted from the food additive definition, their GRAS status for that use is irrelevant because they are already exempt from the food additive approval requirement. However, some dietary ingredients that may be used in a dietary supplement may also be GRAS for use in a conventional food (e.g., vitamin C; calcium carbonate). In addition, a substance that is not a dietary ingredient as defined in section 201(ff)(1) of the FD&C Act must be approved as a food additive when used in a dietary supplement (e.g., as a coating, filler, or binder) unless the substance is GRAS for that use or otherwise excepted from the definition of a food additive.

8. Must FDA approve GRAS substances?

No. If the use of a food substance is GRAS, it is not subject to FDA's premarket review and approval as a food additive.

9. What is GRAS affirmation?

GRAS affirmation is a process that FDA developed in the 1970s. In response to concerns raised by new information on cyclamate salts, then-President Nixon directed FDA to re-examine the safety of substances considered to be GRAS. FDA announced that the agency would evaluate, by contemporary standards of the time, the available safety information regarding substances considered to be GRAS. If the re-evaluations confirmed that the uses were GRAS, FDA promulgated new GRAS regulations, affirming those findings. FDA also established procedures whereby an individual could voluntarily petition FDA to review the GRAS status of substances that would not have been considered as part of the agency's GRAS review.

In a final rule that FDA published on August 17, 2016 (81 Fed. Reg. 54960), FDA removed that voluntary process from its regulations and replaced it with a voluntary GRAS notification procedure. See Question 10.

10. What is the GRAS notification procedure?

The GRAS notification procedure is a voluntary procedure under which any person may notify FDA of a conclusion that a substance is GRAS under the conditions of its intended use in human food (21 CFR part 170, subpart E) or animal food (21 CFR part 570, subpart E). Although the GRAS notification procedure is voluntary, FDA strongly encourages any person

[4] Note that FDA previously published a notice in the *Federal Register* explaining its conclusion that the Dietary Supplement Health and Education Act of 1994 (which established the exception from the definition of "food additive" in section 201(s) of the FD&C Act for a dietary ingredient of a dietary supplement) does not apply to products intended for use in animals (61 Fed. Reg. 17706; April 22, 1996).
[5] "Dietary ingredient" is defined in section 201(ff)(1) of the FD&C Act and generally includes vitamins, minerals, herbs and other botanicals, amino acids, dietary substances, and concentrates, metabolites, constituents, extracts, and combinations of dietary ingredients in the other categories.

who intends to market a food substance on the basis of the GRAS provision to submit a GRAS notice to FDA.

A GRAS notice has seven required parts as shown in Table 3 for a substance intended for use in human food and as shown in Table 4 for a substance intended for use in animal food.

Table 3.—The Seven Required Parts of a GRAS Notice for a Substance Intended for Use in Human Food

Regulatory Citation	Part of a GRAS Notice	Title
170.225	Part 1	Signed statements and certification
170.230	Part 2	Identity, method of manufacture, specifications, and physical or technical effect
170.235	Part 3	Dietary exposure
170.240	Part 4	Self-limiting levels of use
170.245	Part 5	Experience based on common use in food before 1958
170.250	Part 6	Narrative
170.255	Part 7	List of supporting data and information in your GRAS notice

Table 4.—The Seven Required Parts of a GRAS Notice for a Substance Intended for Use in Animal Food

Regulatory Citation	Part of a GRAS Notice	Title
570.225	Part 1	Signed statements and certification
570.230	Part 2	Identity, method of manufacture, specifications, and physical or technical effect
570.235	Part 3	Target animal and human exposures
570.240	Part 4	Self-limiting levels of use
570.245	Part 5	Experience based on common use in food before 1958
570.250	Part 6	Narrative
570.255	Part 7	List of supporting data and information in your GRAS notice

11. If I choose to submit a GRAS notice, how do I do so?

For a substance intended for use in human food, follow the procedure in 21 CFR part 170, subpart E for submission of a GRAS notice to CFSAN.

For a substance intended for use in animal food, follow the procedure in 21 CFR part 570, subpart E for submission of a GRAS notice to CVM.

12. Where do I send my GRAS notice?

For a substance intended for use in human food, send your GRAS notice to the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740. For electronic submission of your GRAS notice, see Ref. 2.

For a substance intended for use in animal food, send your GRAS notice to the Division of Animal Feeds (HFV- 220), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. For electronic submission of your GRAS notice, eSubmitter is available for use (http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm).

13. If I submit a GRAS notice, how long will it take for me to receive a response from FDA?

The GRAS notification procedure requires that FDA respond to a GRAS notice within 180 days, with an option to extend the 180-day timeframe by 90 days on an as needed basis.

