Generally Recognized As Safe (GRAS) Determinations

Regulatory Services — US

Under the Federal Food, Drug and Cosmetic Act, any substance intentionally added to food is considered a food additive, and all food additives are subject to premarket approval by FDA. However, those substances that have been determined to be Generally Recognized as Safe (GRAS) by qualified experts, either by scientific procedures or through history of use in food, are excepted from the premarket approval requirement.

FDA's GRAS process has evolved significantly over the years . While previously FDA would affirm the GRAS status of a substance through a petition process, they have now moved to a voluntary GRAS notification process. This self-affirmation process is undertaken by industry. While the notification process is voluntary, FDA encourages the submission of GRAS determinations. FDA will respond to GRAS notifications by either indicating they have no questions, or that they do not believe the notice provides a sufficient basis for a GRAS conclusion. FDA will not affirm the GRAS determination.

While GRAS substances do not require premarket approval from FDA, there is still a significant amount of work that goes into making a GRAS determination. The data must be of the same quality and quantity as what is typically required for pre-market approvals and the determination must be made by qualified experts.

toXcel can assist in determining whether a substance is a good candidate for GRAS status. Our experienced team will perform literature searches to determine available public literature, review data and determine potential data gaps, assist in selection of labs and conduct of required studies, organize an expert panel, and prepare a GRAS dossier in compliance with FDA standards.

There are additional exemptions to the definition of a food additive, including those for ingredients approved for use prior to implementation of the food additive regulations as well as exemptions for color additives and pesticides where other approval requirements apply, such as EPA tolerance exemptions. There are also multiple premarket approval pathways available for food additives including food contact notifications and food additive petitions. toXcel can assist in determining the regulatory pathway that best fits your product.

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