



January 12, 2009

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

RE: Docket No. FDA-2008-N-0429: Food Labeling: Current Trends in the Use of Allergen Advisory Labeling: Its Use, Effectiveness, and Consumer Perception; Public Hearing; Request for Comments

To Whom It May Concern:

The International Dairy Foods Association (IDFA) is pleased to provide comments regarding allergen advisory labeling. Dairy processors are very concerned about providing useful and accurate information to their consumers, particularly related to allergens which can pose serious health risks for some consumers.

IDFA, which represents the nation's dairy processing and manufacturing industries and their suppliers, is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI), and the International Ice Cream Association (IICA). Its 250-plus members range from large multinational corporations to single-plant operations, representing more than 85% of the volume of milk, cultured products, cheese, ice cream and frozen desserts produced and marketed in the United States.

The following comments address issues raised in FDA's request for comments and also from the public meeting held on September 16, 2008 on the topic of allergen advisory labeling.

IDFA believes that any FDA guidelines regarding allergen advisory labeling should be strictly voluntary. Guidance on the format of such statements would be appropriate so that consumers see a consistent appearance and information. Additionally, guidance would be useful to standardize a few phrases for use in advisory labeling. This will provide manufacturers the flexibility to provide information to consumers using truthful statements regarding the possible presence of allergens while also giving information to consumers in a clearly understandable format and with language that they trust. If voluntary guidelines were to be issued, FDA could still enforce the accuracy of advisory statements through the general requirement for all labeling statements to be "truthful and not misleading."

Dairy manufacturers occasionally use allergen advisory statements to communicate to allergic consumers or their caregivers that the food could have a potential risk of contamination from an undeclared allergen and that it may not be safe for them to consume. An advisory statement is usually the most truthful way to communicate this message because declaring the allergen in the ingredient statement or a "contains" statement would indicate the intentional and continuous presence of the allergenic ingredient.

The issue of allergen advisory labeling once again raises the importance of having reliable thresholds that are based on science and trusted by consumers and the food industry. Currently, without thresholds, there is zero tolerance for allergenic protein and ingredients are being labeled or eliminated at significant cost with an unknown health benefit. Similarly, thresholds are important for companies trying to make informed decisions about allergen advisory labeling. If thresholds were set that defined the levels at which advisory statements should be made, this would allow companies to make the most accurate and useful statements for their consumers.

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 and use the risk assessment results as the basis for threshold levels. 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 believe that there is research underway now to conduct a statistical risk assessment for peanut allergens. This research could be useful in setting a functional threshold that will make allergen labeling more accurate and useful.

These threshold levels would not replace the need for Good Manufacturing Practices in food manufacturing facilities. These levels would guide a company to use the most appropriate labeling if an allergen was present, despite the use of Good Manufacturing Practices.

In addition to defined allergen threshold levels, there must be validated analytical testing 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. Additional test 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.

In response to the specific questions posed by FDA, IDFA will address the use of advisory labeling by dairy processors.

Question 1: What manufacturing circumstances prompt manufacturers to place advisory statements on a food label? What manufacturing

circumstances do not prompt manufacturers to include an advisory statement? Why?

There are many reasons for processors to make allergen advisory statements declaring the potential of unintentional cross-contact affecting the product. Companies examine their ingredients, processes and equipment to identify areas where unintentional cross-contact may occur. Based on the details of the manufacturer's ingredients and processes, companies make a decision to add advisory labeling statements as appropriate.

There are some particular areas of concern that pose problems for many companies where it is difficult to determine appropriate labeling that is still helpful for allergic consumers. Companies try to find the best alternative that will be helpful for consumers while still be workable for the company.

One of these problematic situations is how to appropriately label a product with a single SKU that is manufactured in multiple locations that represent different risks of cross contact. Some companies choose to make all the allergen labeling the same, meaning that some packages with no possibility of cross-contact with an allergen are over-labeled and not available to allergic consumers. Some companies choose to have a different label for each manufacturing situation, meaning that the labeling is more accurate, but packaging inventory can be more complicated and consumers may be confused if they see two packages of the same product with different allergen advisory information. Any guidance on allergen advisory labeling needs to be flexible enough to allow companies to tailor their allergen messages based on the company's situation and the feedback that they receive from their particular consumers.

Many companies also wrestle with issues related to seasonality of certain products. For example, many fluid milk plants only deal with milks and possibly juices for the majority of the year. This means that only one allergen (milk) is present in the plant for that time. However, in the fall, many of these plants start producing eggnog as a seasonal specialty. This introduces egg as a second allergen into the plant and the possibility of cross-contact. Depending on the company, different packaging may be used to designate the presence of egg in the facility at this time of year. However, this can lead to consumer confusion when eggnog season is over and the advisory labeling disappears-- consumers are unsure whether the company's allergen labeling policy has changed or if the actual risk has changed.

