

A Food Ingredient's Journey to Your Dinner Table

Today's foods and beverages contain many different ingredients that perform a variety of specific functions, including to improve our food's taste, texture, nutrition, convenience, safety, and affordability. While there is more than one path to determine an ingredient's safety, their safety must be established before they can be added to foods and beverages.

Let's follow a food ingredient's journey to your dinner table:

Start here:

Step 1

Food science professionals and researchers work to develop a new food ingredient or identify an additional use for an already approved ingredient.



Step 2

They then gather existing data (*often extensive*) and may conduct additional research on the ingredient to ensure its safe use in foods and beverages.

Step 3

Assessing safety:

If the data support the safety of the ingredient for its intended use(s), the producer may self-determine the ingredient to be safe. This determination of safety relies on critical expert knowledge. (See Q&A)
It can then do one of 3 things:

A

Submit a GRAS Notice to the U.S. Food and Drug Administration (FDA).

OR

B

Submit a Food Additive Petition.

(What is a Food Additive Petition? See Q&A.)

OR

C

Producer calls the use of the ingredient GRAS.

Skip to Step 6

Step 4

FDA evaluates information on the ingredient, including data on safety, chemistry, and consumption.

POSSIBLE OUTCOMES

A

GRAS Notice: FDA has "No questions" about the producer's determination that the intended use of the ingredient is Generally Recognized as Safe.

OR

B

Food Additive Petition: FDA finds no safety concerns with the food additive for its intended use(s) in foods and beverages.

OR

C

FDA determines the GRAS Notice or Food Additive Petition did not provide enough support for the safety of the ingredient for its intended use(s).

POSSIBLE OUTCOMES The producer may:

Step 5

FDA publishes a regulation allowing use of the ingredient.

Step 6

The ingredient can now be used in foods and beverages as specified.



For more information, see the Q&A.



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Questions and Answers about the Food Ingredient Regulatory Review Process

Food ingredients are carefully regulated by the U.S. Food and Drug Administration (FDA) to ensure that foods and beverages containing them are safe to eat.

In general, the ingredients in the Ingredient List on product labels (i.e. flavors, colors, preservatives, etc.) are regulated as either food additives or GRAS ingredients.

What is a GRAS ingredient?

GRAS stands for “Generally Recognized as Safe.” For a GRAS ingredient to be added to foods and beverages for a particular use, key information that supports the ingredient’s safety must be publicly available and accepted within the scientific community. Regardless of whether it is classified as GRAS or as a food additive, all ingredients must satisfy the same rigorous standards demonstrating safety for use in food and beverage products.

What does it mean to “self-determine” an ingredient as GRAS?

To self-determine an ingredient as GRAS means that the producer has determined, based on scientific research, that the ingredient has met FDA’s criteria for its use in foods and beverages. In essence, a GRAS ingredient must meet one of the following criteria:

1. It must have an established history of safe use as an ingredient prior to 1958 (when the Food Additives Amendment was passed); or
2. Key information about the safety of the ingredient must be publicly available and there should be agreement among qualified expert scientists that there is a reasonable certainty that the ingredient is safe for its intended use.



The FDA may be notified of the self-determination of a particular use of an ingredient as GRAS and this is captured on FDA’s website of [GRAS Notices](#). The producer has the responsibility to determine an ingredient to be GRAS, so regardless of whether a GRAS Notice is submitted, the ingredient has been determined to be GRAS. Food and beverage producers are ultimately responsible and held accountable by FDA for the safety of their products, including being forced to discontinue use of an ingredient if it is found to pose a safety concern.

How are food ingredients tested for safety before they are used?

Food ingredients are among the most studied parts of the food supply. Researchers test new ingredients before they are added to foods and beverages to ensure they are safe for consumption. The types of studies that may be performed to determine the safety of an ingredient depend on the chemical structure and the amount of the ingredient expected to be consumed. For example, studies that may be conducted include: safety and toxicity studies, including those to assure the ingredient does not cause cancer or other harm to reproductive health, digestive health, heart health, etc. Every ingredient is assessed on its individual merit, therefore requiring different levels and types of research.

Who are the expert reviewers and what do they know about food ingredient safety?

The experts who evaluate the safety of both GRAS ingredients and food additives are uniquely qualified through their education and experience to evaluate the science regarding the safety of GRAS ingredients and food additives. Upon receiving a Food Additive Petition or GRAS Notice, FDA requests that these experts conduct and/or review the necessary research regarding the ingredient’s safety and potential health effects to determine whether it is safe for the intended use(s).



Questions and Answers about the Food Ingredient Regulatory Review Process

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What is a Food Additive Petition?

A Food Additive Petition is a submission by a food and beverage producer to the FDA requesting that it issue a regulation for a new ingredient, or after FDA has conducted its premarket review, expanded use(s) of an existing ingredient. A Food Additive Petition may be submitted for a several reasons, such as for approval of a new food additive; approval of a different use for an already approved food additive; or approval of a different amount of an existing additive. Similar to other ingredients, including those that are GRAS, FDA requires information that shows the food additive to be safe for its intended use and not to cause adverse health effects.



How are the review processes for GRAS ingredients and food additives similar?

Both food additives and GRAS ingredients must be shown through scientific research to be safe and not to cause adverse health effects when consumed in foods and beverages. All ingredients must meet the same standard of safety before they are permitted for use in foods and beverages. As a result, GRAS ingredients and food additives are required to be reviewed to the same standard of safety.

How are they different?

In the case of a food additive, the producer submits the information to the FDA in the form of a Food Additive Petition requesting approval for use. Once a safety decision is made by FDA, a final regulation is published, allowing the use of the ingredient. For ingredients that are permitted as GRAS, FDA premarket review is not required; however, safety information must be publicly available. As noted above, the producer is still responsible for the safety of the ingredient and must still make a determination that the ingredient is GRAS before using it in foods and beverages. *For more on this, see the FDA [FAQ](#) on the criteria that distinguish between a GRAS ingredient and the approved use of a food additive.*

Does it matter whether an ingredient is classified as GRAS or as a food additive?

Regardless of whether an ingredient is self-determined as GRAS or approved as a food additive, the producer is still held accountable for ensuring the safety of the ingredient. In this way, both food additives and GRAS ingredients are held to the same safety standards, and food and beverage producers are responsible for ensuring their safety of their products.

Where can I find a list of GRAS Notices?

For a list of GRAS Notices, visit FDA's [GRAS Notices](#) webpage on www.fda.gov.

Where can I find a list of food additives?

For a list of Food Additives, visit [FDA's Food Additive Status list](#) webpage on www.fda.gov.

For more information:

"Everything Added to Food in the United States" on www.fda.gov

"What's in Our Food: Understanding Common Food Ingredients"

on www.foodinsight.org

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