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

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The US Food and Drug Administration (FDA) has issued this final rule detailing the criteria for concluding that the use of a substance in human or animal food is "generally recognized as safe" (GRAS). By way of background, if an ingredient is GRAS, food additive petition is not required and FDA does not have to approve the ingredient before it can be used in foods. FDA has been studying the existing process that currently results in a company conducting the GRAS assessment via a panel of experts and then either proceeding to immediately use the ingredient in foods, or submitting a GRAS affirmation petition to FDA before the ingredient is used in a food.

FDA's new regulation provides the information FDA believes a company should have to make a GRAS determination or conclusion. Manufacturers remain free to conduct their own GRAS evaluations and then proceed to incorporate the substance into food. FDA's final rule changes what had been a voluntary GRAS affirmation process into a voluntary "notification" process. Under this new process, if a company decides to use the notification process, the company conducts the requisite safety assessment and then prepares a notification submission to the FDA. The contents of the notification submission are detailed in the regulation. Once the voluntary notification had been submitted to FDA, the agency is supposed to respond within 180 days, though that can be extended for an additional 90 days (for a total of 270 days) before the substance can be included in a food, assuming FDA does not question the basis for the notifier's GRAS conclusion.



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