

Legal News is part of our ongoing commitment to providing legal insight to our Food Industry clients and colleagues.

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House Panel Holds Second Food Safety Hearing

On Tuesday, July 17, 2007, the House Energy and Commerce Subcommittee on Oversight and Investigations held a second hearing on the U.S. Food and Drug Administration's (FDA) ability to safeguard the nation's food supply. The hearing, entitled "Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply? - Part 2," followed the subcommittee's first hearing on this issue which was held on April 24. Below are highlights of the testimony and discussions held during the hearing.

Witness Panels

Three panels of witnesses testified at the hearing. The witness list can be accessed at the following Web site along with the Webcast from the hearing: http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.071707.FoodSafety.Part2.shtml.

The first panel was comprised of investigative staff from the House Committee on Energy and Commerce who testified regarding FDA's handling of recent food safety problems as well as the Agency's capacity to deal with such problems in the future. A particular issue for the investigators was FDA's "systematic" lack of responsiveness to the committee and its investigative staff. The investigators indicated that it was "like pulling teeth" to get any information from FDA on food safety and other issues. In short, the committee's investigative staff drew the following conclusions from their investigation of FDA's response to the recent food contamination problems:

1. FDA regulation of food imports is minimal.
2. FDA's proposed reorganization of its field staff would likely expose Americans to even more danger from unsafe food, particularly imported food.
3. The spinach and peanut butter food poisoning outbreaks may highlight flaws in FDA's voluntary compliance approach to regulation.

The second panel was comprised of several district directors from FDA district offices in various states as well as former associate FDA commissioner William Hubbard and Caroline Smith DeWaal of the Center for Science in the Public Interest. A principal focus of this segment of the hearing was FDA's reorganization plan and the likely closure of several labs as well as the manner in which the labs and district offices responded to recent food contamination outbreaks. Former associate commissioner Hubbard provided some very insightful testimony, especially concerning FDA's ability and capacity to effectively respond to — as well as prepare for — food safety issues. Specifically, Mr. Hubbard suggested that FDA would need to double in size to adequately address food safety concerns in the United States. Mr. Hubbard also addressed the issue of mandatory country of origin labeling (COOL) for all food products sold in the United States and FDA certification of foreign food producers.

FDA Commissioner Dr. von Eschenbach, along with other FDA officials, including Dr. Robert Brackett, Director of the Center for Food Safety and Applied Nutrition and Margaret O'K. Glavin, Associate Commissioner for Regulatory Affairs, made up the third panel. Dr. von Eschenbach faced questioning from the committee on a variety of issues ranging from FDA's lack of responsiveness to the committee and concerns about FDA's reorganization plan to whether the Agency should be given mandatory recall authority and how it is funding personnel retention bonuses.

Issues Raised During the Hearing

■ **Country of Origin Labeling.** Former associate commissioner Hubbard suggested that imposing COOL requirements on the food industry would not be a good way to address food safety issues and that such requirements should not be used as a substitute for safe food. In particular, Mr. Hubbard cited the recent case of contaminated wheat gluten imported from China where the labels on the product were altered as an example of how easy it would be for bad actors to circumvent COOL requirements. Additionally, Mr. Hubbard suggested that

compliance with COOL requirements would present a logistical nightmare for food companies and U.S. Customs & Border Protection.

■ **FDA Reorganization.** The committee expressed concerns about FDA's reorganization plan and what it will entail. Of particular concern is FDA's lack of communication with the committee about the particulars of the plan, and FDA's plan to close certain labs across the country. Chairman Stupak indicated the committee may seek to impose language in FDA's funding legislation to prohibit the Agency from closing any labs until such time as the committee deems it appropriate. Also, concerns were noted that the reorganization will lead to a reduction in full time employees (FTEs) at the Agency. However, Commissioner von Eschenbach said that the reorganization plan is not intended to reduce the number of FTEs, but rather to consolidate and redeploy existing staff. The Commissioner further stressed that the reorganization will not lead to a reduction of functionality of the Agency and that it will be phased in over a period of several years.

■ **Mandatory Recall Authority.** As it was during the April hearing, the issue of whether FDA should have mandatory food recall authority was once again raised. Commissioner von Eschenbach indicated that, while he believes the voluntary recall system worked very well in the recent spate of food contaminations, it would be good for the Agency to have mandatory recall authority.

■ **Personnel Retention Bonuses.** Subcommittee Chairman Stupak expressed concern that \$10 million in funds authorized by the committee to be allocated for food safety and inspection purposes was spent on personnel retention bonuses. While Commissioner von Eschenbach indicated this was not the case and that the bonuses came from each Center's budget allocation, this response did not seem to assuage the Chairman's concerns.

■ **Foreign Certification/Authority for FDA to Impose Standards on Foreign Companies -** Unlike the United States Department of Agriculture (USDA), FDA does not currently have the authority to require that foreign countries and

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foreign food producers comply with U.S. food production and safety standards. This issue received much attention during the hearing with many members of the committee expressing their views that FDA should be given this authority. Commissioner von Eschenbach agreed that foreign countries should be held accountable for the quality of the products they export to the United States and indicated that FDA is considering whether it needs to request the authority to require and/or carry out foreign certifications similar to those imposed by USDA.

■ **FDA Restriction of Food Imports to Certain Ports.** It was noted during the hearing that USDA restricts imports of products it regulates to 10 ports so that inspection expertise can be concentrated at those locations. It was suggested that FDA should be given the same authority, although Commissioner von Eschenbach seemed reluctant to agree that this approach was a good idea for FDA-regulated food imports.

Implications for Industry

The committee members appeared convinced that FDA should be given the authority to certify foreign producers commensurate with USDA's authority in this area. Additionally, the committee continues to consider giving FDA mandatory recall authority. Further, the committee is obviously keeping a very close eye on FDA's use of resources and plans for reorganization. It continues to appear likely that the Agency will receive increased funding for food safety and inspection functions, with increased oversight from the committee as to how those funds are spent.