

Generally Recognized as Safe (GRAS), and Other Documentations of Food Ingredient Safety



Before a substance can be legally added to food in the U.S., with rare exceptions, it must be either an approved food additive, prior-sanctioned, or determined to be generally recognized as safe (GRAS) for use in food. Today, many companies choose the GRAS option, establishing general recognition of safety based upon scientific procedures, as the way to meet this requirement.

Whether seeking to submit a GRAS Notification, (where a prepared notice is submitted to FDA for review and comment); or Independent (self) GRAS conclusion where the stakeholder makes the determination that the use of the substance is GRAS, both options require diligent study assessments of the safety of the ingredient in question. EAS Consulting Group, LLC has a long and successful history of leading companies through the GRAS process. EAS has expert consultants in the areas of toxicology and regulatory requirements to take you through the steps of a GRAS determination.

EAS Consulting Group, LLC is a leading provider of regulatory services to the food, dietary supplement, pharmaceutical, medical device, tobacco, and cosmetic industries. Originally founded in 1960, EAS has over 50 years of experience assisting clients in developing regulatory strategies, implementing quality systems, filing regulatory submissions, and ensuring compliance with all Food and Drug Administration (FDA) regulations.

Choose EAS for:

- ✓ Performing an initial feasibility study
- ✓ Determining required performance outcomes and identifying appropriate studies to perform
- ✓ Developing study designs and protocols
- ✓ Identifying an appropriate Contract Research Organization (CRO)
- ✓ Coordinating study initiation and management oversight with the CRO
- ✓ On-going monitoring of study protocols and outcomes
- ✓ Providing input of appropriate data for inclusion in study reports
- ✓ Support in the writing of the dossier documenting the safety of the ingredient
- ✓ Convening the expert GRAS Panel
- ✓ Submission of the GRAS Notice to FDA for review

In addition to GRAS, EAS can help with other options such as food additive petitions, food contact notification, NDIs, and more.