Questions and Answers
Generally Recognized As Safe (GRAS)

Regulatory Process:

1. What is a “food additive”? Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive. Food additives are 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 excluded from the definition of a food additive. Excluded from the definition of “food additive” are 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 approved for such use prior to September 6, 1958 when Sections 201(s) and 409 were enacted as part of the Food Additives Amendment to the Act.

2. What does “GRAS” mean? "GRAS" is an acronym for the phrase Generally Recognized As Safe. While it is impracticable to list all ingredients whose use is generally recognized as safe, FDA published a partial list of food ingredients whose use is generally recognized as safe to aid the industry's understanding of what did not require approval.

3. What are the criteria for GRAS status? FDA regulations state that 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. See Sections 201(s) and 409 of the Act, and FDA’s implementing regulations in 21 CFR 170.3 and 21 CFR 170.30.

   a. General recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information. 21 CFR 170.30(b),

   b. General recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers. 21 CFR 170.30(c) and 170.3(f),

4. Must FDA approve GRAS ingredients? If the use of a food ingredient is GRAS, it is not subject to the premarket review and approval requirement by FDA.

5. What is GRAS self-affirmation or self-determination? This is a process whereby the manufacturer or user of an ingredient has performed all the necessary research to assure safety and is prepared to use these findings to defend the GRAS status of the ingredient for its intended use.
6. What is the GRAS notification program?
The GRAS notification program is a voluntary procedure that is operating under a proposed rule issued by FDA in 1997 (62 Fed. Reg. 18938; April 17, 1997). The notification program is intended to provide a mechanism whereby the FDA is informed of a determination that the use of a substance is GRAS rather than petition FDA to affirm that the use of a substance is GRAS. The submitted notice includes a succinct description of the substance, the applicable conditions of use, and the statutory basis for the GRAS determination (i.e., through scientific procedures or through experience based on common use in food). A GRAS notice also includes information about the identity and properties of the notified substance and a discussion of the publicly available scientific data used to support a conclusion that the substance is GRAS for its intended use.

7. If a GRAS notice is submitted, must the sponsor wait for a reply prior to marketing that ingredient?
A sponsor may market a substance that they determine to be GRAS for a particular use without informing FDA or, if FDA is so informed, it may market the substance while FDA is reviewing that information (62 Fed. Reg. 18951; April 17, 1997). However, some firms prefer to know that FDA has reviewed its notice of a GRAS determination, without raising safety or legal issues, before marketing.

8. What is the GMA GRAS Code of Practice?
On August 22, 2014, the GMA Board of Directors adopted a Code of Practice on the conduct of GRAS food ingredients assessments that defines the steps needed to ensure GRAS assessments are robust and consistent.

9. How does GMA measure compliance with the GRAS Code of Practice?
Companies are asked to certify their commitment to the Code either through completion of a short form or by letter by May 1, 2015. Companies that certify as such will be listed on GMA’s website.

10. What is the Publically Available Standard (PAS)?
The PAS is a science-based framework that defines the contents and conduct of generally recognized as safe (GRAS) determinations of food ingredients that will meet the regulatory requirements under sections 201(s) and 409 of the Food, Drug, and Cosmetic Act, and the implementing regulations in 21 CFR 170.3 and 170.30, and in accordance with the GMA Code of Practice.

11. What is the benefit of PAS?
A PAS defines a state of the art standardized structure and procedure for GRAS self-determination. The PAS is developed by a technical committee of experts in a transparent public process that includes all interested stakeholders. The PAS will contain criteria that will serve as the basis for independent verification of implementation of an effective GRAS assessment process. Item 14 below explains how the verification will work.

12. How will the PAS be developed?
The framework is to be developed by a certified independent body and will be suitable for accreditation using an independent official accreditation body (American National Standards Institute: ANSI).

The PAS will include information and requirements necessary to ensure a high integrity review process such as:

- A procedure to ensure the GRAS assessments include all relevant publically available data
- A procedure to ensure appropriate estimation of intake of ingredient
- A procedure to ensure all pivotal scientific data to the GRAS determination are publically available
- A procedure to ensure experts conducting GRAS assessments are appropriately independent and potential conflicts of interest are made fully transparent

13. **Is the PAS only for GMA members?**
The PAS is available for use by all interested parties. The PAS is public standard, developed in an open transparent manner with involvement from all interested stakeholders.

