



**International Dairy Foods Association**  
Milk Industry Foundation  
National Cheese Institute  
International Ice Cream Association

August 16, 2005

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**RE: Docket No. 2005N-0231. Draft Report of the Threshold Working Group, Center for Food Safety and Applied Nutrition: Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food; Availability; Request for Comments and for Scientific Data and Information.**

Dear Sir or Madam:

The International Dairy Foods Association (IDFA) appreciates the opportunity to comment on the draft report, "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food." These comments are submitted on behalf of IDFA and its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. The 500 member companies of these associations represent processing and manufacturing facilities and their suppliers, and account for about 85% of the dairy products consumed in the United States.

As dairy processors and other food manufacturers move toward compliance with the Food Allergen Labeling and Consumer Protection Act (FALCPA), labeling minute amounts of allergenic proteins is proving complicated to accomplish with no proven benefit to the allergic community. Allergen thresholds, based on scientific data, will help the food industry provide the information needed by allergic consumers. As demand increases for gluten-free products, dairy processors, particularly cheesemakers, are interested in producing products that contain gluten at levels that would not compromise the health of consumers with celiac disease. Therefore, we appreciate FDA's thoughtful progress toward setting threshold levels for food allergens and gluten and we offer the following comments regarding the process.

## Allergens

As dairy processors consider the labeling requirements and ingredient implications of FALCPA, there are many issues related to the lack of threshold levels. While companies feel that the health and wellbeing of their consumers is of the utmost importance, they must also deal with the practicalities of providing food that is consistent and acceptable in flavor, texture and healthfulness to the general public. For reasons of consistency, availability and public acceptability, some ingredients are used in very small amounts. If these ingredients contain a protein derived from a major food allergen, the protein may be present in the finished food only in minute levels. Without threshold levels, the company may choose to eliminate the ingredient and completely re-formulate their product or to label their product as containing a major food allergen. Both of these options would involve significant costs and could cause a loss of sales. Additionally, labeling a product as containing a food allergen that is only present in a minute amount that may not cause an allergic reaction has the impact of severely limiting food choices for allergic consumers. If the amount of protein from an allergenic source is at such a low level that no allergic reaction would occur, an expensive change has been made without improving the safety of the product. Dairy processors are prepared to label ingredients that could cause an allergic individual to have a reaction, but reformulation or labeling changes with a significant economic impact but no health benefit are not acceptable.

IDFA strongly encourages FDA to carry out an allergen risk assessment in order to determine what levels of allergenic protein can cause reactions in allergic individuals. This risk assessment should also address whether there are some ingredients that may contain trace levels of protein from allergenic sources, but do not cause reactions in allergic individuals. Ingredients of particular concern include soy lecithin and fish gelatin.

We also urge FDA to review the information on allergens from other countries, such as Canada's database on adverse reactions, and the European Union's directive on exemptions of certain food ingredients. The information on adverse reactions and the data supporting ingredient exemption could be helpful in determining what data are needed to set thresholds.

No matter which method is eventually used to set allergen threshold levels, there must be validated analytical methods for all allergens before the thresholds are implemented. If allergen labeling relies on the accurate determination of levels above or below the set thresholds, then accepted methods must be available to test whether allergens are present above or below the thresholds. Currently, only one validated analytical method exists; other methods must be accepted by FDA or another independent authoritative body, such as AOAC, before the food industry can be held to defined threshold levels.

Analytical Methods-Based Approach: While this method could be used more quickly in some cases than the other approaches outlined by the report, there are some potential problems with this approach. Currently there is only one validated method for allergen testing, that for peanut protein, which means that there would be no analytical level for

use in setting thresholds for the other major allergens. Another potential problem is the continual improvements in testing sensitivity. As the tests become more sensitive and capable of detecting smaller and smaller levels of allergenic proteins, the detection limits may well become lower than the levels at which allergic individuals react. This would cause labeling of allergens when there is no danger of an allergic reaction. Based on these two significant problems, IDFA does not recommend the use of the analytical methods-based approach in the long term. If it were to be used in the short term, the levels derived from analytical methods should apply only to the allergen tested for by that specific method. For example, the validated method for peanut should only be used to set a threshold for peanut protein, not for hazelnut or cashew.