Question 2: If we decide to develop guidance for using advisory labeling, should we incorporate any of the guidelines from the Food Allergy Issues Alliance or the principals of the VITAL system? If so, why?

As a member of the Food Allergen Issues Alliance, IDFA would strongly encourage FDA to utilize the criteria developed by that group as the basis for any federal guidelines regarding allergen advisory labeling. These guidelines address many of the concerns that consumers have regarding confusing allergen advisory labeling. At the same time, there

is enough flexibility in the program to allow each company to adapt the labeling to the particular manufacturing situation and the needs of their consumers.

The VITAL program is based upon threshold levels that define the type of labeling that should appear on a food label. Without defined thresholds for each food allergen, the VITAL system is not feasible for use in the United States at this time.

Question 3: Are there circumstances under which there is no possibility of cross-contact with a food allergen? If so, what are they?

While food manufacturers and their suppliers can take every precaution available to them to reduce the risk of cross-contact with a food allergen, there is never zero risk. Because of the possibility of human error and the ubiquity of many food allergens, there is always the possibility of cross-contact throughout the food chain, from farm to fork. Cross-contact can occur at any point before a person consumes a food or beverage, not just in manufacturing facilities. Consistent with past FDA guidance and the Food Allergy Issues Alliance, labeling cannot be used in place of Good Manufacturing Practices, but GMPs allow for risk management, not the complete elimination of risk.

Question 4: When manufacturers declare an allergenic ingredient in the ingredient list or in the "Contains" statement, do they also use an advisory statement indicating the presence of that ingredient? If so, why?

Our members report that they include allergens known to be in the product in the ingredient statement or a separate "contains" statement in accordance with the requirements of the Food Allergen Labeling and Consumer Protection Act (FALCPA). For allergens that may or may not be present in the food, most dairy companies use an advisory statement since it is a truthful statement that gives appropriate information to allergic consumers. These companies do not declare the same ingredient in both statements since this could result in consumer confusion.

Question 5: What criteria and considerations does a small firm rely on when determining whether to use advisory labeling? Are these the same criteria and considerations that a large firm relies on? How frequently does a small firm use advisory labeling compared to a large firm? If we decide to develop guidance for using advisory labeling, what options should we investigate to consider the circumstances of small firms?

The criteria and considerations for allergen labeling are more likely to vary between individual companies, based on their production systems, ingredients and products rather than varying between companies based on size. For larger companies that have multiple production sites, the risk of cross-contact and therefore the considerations for using labeling, can vary within the company as well.

One major issue to consider is that if mandatory labeling changes are required, the costs of such a labeling change can disproportionately affect smaller companies, particularly those with significant numbers of SKUs and unused packaging inventory.

Question 6: How do manufacturers decide whether to label their finished products with advisory labeling when their incoming ingredients are labeled with advisory statements?

Ingredients that make "may contain" or other allergen advisory statements can be particularly troublesome for food processors and manufacturers. Often, companies will work with their supplier to investigate the Good Manufacturing Practices in use by the supplier and the reasons behind the statement on the ingredient. Depending on the reasons for labeling of the ingredient, the company makes the decision about how to label their finished product. They may also choose to reformulate their product to eliminate an ingredient that has problematic labeling or they may choose to change suppliers to another company that does not have the same level of risk for cross-contamination.

One major concern for companies is the issue of legal liability. Even if they feel that there is no need to label "may contain" on the finished product, a company may still do so because of the concern of liability from not bringing the statement forward. Many companies have a policy of bringing advisory labeling forward to a finished product label to eliminate the possibility of liability that could result from not including these statements.

Any guidance should make clear that the criteria for making allergen advisory statements on finished products should also apply to ingredients as well. While the statements on finished products would provide reassurance to consumers, similar statements on ingredients would reassure manufacturers that the statements they carry forward are truthful and accurate. In the end, this could reduce possible overlabeling of allergens on both ingredients and food products and help assure consumer confidence in advisory statements.

IDFA agrees that guidance from FDA regarding allergen advisory statements would be useful to the food industry and helpful to consumers. A consistent approach would allow consumers to understand the messages they see on the food labels. However, it is important that this guidance be flexible enough to allow for truthful statements that appropriately characterize the potential presence of allergens in a food or beverage. Dairy processors are proud of the healthy products they provide to Americans and will continue to work to ensure that the products are safe for all consumers, including those with food allergies.

Sincerely,



Cary Frye
Vice President, Regulatory and Scientific Affairs