

# Food Ingredients Generally Recognized as Safe: GRAS at Last



Article By

[Food and Drug Law at Keller and Heckman](#)  
[Keller and Heckman LLP](#)  
[The Daily Intake](#)

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Monday, August 15, 2016

## **FDA Issues Final Rule on Food Ingredients that May Be “Generally Recognized as Safe” (GRAS)**

- Although FDA has premarket review authority over food additives, a food manufacturer can intentionally add a substance to human food or animal food without the Agency’s premarket review or approval if the substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use, i.e., GRAS. Until now, FDA has operated a voluntary GRAS Notification Program provided for under a 1997 proposed rule.
- As part of a settlement of a lawsuit filed against the U.S. Food and Drug Administration (FDA) by the Center for Food Safety (CFS) in 2014, FDA agreed to issue a final rule on its voluntary GRAS Notification Program by August 31, 2016. In its lawsuit, CFS claimed that FDA was operating its GRAS Notification Program under a 1997 proposed rule that was never subject to final rulemaking, essentially making the program illegal under the Administrative Procedure Act (APA).
- With two weeks to go, on August 12, 2016, FDA released a [final rule](#) which:
  - Formalizes its GRAS Notification Program and;
  - Details the criteria for concluding that the use of a substance in human or animal food is “generally recognized as safe” (GRAS).
- Here we note that the final rule clarifies the criteria for eligibility for

classification as GRAS as follows:

- A substance cannot be classified as GRAS under the conditions of its intended use if the available data and information do not satisfy the safety standard for a food additive under the Federal Food, Drug, and Cosmetic Act;
- General recognition of safety requires common knowledge, throughout the expert scientific community knowledgeable about the safety of substances directly or indirectly added to food, that there is a reasonable certainty that the substance is not harmful under the conditions of its intended use;
- “Common knowledge” can be based on either “scientific procedures” or on experience based on common use of a substance in food prior to January 1, 1958; and
- General recognition of safety through scientific procedures must 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.

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