Safety Assessment-Based Approach: IDFA believes that this would be an appropriate method for setting allergen thresholds. Currently, enough data exists to establish threshold levels for peanut, egg and milk, however additional information will be needed to determine the No Observed Adverse Effect Level (NOAEL) or the Lowest Observed Adverse Effect Level (LOAEL) in order to set thresholds for other allergens. According to data presented at the Food Allergen Research and Resource Program's first Threshold Conference, multiple studies since the 1970s have shown LOAELs for peanut (0.25 - 66 mg), egg (0.13 - 200 mg) and milk (0.6 - 180 mg). An uncertainty factor of 100 should allow for the intraspecies difference with extra allowance for particularly sensitive individuals. The number of studies currently available for these three allergens is sufficient to set a threshold level.

In regard to other allergens for which enough information does not yet exist, safety studies from other countries may be helpful, either for the data gathered from those studies (if it can be generalized to the American population) or for using similar testing protocols that allow the most sensitive individuals to participate in American studies.

FDA's draft report proposes the option of setting a single threshold level at the LOAEL of the most potent allergen. This brings forward the complication of determining which allergen has the lowest LOAEL without already knowing the LOAEL for each allergen. In addition, this approach would most likely set the threshold lower than would be required for the majority of food allergens, unnecessarily limiting the foods available to allergic consumers. This strategy of using the single lowest LOAEL to set a threshold level for all allergens would not be an appropriate way to set threshold levels.

IDFA urges FDA to use the safety assessment-based approach to set threshold levels for peanut, milk and egg allergens immediately. Data collection on the other allergens should continue in order to develop NOAELs or LOAELs and threshold levels for each allergen.

Risk Assessment-Based Approach: The risk assessment-based approach has many of the same strengths and weaknesses of the safety assessment-based approach. With an adequate scientific base, this approach could be an acceptable method to set allergen thresholds. At this time, however, there is not enough data to adequately address the risks involved and decide what threshold levels are appropriate. A risk assessment and

additional research on allergenic reactions should be conducted before this approach is used. As with the safety assessment-based approach, determining an uncertainty factor will be a challenge, as will identifying an acceptable level of risk.

Statutorily Derived Approach: Since FALCPA exempted highly refined oils from the definition of major food allergens, the final approach outlined in the report sets allergen thresholds at the level of protein found in these highly refined oils. Based on information provided at the public meeting of the Food Advisory Committee, there are such significant problems with determining the amount of protein in highly refined oils that this approach might not be accurate or helpful. According to Dr. Susan Hefle, the method for removing the protein from the oil in order to measure the protein content has flaws that interfere with an accurate measurement. Without an accurate quantification of the allergenic protein in ingredients that are already exempted from labeling, there will not be a strong basis for this method. Unless there was a way to accurately assess the level of protein in highly refined oils, IDFA does not recommend the use of the statutorily derived approach.

Another option for an approach to set allergen thresholds is to meld together the various approaches, based on what would work best for each allergen, with a move toward one of the scientific based approaches (safety assessment-based or risk assessment-based) as more data becomes available. This would give the food industry the ability to use thresholds for labeling before the collection and analysis of the large amount of data required for the safety assessment-based or risk assessment-based approaches. As an example, an ingredient could initially be exempted when it is shown to contain a non-detectable level of protein from a major food allergen. As more data becomes available, a risk assessment or safety assessment could be conducted in order to set a threshold for that major food allergen. When the threshold is set, the exemption for that ingredient should no longer be based on non-detection of protein, but instead on the scientifically based threshold level. Each allergen should move independently through this process. Allergens for which enough data already exists to determine a threshold using the safety assessment-based method should have threshold levels set through that approach.

