FDA Holds Public Hearing on Allergen Advisory Labeling

On September 16, 2008, the U.S. Food and Drug Administration’s (FDA’s) Center for Food Safety and Applied Nutrition (CFSAN) held a public hearing entitled “Current Trends in the Use of Allergen Advisory Labeling.” Allergen advisory labeling – also known as “may contain” labeling, precautionary labeling, or supplemental labeling – is voluntary labeling on food products that is intended to describe whether an allergen may be present in a product unintentionally. Examples of advisory labeling include: “May contain peanuts and wheat,” “Produced in a facility that processes egg,” or “Made on equipment that also manufactures products containing soy and milk.” The use of advisory labeling has proliferated within the past decade.

FDA’s objective for the hearing was to obtain information to assist the agency as it develops a “long-term strategy” to help manufacturers use allergen advisory labeling that is truthful and not misleading. FDA sought information concerning three primary issues: how manufacturers currently use advisory labeling; how consumers interpret advisory labeling statements; and how to communicate most effectively to consumers about the likelihood that an allergen unintentionally may be present in a food. The complete list of specific questions about which FDA has solicited comment is set forth at 73 Fed. Reg. 46302 (Aug. 8, 2009), Docket No. FDA-2008-N-0429.

Given the importance of allergen labeling to the health and safety of the millions of American consumers with food allergies, the strategy that FDA ultimately develops concerning advisory labeling may have wide-reaching impact on food labeling and potentially on food manufacturing practices. Food companies wishing to submit comments to FDA have until January 14, 2009 to do so.

Background

An allergen can be inadvertently introduced into food products that are not intended to contain that allergen through contact with a food contact surface (such as harvesting equipment or production or handling machinery) or airborne particles bearing the allergen. Such “cross-contact” can potentially occur at any stage of the manufacture of a food ingredient or product.

In 2004, Congress enacted a law intended to help improve allergen labeling: the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). The FALCPA imposed additional labeling declaration requirements on packaged food products that contain “major food allergens.” The FALCPA did not, however, impose labeling requirements when food products may inadvertently contain major allergens. The use of voluntary advisory labeling has therefore continued without federal regulation.

2 Id.
3 Id.
4 Title II of Public Law No. 108-282, 118 Stat. 891.
5 21 U.S.C. § 321(qq)(1) defines the eight major food allergens as milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, and any protein derived from these foods.
Although it did not impose advisory labeling requirements, the FALCPA directed the Secretary of the Department of Health and Human Services to submit to Congress a report analyzing, among other things, the prevalence of cross-contact, ways to mitigate cross-contact, how manufacturers use advisory labeling, how consumers would like information about cross-contact to be communicated, and the extent to which the Secretary and the food industry have effectively addressed cross-contact.\(^6\) FDA’s report, issued in July 2006, discussed the allergen control practices in some facilities, the ways in which some firms use advisory labeling, and the results of a survey on consumer interpretations of and preferences for various advisory labeling statements.\(^7\)

**Discussion at the Public Hearing**

Six panelists spoke at the public hearing; two people represented the food industry, consumer, and international perspectives on advisory labeling, respectively.\(^8\) All the panelists supported making the use and meaning of advisory labeling more standardized. Panelists who discussed the current use of advisory labeling in the United States stated that industry employs many different advisory labeling statements and no industry agreement exists about when particular statements are appropriate. This inconsistency has caused confusion among consumers about how to interpret the statements and has prompted some consumers to ignore advisory labeling altogether because they believe it is overused or not meaningful.

The industry representatives stated that advisory labeling should convey the message that consumers with a relevant food allergy should not consume the product. In contrast, the panelists representing consumers expressed an openness to potentially allowing advisory labeling – if it could be made more meaningful – to help food-allergic consumers assess the likelihood of risk posed by consuming a product. Panelists that addressed the placement of advisory labeling supported having advisory labeling appear near the ingredient list so that consumers can refer to a single place on a package to locate allergen information. The panelists that represented industry and international perspectives also affirmed that advisory labeling should not substitute for compliance with current good manufacturing practices.

FDA\(^9\) asked panelists a number of questions concerning the following topics:

- how to handle situations where the potential for cross-contact is extremely limited but would pose a significant threat to an allergic consumer if it did occur;
- whether the goal of advisory labeling should be to communicate that individuals with certain food allergies should not consume the product or to communicate the level of risk that the product may pose to food-allergic individuals;

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\(^6\) See FALCPA § 204.


\(^8\) Regina Hildwine, Senior Director, Food Labeling and Standards, Grocery Manufacturers Association of America, and Alison Bodor, Vice President of Regulatory and Scientific Affairs, National Confectioners Association, represented industry perspectives. Fiona Fleming, Consumer and Regulatory Affairs Director, George Weston Technologies, Australia and Sue Hattersley, Food Allergy Branch, United Kingdom represented international perspectives. Anne Muñoz-Furlong, Founder and CEO, Food Allergy & Anaphylaxis Network, and Scott Sicherer, MD, Associate Professor of Pediatrics, Jaffe Food Allergy Institute, Mount Sinai School of Medicine, New York, represented consumer perspectives.

\(^9\) The following FDA representatives asked questions: Barbara Schneeman, Ph.D., Director, Office of Nutrition, Labeling and Dietary Supplements (ONLDS), CFSAN; Felicia Billingslea, Director, Food Labeling and Standards Staff (FLSS); ONLDS, CFSAN; Valerie Madamba, General Attorney, Office of Chief Counsel, FDA; Stefano Lucchioni, MD, Medical Officer, Office of Food Additive Safety, CFSAN; Geraldine June, Supervisor, Product Evaluation and Labeling Team, FLSS, ONLDS, CFSAN; Edward Puro, Economist, Division of Social Sciences (DSS), Office of Regulations, Policy and Social Sciences (ORPSS), CFSAN; and Linda Verrill, Ph.D. Consumer Science Specialist, DSS, ORPSS, CFSAN.
whether consumers or health care providers prefer that allergen labeling statements indicate possible allergen levels, thereby providing a potential basis for evaluating risk; and

the impact that approaches to advisory labeling could have on small businesses.

FDA also asked panelists about the following initiatives on advisory labeling:

• voluntary guidelines for advisory labeling that were published in 2001 by the Food Allergy Issues Alliance, a coalition in the United States of industry representatives, a consumer group, and the academic community;

• an industry-developed initiative in Australia and New Zealand called Voluntary Incidental Trace Allergen Labeling (VITAL); and

• advisory labeling guidelines developed by the United Kingdom.

The Future of Advisory Labeling

In FDA’s opening comments and the questions it asked panelists, the agency did not indicate what elements its “long-term strategy” on advisory labeling would ultimately include (e.g., issuing guidance and/or promulgating formal regulations). Some questions that FDA posed in the Notice of Public Hearing begin with the phrase "if we develop guidance for using advisory labeling," suggesting that the agency is at least considering developing guidance on the topic.

In any event, it is likely that any action taken by FDA will take time. FDA characterized the public hearing as the "first step" in developing its strategy toward allergen advisory labeling. In addition, a number of panelists stated that they believe additional studies of consumer and health care provider behavior and preferences would be useful to FDA as it develops its strategy on this matter.

Given the potentially significant impact that any FDA action regarding advisory labeling could have on food labeling, and potentially on food manufacturing practices, food companies may wish to submit comments to FDA addressing the questions it raised in its Notice of Public Hearing. Written or electronic comments may be submitted to FDA until January 14, 2009.

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

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11 Id. at 46302.