From GRAS to FAP:

Navigating FDA Regulations for Food & Beverage Ingredient Safety

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1-Minute Summary

- The GRAS designation by FDA ensures ingredient safety in the food and beverage industry.
- Unapproved food additives may render a product adulterated and illegal for marketing.
- The FDA maintains lists of GRAS ingredients; anything not on the list requires a GRAS assessment by the manufacturer.
- The GRAS and Food Additive Petition processes differ; GRAS relies on historical use or expert consensus, while FAP requires rigorous scientific evaluation.
- Completing a GRAS assessment or Food Additive Petition (FAP) is complex; GRAS generally takes 6-18 months, while FAP typically takes 2-5 years.

One trend in the food and beverage industry is to use novel substances such as botanical ingredients or extracts in beverages and conventional foods in response to consumer demand for healthier options.

These novel ingredients, however, may be unapproved food additives, while other substances, long used in our food supply, are being integrated into new products or used in quantities exceeding traditional levels.

designation becomes ever more pertinent in ensuring both regulatory compliance and product quality.

This guide aims to help food and beverage manufacturers understand the importance of GRAS, the process of obtaining GRAS status, and how to ensure your products meet the necessary GRAS standards.

What is GRAS (Generally Recognized as Safe)?

Before exploring the intricate regulatory framework of the GRAS process, let's answer the question, What is GRAS?

The term GRAS, or "Generally Recognized as Safe", pertains to the **safety of ingredients used in foods and beverages**. According to 21 Code of Federal Regulations, ingredients that meet minimum safety requirements, as long as they're consumed under the same conditions as during the assessment, are deemed GRAS.

It's important to understand that **GRAS is not indicative of premarket review and approval by FDA**. Instead, it signifies that an ingredient has undergone scientific safety evaluations of the same caliber as required to obtain approval of food additives.

Understand the Risks of Unapproved Food Additives

So, what happens if an ingredient or other substance is not deemed Generally Recognized as Safe (GRAS) by qualified experts for its intended use and does not qualify for other exemptions?

In this case, the ingredient may not be used in the food supply.

This is a vital point because any unapproved food ingredients used in a food or beverage **render the product adulterated under the Food, Drug & Cosmetic Act, making it illegal to import or market in the United States**.

Which Ingredients Are *Not* Considered Safe for My Products?

In a similar vein, when designing a new food or beverage product, it is important to know which ingredients are **not** considered safe.

FDA publishes a list of substances prohibited from use in human food and beverages in 21 CFR 189 based on a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe.

This list is a good place to start when researching and developing a potential formulation.

How Do I Know if My New Ingredient is Deemed GRAS?

Manufacturers are often faced with the question: How do I know if my new ingredient is Generally Recognized as Safe (GRAS)?

FDA requires rigorous safety assessments for new ingredients before they can be added to foods and beverages. If your ingredient doesn't fit in the allowable GRAS lists provided by the FDA (shown below), it is your responsibility to conduct your own GRAS assessment (more on that later).

- Directly added food substances listed in 21 CFR 184.
- Indirectly added substances listed in 21 CFR 186.
- List of self-GRAS determinations or GRAS substances for which FDA has received notification from food manufacturers.

These lists aren't all-inclusive. Some ingredients used in the food supply before 1958 are grandfathered into a GRAS designation, and others may have undergone GRAS safety studies that haven't been submitted to the FDA.

The lists are dynamic, with new GRAS and food/color additive designations added, and prohibited ingredients updated, based on new safety data.

Make sure to consult these lists frequently. In addition, be sure to understand another important category of ingredients that merit further discussion: food additives.

If your ingredient doesn't appear in FDA's lists of allowable substances, it's your responsibility to conduct your own GRAS assessment.

The Difference Between GRAS and a Food Additive Petition (FAP)

Food additives undergo a different evaluation process called a Food Additive Petition (FAP).

Color Additives, which are substances capable (alone or through reactions with other substances) of imparting color, are required to undergo still a different approval process, a Color Additive Petition (CAP). (Find out more about Color Additive Petitions here.)

It is important to note that **GRAS is not an option for food colors**.

The key difference between GRAS and a Food Additive Petition lies in the level of scrutiny and required evidence. GRAS relies on historical common use or expert consensus, while Food Additive Petitions require a **more rigorous and extensive scientific evaluation**.

