

Generally Recognized as Safe (GRAS)

"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 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.

- Under sections 201(s) and 409 of the Act, and FDA's implementing regulations in 21 CFR 170.3 and 21 CFR 170.30, 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. Under 21 CFR 170.30(b), 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. General recognition of safety through scientific procedures is 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are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.
- Under 21 CFR 170.30(c) and 170.3(f), 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.

Overview

- [About the GRAS Notification Program \(/food/generally-recognized-safe-gras/about-gras-notification-program\)](#)
- [How FDA's GRAS Notification Program Works \(/food/generally-recognized-safe-gras/how-us-fdas-gras-notification-program-works\)](#)

- [FDA's Approach to the GRAS Provision: A History of Processes \(/food/generally-recognized-safe-gras/fdas-approach-gras-provision-history-processes\)](/food/generally-recognized-safe-gras/fdas-approach-gras-provision-history-processes)

GRAS Final Rule

- [Federal Register Notice – the GRAS Final Rule \(https://www.federalregister.gov/articles/2016/08/17/2016-19164/substances-generally-recognized-as-safe\)](https://www.federalregister.gov/articles/2016/08/17/2016-19164/substances-generally-recognized-as-safe) (81 FR 54960 – August 17, 2016)
- [Federal Register Notice - the GRAS Proposal \(http://www.gpo.gov/fdsys/pkg/FR-1997-04-17/pdf/97-9706.pdf\)](http://www.gpo.gov/fdsys/pkg/FR-1997-04-17/pdf/97-9706.pdf) (62 FR 18937 - April 17, 1997)
- [Federal Register Notice - Substances Generally Recognized as Safe; Reopening of the Comment Period \(https://www.gpo.gov/fdsys/pkg/FR-2010-12-28/pdf/2010-32344.pdf\)](https://www.gpo.gov/fdsys/pkg/FR-2010-12-28/pdf/2010-32344.pdf) (75 FR 81536 - Dec 28, 2010)

Inventory for Human Food

- [GRAS Notice Inventory \(/food/gras-notice-inventory/recently-published-gras-notice-and-fda-letters\)](/food/gras-notice-inventory/recently-published-gras-notice-and-fda-letters)

Related Databases

- [GRAS Substances \(SCOGS\) Database \(/food/generally-recognized-safe-gras/gras-substances-scogs-database\)](/food/generally-recognized-safe-gras/gras-substances-scogs-database)
- [Microorganisms & Microbial-Derived Ingredients Used in Food \(Partial List\) \(/food/generally-recognized-safe-gras/microorganisms-microbial-derived-ingredients-used-food-partial-list\)](/food/generally-recognized-safe-gras/microorganisms-microbial-derived-ingredients-used-food-partial-list)
- [Enzyme Preparations Used in Food \(Partial List\) \(/food/generally-recognized-safe-gras/enzyme-preparations-used-food-partial-list\)](/food/generally-recognized-safe-gras/enzyme-preparations-used-food-partial-list)

Regulatory and Policy Guidance

- [Guidance for Industry: Best Practices for Convening a GRAS Panel \(/food/guidance-documents-regulatory-information-topic/draft-guidance-industry-best-practices-convening-gras-panel\)](/food/guidance-documents-regulatory-information-topic/draft-guidance-industry-best-practices-convening-gras-panel)
- [Regulatory Framework for Substances Intended for Use in](#)

[Human Food or Animal Food on the Basis of the Generally Recognized as Safe \(GRAS\) Provision of the Federal Food, Drug, and Cosmetic Act \(/food/guidance-documents-regulatory-information-topic/guidance-industry-regulatory-framework-substances-intended-use-human-food-or-animal-food-basis\)](#)

- [Guidance for Industry: Frequently Asked Questions About GRAS for Substances Intended for Use in Human or Animal Food \(/food/guidance-documents-regulatory-information-topic/guidance-industry-frequently-asked-questions-about-gras-substances-intended-use-human-or-animal-food\)](#)
- [Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That Are Color Additives \(/food/guidance-documents-regulatory-information-topic/guidance-industry-assessing-effects-significant-manufacturing-process-changes-including-emerging\)](#)
- [Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements \(/regulatory-information/search-fda-guidance-documents/guidance-industry-considerations-regarding-substances-added-foods-including-beverages-and-dietary\)](#)
- Providing Regulatory Submissions to OFAS
 - [CFSAN Online Submission Module \(COSM\) \(/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm\)](#)
- [Guidance for Industry: Frequently Asked Questions about FDA's Regulation of Infant Formula \(/food/guidance-documents-regulatory-information-topic/guidance-industry-frequently-asked-questions-about-fdas-regulation-infant-formula\)](#)

Scientific Guidance

- [Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Food Additive Petitions and GRAS Notices for Enzyme Preparations \(/food/guidance-documents-regulatory-information-](#)

[topic/guidance-industry-recommendations-submission-chemical-and-technological-data-food-additive-petitions\)](#)

- [Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions \(/food/guidance-documents-regulatory-information-topic/guidance-industry-recommendations-submission-chemical-and-technological-data-direct-food-additive\)](#)
- [Guidance for Industry: Estimating Dietary Intake of Substances in Food \(/food/guidance-documents-regulatory-information-topic/guidance-industry-estimating-dietary-intake-substances-food\)](#)
- [Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food \(/food/guidance-documents-regulatory-information-topic/guidance-industry-summary-table-recommended-toxicological-testing-additives-used-food\)](#)

Regulations

- [21 CFR 181 - Prior Sanctioned Food Ingredients \(http://www.ecfr.gov/cgi-bin/text-idx?SID=e956d645a8b4e6b3e34e4e5d1b690209&mc=true&node=pt21.3.181&rgn=div5\)](#)
- [21 CFR 182 - Substances GRAS in food \(http://www.ecfr.gov/cgi-bin/text-idx?SID=e956d645a8b4e6b3e34e4e5d1b690209&mc=true&node=pt21.3.182&rgn=div5\)](#)
- [21 CFR 184 - Substances Affirmed as GRAS in Food \(http://www.ecfr.gov/cgi-bin/text-idx?SID=e956d645a8b4e6b3e34e4e5d1b690209&mc=true&node=pt21.3.184&rgn=div5\)](#)
- [21 CFR 186 - Substances Affirmed as GRAS for Use in Food Packaging \(http://www.ecfr.gov/cgi-bin/text-idx?SID=e956d645a8b4e6b3e34e4e5d1b690209&mc=true&node=pt21.3.186&rgn=div5\)](#)