## **Gluten**

Since the approaches recommended by the draft report are the same for gluten as they are for allergens with the exception of the statutorily derived approach, many of the same challenges and strengths exist for setting a gluten threshold. In the dairy industry, gluten is of the most concern for cheesemakers. Many of the ingredients used in very small amounts in cheeses, such as anti-caking agents, may be derived from wheat. In addition, some cheese cultures are grown on bread or wheat-based media. These can be issues of concern for celiac patients and other consumers who need to avoid gluten.

As with food allergens, the international community may be able to provide resources and models for setting a gluten threshold. Canada, Australia and New Zealand have set thresholds for gluten, in addition to work by the Codex Committee on Nutrition and Foods for Special Dietary Uses.

Analytical Methods-Based Approach: While this method could be used more quickly in some cases than the other approaches outlined by the report, there are potential problems with the methodology for detecting gluten. As with allergen testing, as the tests become more sensitive and capable of detecting smaller and smaller levels of gluten, the detection limits may well become lower than the levels at which celiac patients have negative reactions. This would cause products to be ineligible to make "gluten free" statements, even though there is no danger of a reaction. Based on this significant problem, IDFA does not recommend the use of the analytical methods-based approach.

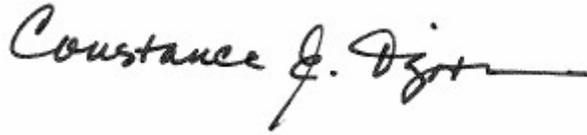
Safety Assessment-Based Approach: There appears to be enough scientific data to reasonably set a Lowest Observed Adverse Effect Level (LOAEL) and therefore, a threshold level, for gluten. As additional data comes forward on chronic exposure to low levels of gluten and on reactions of celiac patients to gluten, this LOAEL may have to be updated. However, IDFA believes that there are enough high quality studies that allow a LOAEL to be set at this time. As more data is collected in order to update the LOAEL, safety studies from other countries may be helpful, either for the data gathered from those studies (if it can be generalized to the American population) or for using similar testing protocols. Determining the uncertainty factor will be another challenge of this approach. Requiring both a 10-fold uncertainty factor to accommodate the extrapolation from a LOAEL and a 6-fold uncertainty factor for chronic exposure seems redundant. A 100-fold uncertainty factor that allows for intraspecies difference and extrapolation from the LOAEL should protect individuals while also allowing the food industry to actually produce foods that can be labeled "gluten free." IDFA believes that the safety assessment-based approach is an appropriate way to set a threshold levels for gluten.

Risk Assessment-Based Approach: The risk assessment-based approach has many of the same strengths and weaknesses as the safety assessment-based approach. With an adequate scientific base, this approach could be successfully used to set a gluten threshold. At this time, however, there is not enough data to adequately address the risks involved and decide what threshold level is appropriate. A risk assessment and additional research on reactions to gluten should be conducted before this approach is used. As with the safety assessment-based approach, determining an uncertainty factor will be a challenge, as will determining what level of risk is acceptable for the approach. The risk assessment-based approach would be a compelling method to derive a gluten threshold when there is adequate science to support the approach.

Identifying appropriate methods for setting thresholds for food allergens and for gluten will allow the determined threshold levels to ensure the safety of consumers who are sensitive to allergens and gluten while also allowing the food industry to continue using ingredients that help provide nutritious products that are enjoyed by all consumers. IDFA believes that the best method for developing a threshold level would be an approach that utilizes the most appropriate method for each allergen and gluten, based on the amount of information available, while moving toward the strong scientific basis of the safety assessment-based approach or the risk assessment-based approach. Setting thresholds is

in the best interest of both consumers and the dairy industry. Please contact us if there is anything we can do to assist in this process.

Sincerely,

A handwritten signature in black ink that reads "Constance E. Tipton". The signature is written in a cursive style with a horizontal line at the end.

Constance E. Tipton  
President and CEO