Manufacturers must submit formal FAP requests to FDA seeking approval for the new food additive or for a new use of an existing additive. This petition must provide comprehensive data and scientific evidence demonstrating

FDA publishes a list of allowable food/color additives and their limitations of use in 21 CFR 172.

As a food or beverage manufacturer, cross-referencing these lists provides insight into the ingredients your formulation can contain – and those it can't. If any of the ingredients don't fit in the allowable lists, and you still want to bring your product to market, it is your responsibility to conduct your own GRAS assessment.

How Do I Conduct a GRAS Food Assessment for My Product?

Conducting a Generally Recognized as Safe (GRAS) assessment for an ingredient in your food or beverage product can be a complex process, involving several key steps.

The time it takes can vary greatly depending on the nature of the ingredient, its intended use, and the amount of data available. However, it generally takes between **6-18 months** to complete a thorough GRAS assessment.

Identify the Substance: Detail the chemical identity of the substance and its method of manufacture. This includes the common or usual name, chemical name, and the Chemical Abstracts Service (CAS) number, if any.

Research and Gather Evidence: Collect historical data about the safe use of the substance in food products and gather relevant scientific research data. This can include toxicology studies, metabolic studies, allergenicity studies, and studies of the ingredient's potential effects on specific populations such as infants, pregnant women, or people with certain medical conditions.

Conclude the Safety of Use: Based on the evidence and expert review, determine whether the substance is safe for its intended use in food or beverages. The standard is a reasonable certainty that the substance is not harmful under the conditions of its intended use.

Prepare a GRAS Notice: This notice should include a comprehensive account of the above steps, as well as a conclusion about the GRAS status of the substance.

Expert Review: A panel of independent and qualified experts should conduct a thorough review of all the evidence. The panel should include professionals with expertise in toxicology, nutrition, chemistry, and other relevant fields. At this point, the substance is considered Self-Determined GRAS, allowing the material to be marketed and distributed in the U.S.

Submit GRAS Notice to FDA: Though not required, it's a good idea to submit your GRAS notice to the FDA. They will review the notice and respond with a letter that either states the agency has no questions or has further questions/issues regarding the notice's conclusion.

Remember, the GRAS process is about ensuring safety. If the substance does not meet the criteria for GRAS status, another option may be FDA's food additive petition process, which involves additional steps and may take even more time.

How Do I Complete a Food Additive Petition?

provide expert guidance for your Food Additive Petition.

Identify the Substance and its Purpose: Define the chemical identity of the substance and its intended function in the food or beverage. This should include the substance's common or usual name, its Chemical Abstracts Service (CAS) number, and details on how it's produced.

Compile Safety and Utility Data: Collect comprehensive data on the safety and functionality of the substance. This could include laboratory studies, animal studies, human trials, and any other relevant scientific data. You should also include data on the substance's effect on the characteristics of the food (e.g., its taste, texture, shelf-life).

Estimate Dietary Exposure: Predict the likely consumption level of the substance by different population groups (e.g., children, adults, elderly) based on its proposed use. This should consider both the amount of the substance in the food and the expected consumption of the food itself.

Prepare Environmental Impact Statement: Assess the potential environmental effects of the production, use, and disposal of the substance. This statement is required under the National Environmental Policy Act (NEPA).

Complete the FAP Form: Fill in FDA's specific Food Additive Petition form, which includes all the above information and more. Make sure to provide clear and concise summaries of the data and arguments that support the safety and effectiveness of the substance.

Submit the FAP to FDA: Once complete, submit the Food Additive Petition to FDA for review. The Agency will evaluate the petition, which includes a thorough review of all safety data and conclusions. If FDA concludes that the data supports the safety of the proposed use of the additive, they will issue a regulation amending the food additive regulations to include the new additive.

Understanding and complying with FDA's GRAS and Food Additive Petition processes are essential for food and beverage manufacturers. Ensuring your ingredients meet these stringent safety standards is vital for regulatory compliance, product quality, and above all, consumer trust. With the right knowledge and expert guidance, navigating these complex regulations can become a smooth journey to market.

Remember, if you need help with the GRAS or Food Additive Petition processes, contact our regulatory arm, EAS Consulting Group. Let them put their years of experience to work for your company.

Topics: **GRAS Food**, **GRAS**

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