14. If I submit a GRAS notice about a substance intended for use in human or animal food, must I wait until I receive a response from CFSAN or CVM before I market that substance?

No. If you are correct in concluding that a substance is GRAS under the conditions of its intended use, there is no requirement under section 409 of the FD&C Act for FDA review and approval for that use of the substance. Your decision to submit a GRAS notice to CFSAN or CVM is voluntary, and the response to a GRAS notice from CFSAN or CVM is not an approval. You may market a substance that is GRAS under the conditions of its intended use without informing CFSAN or CVM or, if CFSAN or CVM is so informed, while the applicable Center is evaluating your GRAS notice. (See Response 114, 81 Fed. Reg. 54960 at 55022). We recognize, however, that some firms prefer to know that the applicable FDA Center has evaluated a submitted GRAS notice, without raising safety or legal issues, before marketing.

15. Does FDA have a list of substances that are used in food on the basis of the GRAS provision?

FDA's regulations in 21 CFR include several lists of substances that are used in food on the basis of the GRAS provision (see Table 5 and Table 6). Importantly, these lists are not all-inclusive. Because the use of a GRAS substance is not subject to premarket review and approval by FDA, it is impracticable to list all substances that are used in food on the basis of the GRAS provision.

CFSAN's Web site entitled "Generally Recognized as Safe (GRAS)," and CVM's Web site entitled "Generally Recognized as Safe (GRAS) Notification Program," each contain a list of substances that have been the subject of a GRAS notice to FDA, whether to CFSAN (for intended use in human food) or to CVM (for intended use in animal food). You can access these lists, along with the response from CFSAN or CVM to the notifier, from CFSAN's Web site and CVM's Web site (Ref. 3 and Ref. 4).

Table 5.—Lists of Substances Intended for Use in Human Food on the Basis of the GRAS Provision

List	Description
21 CFR part 182	Contains the remnants of a list that FDA established in its human food regulations shortly after passage of the 1958 Food Additives Amendment. The list is organized according to the intended use of these substances. As part of CFSAN's comprehensive review of GRAS substances in the 1970s, CFSAN affirmed that the use of some of the ingredients on this original GRAS list are GRAS, and moved the affirmed uses of the substance to 21 CFR Part 184.
21 CFR part 184	Contains a list of substances that CFSAN affirmed as GRAS as direct human food ingredients for general or specific uses. This list derives from CFSAN's 1970s comprehensive review of GRAS substances and from petitions that CFSAN received to affirm the GRAS status of particular uses of some food ingredients.
21 CFR part 186	Contains a list of substances that CFSAN affirmed as GRAS for certain indirect food uses (e.g., in the manufacture of paper and paperboard that contact human food).

Table 6.—Lists of Substances Intended for Use in Animal Food on the Basis of the GRAS Provision

List	Description
21 CFR part 582	Contains the remnants of a list that FDA established in its animal food regulations shortly after passage of the 1958 Food Additives Amendment. The list is organized according to the intended use of these substances.
21 CFR part 584	Contains a list of substances that CVM affirmed as GRAS as direct animal food ingredients for general or specific uses. This list derives from petitions that CVM received to affirm the GRAS status of particular uses of some food ingredients.

16. Can the use of a substance be GRAS even if it is not listed by FDA?

Yes. Because the use of a substance that is GRAS is not subject to premarket review and approval by FDA, it is impracticable to list all substances that are used in food on the basis of the GRAS provision (21 CFR 182.1(a) and 21 CFR 582.1(a)). The use of a substance is GRAS because of widespread knowledge among the community of qualified experts, not because of a listing or other administrative activity.

III. How to Contact FDA With Questions About GRAS

You may contact CFSAN:

- By contacting Dr. Paulette Gaynor at (240)402-1192

- By email to premarkt@fda.hhs.gov
- By mail sent to the following address:

  FDA/CFSAN
  Office of Food Additive Safety
  5001 Campus Drive
  College Park, MD 20740

You may contact CVM:

- By contacting Mr. Geoffrey Wong at (240)402-5838
- By email to AskCVM@fda.hhs.gov
- By mail sent to the following address:

  FDA/CVM
  Office of Surveillance and Compliance, Division of Animal Feeds (HFV-220)
  7519 Standish Pl.
  Rockville, MD 20855

IV. References

1. FDA, "Guidance for Industry: Estimating Dietary Intake of Substances in Food," (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm074725.htm), 2006.
2. FDA, "Guidance for Industry: Providing Regulatory Submissions in Electronic or Paper Format to the Office of Food Additive Safety; Draft Guidance," (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm2021277.htm), 2010.
3. GRAS Notice Inventory, (http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm).
4. Current Animal Food GRAS Notices Inventory, (http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm)