GAO Concludes FDA Should Strengthen its Oversight of GRAS Ingredients

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On March 5, 2010, the General Accountability Office (GAO) issued a report evaluating the Food and Drug Administration's (FDA's) policies concerning food ingredients that have been determined to be "Generally Recognized As Safe" (GRAS). GRAS ingredients are excluded from premarket clearance requirements for food additives under the Federal Food, Drug, and Cosmetic Act (FDCA). The GAO report was prepared at the joint request of Sen. Tom Harkin (D., Iowa), Chairman of the Senate Committee on Health, Education, Labor and Pensions, and Rep. Rosa DeLauro (D., Conn.), Chair of the House Committee on Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies, and was prompted by apparent congressional interest in FDA oversight of food ingredients, including those developed through nanotechnology and other emerging technologies.

The GAO evaluation considered data on FDA's voluntary notification program from the first year a GRAS notice was submitted, 1998, through 2008; laws and regulations regarding GRAS substances; the 11 citizen petitions related to GRAS substances that were submitted to FDA between 2004 and 2008; information from FDA officials regarding the agency's response to the 11 citizen petitions; FDA's policies and guidance to companies regarding engineered nanomaterials; the activities of foreign governments—namely, Canada and the European Union—that have been particularly active in considering regulation of engineered nanomaterials in food; and interviews with a wide range of stakeholders, including officials from FDA, industry and trade organizations, consumer advocacy groups, academia, and foreign governments.

Based on the evaluation, the new GAO report concludes that greater FDA oversight is needed with respect to GRAS determinations concerning both (a) food ingredients and components that previously were determined to be GRAS ingredients and for which GRAS status has been challenged in pending citizen petitions (*e.g.*, high fructose corn syrup, salt, hydrogenated oils), and (b) ingredients and components that are the subject of new GRAS determinations, including those developed through nanotechnology and other emerging technologies.

Based on these findings, GAO further concludes that "FDA should take steps to better ensure the safety of GRAS substances," and recommends that FDA:

- Require companies that undertake a GRAS determination to make a submission to FDA identifying the substance and the conditions of use the company has determined to be GRAS, and make this information publicly available through the FDA website;
- Establish standards aimed at minimizing the risk of conflicts of interest among scientists who serve as experts on GRAS panels, including by requiring information concerning potential conflicts to be submitted to FDA;

- Evaluate the adequacy of GRAS determinations through random audits or other assessment procedures;
- Establish standards with respect to the nature and scope of scientific evidence required to establish GRAS status, and procedures for documenting determinations of GRAS status;
- Finalize FDA's pending proposed regulation governing the current voluntary GRAS notification program established by FDA (see "Substances Generally Recognized As Safe; Proposed Rule," 62 Fed. Reg. 18937 (Apr. 17, 1997));
- Establish standards and systematic procedures governing FDA's reconsideration of substances previously determined to be GRAS, including through timely responses to citizen petitions, appropriate allocation of FDA resources; and the development of criteria defining the circumstances in which FDA reconsideration of GRAS status will be undertaken; and
- Issue guidance responding to the recommendations of the FDA Nanotechnology Task Force issued in 2007, defining "engineered nanomaterials," and establishing premarket notification requirements for substances involving engineered nanomaterials.

FDA regulation of GRAS substances has been subject to heightened scrutiny over the past few years.

In 2006, Michael Taylor, J.D. wrote a report on nanotechnology, titled "Regulating the Products of Nanotechnology. Does FDA have the tools it needs?" Taylor concluded that, in addition to "missing some of the legal tools it needs," FDA's "readiness for nanotechnology is most seriously hampered by the lack of resources required to respond promptly to products in the market and in the development pipeline."[1] To address these issues, Taylor recommended that FDA "promptly establish criteria for judging when a nanomaterial is "new" for legal and regulatory purposes, *i.e.*, for purposes of distinguishing it from versions that are already listed in FDA's GRAS, food additive and food packaging regulations," and "establish criteria for determining when a nanomaterial should be considered "new for safety evaluation purposes."[2] Michael Taylor is currently Deputy Commissioner for Foods at FDA.

In August 2006, FDA convened the FDA Nanotechnology Task Force, "charged with determining regulatory approaches that encourage the continued development of innovative, safe, and effective FDA-regulated products that use nanotechnology materials. . . [and] recommend[ing] ways to address any knowledge or policy gaps that exist so as to better enable the agency to evaluate possible adverse health effects from FDA-regulated products that use nanotechnology materials."[3] In July 2007, the Task Force issued a report of its findings, noting that "the emerging and uncertain nature of the science [regarding nanotechnology] and potential for rapid development of applications for FDA-regulated products highlights the need for timely development of a transparent, consistent, and predictable regulatory pathway," for use of nanotechnology, and including a recommendation that FDA "provide guidance to manufacturers about when the use of nanoscale ingredients may require submission of additional data, change the product's regulatory status or pathway, or merit taking additional or special steps to address potential safety or product quality issues."[4]

In July 2009, the House passed, H.R. 2749, which contained a provision requiring FDA to post notice of a determination that a substance is GRAS, and the supporting scientific justifications, on FDA's website within 60 days of receipt of a GRAS notification. Although the current Senate version of the bill, S. 510, does not contain this GRAS provision, the Senate bill is expected to reach the Senate

floor by Easter.

In January 2010, Sen. Pryor, (D. AZ) introduced S. 2942, “to amend the Federal Food, Drug, and Cosmetic Act to establish a nanotechnology program.” The legislation has been referred to the Senate Health, Education, Labor, and Pension Committee.

Kelley Drye & Warren LLP

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[1]Taylor, M.R., *Regulating the Products of Nanotechnology: Does FDA Have the Tools it Needs?* (October 2006), p. 3, visit external resource.

[2]*Id.* at 8.

[3]FDA Website, About the Task Force, visit external resource.

[4]FDA Website, Nanotechnology Task Force Report, visit external resource.