Food Allergen Labeling Without Allergen Thresholds

by Evangelia C. Pelonis

Labeling for the top eight food allergens has been legally required since January 1, 2006 pursuant to the Food Allergen Labeling and Consumer Protection Act (FALCPA). Since that time the food industry has faced challenges in implementing the law, mostly due to the fact that allergen thresholds have not yet been established by the Food and Drug Administration (FDA). Thresholds are a de minimis level at which an allergen can be present in food without triggering a reaction in a sensitive individual. Establishing thresholds is no easy task because it is extremely difficult to determine the level of allergenic protein that poses a health risk since these levels vary based on the specific allergen and the individual’s sensitivity. Nevertheless, FDA must move forward to establish thresholds to prevent excessive labeling of products, which ultimately limits allergic consumers’ food choices.

Allergen Labeling Required by FALCPA

FALCPA, which amends the Federal Food, Drug and Cosmetic Act (FDCA), requires foods that are one of the top eight major food allergens and foods that contain protein from any of the top major food allergens to be labeled to inform the consumer that allergenic protein is present in the food. FDA will consider the food to be misbranded if the allergens are not disclosed. The top eight major food allergens include milk, egg, fish (e.g., bass, flounder or cod), Crustacean shellfish (e.g., crab, lobster or shrimp), tree nuts (e.g., almonds, pecans or walnuts), wheat, peanuts and soybeans.

Food allergen labeling can be accomplished in one of two ways. First, the allergen can be listed in the ingredient declaration as part of the ingredient name or in parentheses after the ingredient name, e.g., “artificial flavor (soybeans)” or “casein (milk).” In the alternative, or in addition to the ingredient declaration, the allergen can be listed in a “contains” statement, e.g., “contains milk.”

Previous to this law the common or usual name of some food ingredients did not disclose the presence of allergens. For example, before FALCPA, “casein,” a milk protein, was declared only by its common or usual name; now, under FALCPA the fact that this ingredient contains milk protein must be disclosed. Also, previous to FALCPA, spices, flavors and colors could be declared collectively without disclosing that they may contain allergenic protein. For example, an artificial flavor that contained soy protein did not have to communicate this to the consumer and could just be declared as “artificial flavor;” now, under FALCPA this information must be delivered to the consumer. Finally, FALCPA confirmed FDA’s position that incidental additives such as processing aids that contain allergenic protein must declare the presence of the allergenic protein.

Exemption Methods

FALCPA carves out two possible avenues to achieve an exemption from allergen labeling—the notification process and the petition process. Notifications must contain scientific evidence demonstrating that an ingredient does not contain allergenic protein. Petitions must provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that an ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health. Thresholds would help the food industry navigate the notification and petition process. For example, if thresholds existed, the petitioner could show that the protein is present below the particular threshold of concern and thus does not

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cause an allergenic response. Seven notifications and three petitions have been submitted to date, all of which have either been withdrawn or objected to by FDA.

Finally, highly refined oils and any ingredients derived from highly refined oils are exempt from allergen labeling even though these ingredients may have detectable levels of protein. This exemption has created uncertainty because the term “highly refined oil” is not defined. Allergenic proteins are generally not detected in hot solvent-extracted oils, but have been found in cold-pressed and deodorized oils. Since the legislation itself exempts ingredients with allergen protein it would be reasonable for FDA to establish thresholds so that foods/food ingredients that contain low levels of allergens may be eligible for an exemption.

Legislative History

Congress passed FALCPA to help allergic consumers avoid foods that contain allergenic protein and, thus protect them from potential reactions and health consequences. The legislative history clearly states that FDA should “adopt a reasonable standard for determining whether a food ingredient does not contain an allergenic protein” and that if thresholds are established “ingredients containing allergenic proteins below the established threshold would be eligible for the notification procedures.”

The thresholds referenced in the legislative history may be thresholds that would place the food/food ingredient outside the scope of FALCPA or thresholds that can be used by industry as a basis for submitting a notification or petition. Either way it is clear that Congress saw the need for establishing allergen thresholds and contemplated that FDA would do so.

