

E-ALERT | Food & Drug

March 10, 2010

FOOD SAFETY: GAO REPORT CONCLUDES THAT FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE (GRAS)

On March 5, 2010, the U.S. Government Accounting Office (GAO) released a report recommending that FDA improve its oversight of food ingredients determined to be Generally Recognized as Safe (GRAS).¹

GAO Report Concludes that FDA's Current GRAS Oversight is Not Sufficient.

Senator Tom Harkin and Representative Rosa L. DeLauro requested the GAO study in light of concerns raised by consumer groups regarding the safety of certain GRAS substances, such as salt and trans fats in partially hydrogenated vegetable oils, and the potential for engineered nanomaterials to be considered GRAS for use in food and food packaging.² In its study, the GAO analyzed the following three issues and concluded:

- FDA's current oversight process does not help ensure the safety of all new GRAS determinations.
- FDA is not systematically ensuring the continued safety of current GRAS substances.
- FDA's regulatory approach allows engineered nanomaterials to enter the food supply without the agency's knowledge.

Currently, the Federal Food, Drug, and Cosmetics Act permits companies to determine whether a food ingredient under conditions of its intended use is GRAS without obtaining FDA approval.³ To make a GRAS determination, a company must conclude that there is common knowledge about the safety of the substance among scientific experts qualified to evaluate the safety of the substance. Once a company—domestic or foreign—concludes that a substance is GRAS, it may market that substance as GRAS without informing FDA.

FDA does, however, provide a voluntary GRAS notification program pursuant to a 1997 proposed rule,⁴ which permits a company to obtain FDA review by voluntarily submitting its GRAS determination of a substance. Under this procedure, FDA determines only that the agency has “no further questions” about a substance. FDA does not make an independent determination of the safety of a substance.

¹ GAO, *FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)* (Feb. 2010) [hereinafter *GAO Report*].

² *Id.* at 1-2.

³ This is consistent with the statutory definition of “food additive” that puts the burden on a company initially to decide if a substance is a food additive or GRAS. See 21 U.S.C. § 321(s).

⁴ FDA, *The GRAS Proposal*, 62 Fed. Reg. 18937 (Apr. 17, 1997).

After reviewing the current state of FDA's regulation of GRAS substances, GAO concluded that FDA's ability to strengthen its oversight is limited because FDA currently:

- Does not have authority to require companies to report GRAS findings.
- Has not provided guidance to minimize conflicts of interests to ensure that companies' GRAS determinations are made with an independent panel of experts.
- Has not issued guidance on how companies are to document their GRAS determinations.
- Does not conduct audits of GRAS determinations, and consequently does not know whether companies have conducted and documented their determinations appropriately.
- Has not updated and finalized its 1997 proposed rule related to its voluntary notification program.
- Has only partially implemented its nanotechnology task force's 2007 recommendations.
- Has not developed a definition of engineered nanomaterials and does not require companies to identify whether their GRAS substances incorporate nanomaterials.⁵

GAO Recommends that FDA Increase its Oversight of GRAS Substances by Implementing Six Strategies.

Based on its findings and conclusions, GAO recommended that FDA implement the following six strategies to better ensure the safety of GRAS substances:

1. **Compile All GRAS Determinations**—by requiring any company that conducts a GRAS determination to provide FDA with basic information about the substance's identity and intended uses, which information FDA should incorporate into relevant databases and post on its public website.
2. **Minimize the potential for conflicts of interest in companies' GRAS determinations**—by issuing guidance for companies on conflicts of interest and requiring disclosure in GRAS notices regarding the independence of expert panelists.
3. **Monitor the appropriateness of companies' GRAS determinations**—through random audits or some other means, including issuing guidance on how to document GRAS determinations that are not submitted to FDA.
4. **Finalize the 1997 proposed rule governing the voluntary notification program**—including taking into account the experience of the program to date, incorporating input from a new public comment period, and reporting to Congress and the public a timeline for making it final.

⁵ GAO Report at 33-34.

5. **Conduct systematic reconsiderations of the safety of GRAS substances**—including taking steps such as allocating sufficient resources to respond to citizen petitions in a timely manner, developing criteria for the circumstances under which the agency will reconsider the safety of a GRAS substance, and considering how to collect information from companies on their reconsiderations.
6. **Help ensure the safety of unreported engineered nanomaterials marketed as GRAS substances**—including taking steps such as issuing guidance recommended by the agency’s nanotechnology task force, developing an agency definition of engineered nanomaterials, and requiring companies to inform FDA if their GRAS determinations involve engineered nanomaterials.