14. **How will the PAS be used?**
Companies and organizations using the PAS will seek Product Certification accreditation from an accredited certifying body ("CB"). CBs will verify compliance with requirement, structure, resources, process, and management system specifications of the PAS. CBs will certify that the company or organization conforms to GRAS PAS requirements.

15. **Do all companies and organizations need to be certified they conform to GRAS PAS requirements?**
Companies and organizations have several options to ensure the implementation of a robust GRAS assessment process. As described in the Code of Practice, companies and organizations may choose to:

   i) Be certified and conduct GRAS determinations in-house or with ingredient suppliers that meet the requirements as described in the Code of Practice;
   
   ii) Hire GRAS providers certified they conform to the GRAS PAS; or
   
   iii) Notify FDA of the GRAS assessment through the voluntary FDA GRAS Notification Program.

**Transparency:**

16. **What is a GRAS database?**
The new GRAS database will list ingredients that are self-determined GRAS. The FDA will be able to enter the database, obtain information, and if more information is required, can contact the sponsor directly. Per the GMA Code of Practice, a sponsor will provide information to FDA.

17. **How will the FDA be informed of self-assessed GRAS ingredients in the food supply?**
FDA will have access to the GRAS database. The database will contain the name of the self-determined GRAS ingredient, the intended use, the concentration, and the name of the sponsor. If the FDA requires additional information, the FDA will contact the sponsor. Alternatively, if the sponsor opts not to enter the ingredient into the GRAS database, as specified by the Code of Practice, the company will notify the FDA of the new GRAS use and use level through the FDA voluntary GRAS Notification Program.

18. **How will GMA ensure transparency to the ingredients assessed as GRAS?**
The GRAS database will list ingredients that are self-determined as GRAS. The FDA will be able to enter the database, obtain information, and if more information is required, can contact the...
sponsor directly. Per the GMA GRAS Code of Practice, a sponsor will provide information to FDA.

**Education:**

19. **Explain the GMA education program**
   GMA has a formal and informal out-reach program to educate industry (food manufacturers, ingredient suppliers, GRAS assessment providers) and consumer groups. The FDA is an integral part of the formal program. We will continue to provide webinars, workshops, and conferences conducted as part of the program to educate stakeholders about the program and about the proper conduct of GRAS assessments.

20. **What is CRIS?**
   Center for Research and Ingredient Safety (CRIS) at Michigan State University was formally established in April 2014. CRIS is modeled on successful high-impact centers that have fostered consumer confidence in allergen and microbiological safety. Experts working in this independent Center will provide un-biased analysis and information on the safety of ingredients used in foods and consumer products in order to provide assurance to the world’s consumers that the household products and foods they depend on each day are safe.

**Communication:**

21. **Does the GRAS plan only apply to GMA members?**
   The GRAS Modernization Program is open to all industry participants. GMA encourages and welcomes all trade associations and industry participants to actively engage and contribute to all aspects of the program. The goal is to create an industry-wide standard for the conduct of GRAS determinations. In addition, pursuant to the Code of Practice, GMA members who commit to the Code will only accept GRAS determinations from suppliers if the GRAS determination was conducted in accordance with the provisions defined in the PAS. GMA hopes this will broaden the adoption of the GRAS Modernization Program, creating a more transparent process subject to the rigors of science, and allowing for greater confidence in the nation’s food supply by consumers.

22. **How will GMA communicate to stakeholders?**
   GMA is communicating to stakeholders through personal meetings, educational webinars, symposia, and workshops. GMA has opened the education program to all stakeholders. GMA is also meeting with trade associations, board members of trade associations, individual GRAS assessment providers to educate stakeholders. GMA also plans a series of publications and public presentations at trade scientific symposia.

GMA is publically encouraging all trade associations and industry members to actively engage and contribute to all aspects of the program. GMA’s goal for the GRAS Modernization Program is to create an industry-wide standard for the conduct of GRAS determinations, create a more transparent process subject to the rigors or science, and allow for greater confidence in the nation’s food supply by consumers.