March 28, 2011

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-1997-N-0020

Submitted via FAX: 301-827-6870

IFT comments on Substances Generally Recognized as Safe; in response to reopening of the 1997 comment period

To whom it may concern:

The Institute of Food Technologists (IFT) appreciates the opportunity to provide comments in response to the reopening of the comment period on the 1997 GRAS Notification Proposed Rule, which would replace the voluntary GRAS affirmation petition process with a voluntary notification procedure. IFT supports the proposed voluntary notification procedure, which has been in effective use under the framework of the 1997 proposed rule since its issuance. The Institute of Food Technologists (IFT) exists to advance the science of food. Our long-range vision is to ensure a safe and abundant food supply contributing to healthier people everywhere. Founded in 1939, IFT is a nonprofit scientific society with individual members working in food science, food technology, and related professions in industry, academia, and government. IFT champions the use of sound science across the food value chain through knowledge sharing, education, and advocacy, encouraging the exchange of information, providing educational opportunities, and furthering the advancement of the profession. IFT has offices in Chicago, Illinois, and Washington, D.C. For more information, please visit ift.org.

The GRAS concept is a very useful one that has worked well. More specifically, the voluntary notification procedure effectively allows the FDA to consider and respond to GRAS determinations/conclusions more efficiently, with less burdensome use of resources, than with the former voluntary GRAS affirmation petition process. The framework of the voluntary notification procedure appears to have streamlined the GRAS process, and made it more attractive to companies to participate. There were 310 GRAS notices filed between Feb., 1998 and Dec., 2010, compared with fewer than 100 GRAS affirmation petitions submitted during 1987 to 1996. As described by Kahl (2010), the voluntary notification procedure allows for substantive Agency evaluation of GRAS notifications and public accessibility, through the GRAS Notice Inventory, to information on the notifications. The voluntary GRAS notification procedure allows the Agency to efficiently use its resources to address ingredients added to food within an effective safety standard. A voluntary process that makes the agency more aware of private determinations of GRAS is clearly desirable.

Although there is the potential for an irresponsible GRAS determination/conclusion by a company to not come to the Agency’s attention through the voluntary notification procedure, IFT believes that the benefit of the voluntary notification procedure far outweighs such an unlikely occurrence. IFT would support, however, the Agency requiring any entities making private GRAS determinations/conclusions and not participating in the voluntary notification procedure to inform the Agency of their conclusions and provide supporting data, as has been done for several decades by the Flavor and Extract Manufacturers Association of the United States.
With respect to terminology, FDA appears to use the terms "GRAS notice" (e.g., p. 81537, left column line 10; and p 81539, Issue 9, last paragraph) and "GRAS notification" (p. 81538 middle column, lines 22-23) interchangeably in the Dec. 28, 2010 Federal Register notice. Because the Agency uses “notification” with specific reference to food contact substances in the “Food Contact Substance Notification Program,” we ask whether it is the Agency’s intention to use one or the other term with regard to GRAS status determination/conclusion.

IFT appreciates this opportunity to provide comments on the voluntary GRAS notification procedure.

Sincerely,

Robert Gravani, Ph.D.
President