Finally, GAO suggested that if FDA determines it does not have authority to implement one or more of its six recommendations, FDA should seek the authority from Congress.

FDA Agrees with Most of GAO’s Recommendations, Makes Two Commitments, but states that it Currently Lacks Sufficient Authority to Implement the Most Rigorous Recommendations and Does Not Suggest it Would Seek the Authority from Congress.

FDA responded to GAO’s report and was generally in agreement with the report’s recommendations. Nevertheless, FDA made only two commitments, concluding that it lacked the authority and resources to implement the remainder of the recommendations to their full extent. In response to the fourth recommendation, FDA stated that it would finalize its 1997 proposed rule on the voluntary GRAS notification program after reopening the comment period.⁶ However, FDA did not indicate when it would reopen the comment period and did not include a time frame for finalizing the rule.

In response to the sixth recommendation, FDA stated that “it will soon issue draft guidance that will help developers of food applications of nanotechnology determine the applicability” of the GRAS concept.⁷ FDA also indicated that it would consider establishing a definition of foods nanotechnology.

In response to the remainder of the recommendations, FDA stated that it agreed with the recommendations, but lacked the authority and/or resources to implement them. For example, due to a lack of mandatory notification authority, FDA stated it is unable to ensure that unreported GRAS determinations are rigorous, robust, or consistent with its 1997 proposed rule.⁸ Similarly, without mandatory notification authority, FDA is limited in conducting audits because it does not know which companies made GRAS determinations about particular substances and uses.⁹ In addition, FDA stated that it lacked adequate resources to conduct systematic reconsiderations of GRAS substances.¹⁰ Finally, the report noted that FDA did not discuss the GAO’s recommendation to seek additional authority from Congress.¹¹

⁶ *Id.* at 38.

⁷ *Id.* at 39.

⁸ *Id.* at 36. FDA’s statement that it lacks authority is interesting, in light of its unimplemented proposal to require mandatory notification of genetically modified foods, which would have been essentially GRAS notices. See FDA, Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 2001).

⁹ GAO Report at 37.

¹⁰ *Id.* at 39.

¹¹ *Id.* at 39.

The Immediate Impact on Industry of GAO's Report and FDA's Response Does Not Change the Status Quo.

In the short term, the impact on Industry of the GAO's report and FDA's response is likely negligible. FDA's commitment that it will finalize the 1997 proposed rule will simply result in FDA finalizing the current voluntary GRAS notification program, and FDA's regulation of the finalized voluntary GRAS notification program will remain largely the same as it is presently under the proposed rule. Similarly, FDA's commitment to issue draft guidance on the applicability of the GRAS concept to food applications of nanotechnology is in line with FDA's current approach to nanotechnology and will not change the voluntary nature of submitting GRAS determinations to FDA.

In the long term however, the GAO report and FDA's agreement with the report's recommendations reflect the recent shift in FDA's focus on food safety and FDA's increasing interest in obtaining greater knowledge of food and dietary supplement ingredients. In addition, the report supports the views of several organizations and consumer groups, who will likely use the report in demonstrating a need for increased FDA oversight of food safety. However, until FDA obtains additional authority from Congress, FDA cannot mandate submission of GRAS determinations. Similarly, without additional resources, FDA cannot conduct systematic reconsiderations of the safety of GRAS substances as it contracted for in the 1980's. Until such changes occur, the regulatory landscape of GRAS substances will remain the same.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

Peter Barton Hutt	202.662.5522	phutt@cov.com
Eugene Lambert	202.662.5422	elambert@cov.com
Miriam Guggenheim	202.662.5235	mguggenheim@cov.com
MaryJoy Ballantyne	202.662.5933	mballantyne@cov.com

This information is not intended as legal advice. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

Covington & Burling LLP, an international law firm, provides corporate, litigation and regulatory expertise to enable clients to achieve their goals. This communication is intended to bring relevant developments to our clients and other interested colleagues. Please send an email to unsubscribe@cov.com if you do not wish to receive future emails or electronic alerts.

© 2010 Covington & Burling LLP, 1201 Pennsylvania Avenue, NW, Washington, DC 20004-2401. All rights reserved.