FDA’s Position on Allergen Thresholds

FDA’s Threshold Working Group prepared a report in March 2006 entitled Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food that provides some insight into FDA’s position on allergen thresholds. The report also demonstrates how the scientific knowledge in this area does not meet the legal and regulatory need for well-defined allergen thresholds.

FDA’s report reviews four approaches that might be used to establish thresholds: 1) the analytical methods-based approach, whereby the threshold would be determined by the sensitivity of the analytical method used to verify compliance; 2) the safety assessment-based approach, whereby a safety factor is applied to the no observed adverse effect level (NOAEL) derived from existing human challenge studies; 3) the risk assessment-based approach, whereby the level of risk associated with a particular exposure is determined; and 4) the statutorily-derived approach, whereby a threshold is set by taking an exemption articulated in an applicable law and extrapolates from that to other similar situations. FDA concluded that the risk-assessment based approach provides the strongest, most transparent scientific analyses to establish thresholds, but that the available data are generally insufficient to support setting levels.

Further, the report establishes lowest observed adverse effect levels (LOAEL) in milligrams of protein for six of the top eight allergens. As discussed above, the LOAELs for specific allergens differ, which means it would be difficult to establish a single threshold for all the allergens since a single level would likely be the lowest level, and would be too low for some of the allergens. For example, according to the report, the lowest protein level that elicits an allergic response is 0.02 mg for tree nuts. If this level was chosen as the general threshold, foods containing greater than 0.02 mg protein would have to be labeled even though soy, for example, has not been found to elicit an allergic response in individuals at less than 88 mg.

Problems Relating to Absence of Thresholds

The food industry has encountered several problems as a result of operating without allergen thresholds. The most obvious issues involve the inability to obtain an exemption through the notification or petition process. Another example of issues that arise without thresholds is when alternative processing aids derived from one of the top allergens are required for a limited number of production runs. In such cases, the product would not otherwise be required to label for these allergens but technically if the processing aid contributes any allergenic protein it must be labeled even if only small amounts of the product contain protein for a short period of time.

Yet another example involves the “gluten free” proposed rule. In this proposal, FDA permits the use of a “gluten free” claim as long as the food contains less than 20 parts per million (ppm) gluten, essentially setting a threshold for gluten. The 20 ppm threshold was set based primarily on the level of sensitivity for gluten detection methods, which falls under the analytical methods-based approach. The rule leaves open the possibility that a gluten-free food, one that contains less than 20 ppm gluten, may still have to declare the presence...
of wheat at less than 20 ppm since there is no established threshold for wheat protein. Individuals suffering from Celiac disease are trained to avoid consumption of wheat since gluten is a wheat protein. Therefore, a "gluten-free" product that also declares wheat would cause much confusion among Celiac patients. FDA could eliminate this confusion by establishing a threshold for wheat that is consistent with the threshold for gluten.

FDA is in the process of releasing for comment a scientific safety assessment for gluten. Only after the comments regarding this safety assessment have been reviewed will FDA issue its final rule on gluten-free labeling. The 20 ppm threshold may change but a threshold of sorts will almost certainly be upheld. Without a threshold, gluten free labeling will be extremely difficult to accomplish, leaving those suffering from Celiac disease with few food choices. It has become clear that without thresholds it is also very difficult to deliver meaningful information to consumers who suffer from sensitivity to the other top allergens.

Conclusion

The food allergen arena will remain fluid as the science continues to develop. It is essential for the food industry and regulatory bodies to keep abreast of these developments and set policies that are flexible enough to track these developments. One way this could be accomplished is to set thresholds based on the method of detection, as was done in the gluten-free proposal, with an understanding that the threshold will be revisited on a periodic basis to ensure that the level chosen is the most scientifically sound level that exists at that time. This may be the only way to deliver the best information to the consumer in an environment where our knowledge is in flux.

3 See S. REP. NO. 108-226 (2004); “The committee intends that the Secretary will provide guidance to industry on the information that would be useful for making a determination that foods that contain protein derived from one of the eight food allergens do not cause an allergic response that poses a risk to human health. The committee also intends that the Secretary provide an appropriate process for providing such information to the Secretary that minimizes the burden on the food manufacturer.”