

INDEPENDENT BAKERS ASSOCIATION

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October 24, 2001

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

Re: [Docket No. 00P-1322] Food Safety and Food Labeling; Presence and Labeling of Allergens in Foods,
66 Fed. Reg. 38591 (July 25, 2001)

To the Food and Drug Administration:

The Independent Bakers Association ("IBA") is a Washington, DC based international trade association for the wholesale baking industry. Our over 400 members are mostly small to medium sized family-owned wholesale bakers and allied industry trades.

IBA notes that in recent years food manufacturers have worked diligently to address the concerns and needs of consumers with food allergies. Groups such as the Food Allergy Issues Alliance and the National Food Processors Association are instrumental in these efforts. The food industry's efforts, and the efforts of FDA, are focused on the "major" food allergens: peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat.

IBA's comments primarily concern the following topics: (1) advisory labeling (e.g., "may contain _____" or "made on shared equipment"), and (2) source or "plain English" labeling.

Advisory Labeling

If Cross Contact Could Occur Despite Compliance With GMPs, Advisory Labeling Is Appropriate.

IBA agrees with FDA that advisory labeling statements, such as "may contain _____" or "made on shared equipment" should not be used in lieu of adherence to good manufacturing practices ("GMPs"). We note in this regard that existing GMPs obligate manufacturers to take reasonable precautions to prevent cross contact with major food allergens. Those GMPs, of course, are underpinned by the Food, Drug and Cosmetic Act's legal mandates regarding food manufacturing.

However, in those situations in which such cross contact could occur despite compliance with GMPs, IBA believes that advisory labeling is appropriate and necessary. As FDA stated in the July 25, 2001 notice, the only successful method for a food-allergic person to manage the allergy is to avoid foods containing the allergen. The purpose of advisory labeling is to protect such persons, by giving them the information they need to make an informed decision before purchasing and eventually consuming a product.

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Currently, there are no established quantitative thresholds for the amount of allergenic protein required to cause an allergic reaction. In other words, there are no established "safe" levels for allergenic protein. Manufacturers must therefore assume that even a minute amount of such protein could cause a reaction in certain very sensitive persons.

It is also important to understand that, although it is possible to do some testing for the presence of allergenic protein in foods, the technology for such testing is simply not well developed. Standards that would provide common interpretive scales among the various types of test kits have yet to be established, and much work remains to be done to develop those standards. Further, test kits are not available for all the major allergens.

Given these conditions - no established "safe" levels for allergenic protein, and testing technology at an early stage of development - there will be situations in which a responsible manufacturer should use advisory labeling.

IBA also believes that if a manufacturer uses advisory labeling for an item, all packages of the item should bear that labeling. In order to avoid possible confusion by consumers, the manufacturer should follow this practice even if some units of the item are produced at a facility where there is no risk of cross contact.

Wording of Advisory Labeling

In those situations in which advisory labeling is appropriate, IBA believes that the manufacturer should be permitted to choose the wording of the advisory labeling statement, provided that the statement is truthful and not misleading. In our view the manufacturer is the party that can best determine what wording is appropriate for its particular product. We would oppose a "one size fits all" approach to advisory labeling.

It is especially important that manufacturers be permitted to make truthful, non-misleading statements of fact on the label. In particular, IBA would oppose any attempt to prohibit a "shared equipment" notice. This type of notice (such as "ALLERGEN INFORMATION: MANUFACTURED ON EQUIPMENT THAT PROCESSES PRODUCTS CONTAINING _____") is in widespread use. The "shared equipment" notice has been well received by consumers, and has been endorsed by the Food Allergy Research & Resource Program and the Food Allergy and Anaphylaxis Network (formerly known as the Food Allergy Network).

Location and Prominence of Advisory Labeling

IBA believes that the advisory labeling statement should appear on the information panel of the label, adjacent to the ingredient statement. This location is where consumers are accustomed to looking for information about a product's contents. We also believe that the advisory labeling statement should be in a type size and style that are no less prominent than the type size and style used for the product's ingredient statement.²

IBA's recommendations for location and prominence of advisory labeling are consistent with the consensus of the food industry on this subject. Competitive pressures and consumer demand dictate that

¹ In addition, we note that until the relevant quantitative thresholds for allergenic protein have been developed, it will not be possible to effectively interpret test results.

² Because the ingredient statement and the advisory labeling statement both contain important information for the food-allergic consumer, we do not believe that FDA should mandate a different or special type size or style for the advisory labeling statement.

manufacturers conform their labels to that consensus view. Consequently, we believe that rulemaking activity on this subject is probably not necessary.³

**The Manufacturing Process Mandates Of The
Nine Attorneys General Should Not Be Adopted.**

The petition filed by the attorneys general of nine States (the "nine attorneys general") asserts that advisory labeling should only be permitted if the manufacturer follows certain specified procedures in the production labeling process. Those specified procedures include dedicating facilities and production lines solely to products that do not contain allergenic substances, a requirement that will impose enormous costs on the food industry. The nine attorneys general also propose to mandate periodic testing for migration of allergenic substances, despite the fact that adequate technology for such testing is not well developed.

As noted above, existing GMPs already require that manufacturers take reasonable precautions to prevent cross contact with major food allergens. IBA urges FDA not to adopt these recommendations of the nine attorneys general.

Source or "Plain English" Labeling

IBA Endorses Use Of This Labeling.

IBA endorses the use of source or "plain English" terms in labeling the major allergens. For example, when a milk derivative such as sodium caseinate is included in the ingredient statement, it is appropriate to couple the ingredient name with the simplified term "milk."

We also believe that there is general agreement in the food industry that source or "plain English" labeling is appropriate for the major allergens. Further, although formats for such labeling may differ somewhat among manufacturers, there is a consensus that such labeling should be placed on the information panel and should clearly communicate the simplified information.

Here again we believe that competitive pressure and consumer demand are dictating that manufacturers adhere to the industry consensus, and we question the need for regulations that would mandate source or "plain English" labeling. We understand that, in order to mandate such labeling, FDA would have to amend numerous regulations on standards of identity and other topics. The rulemaking process would be complex and time consuming. In addition, initiation of such rulemaking may cause some manufacturers to take a "wait and see" approach and not implement source or "plain English" labeling until the rulemaking has been completed.

IBA Opposes the Recommendations of the Nine Attorneys General.

The nine attorneys general have proposed that FDA mandate two label notices: "ALLERGEN INFORMATION: This product contains _____," and "ALLERGEN INFORMATION: May contain _____." We are concerned that the juxtaposition of these two notices may prove confusing to consumers, and may cause consumers to question the integrity of the product's ingredient statement. Consequently, we do not support that proposed format.

The nine attorneys general have also asked FDA to require that all food packages which contain a major allergen display a "circle A" insignia on the principal display panel. Implementation of that

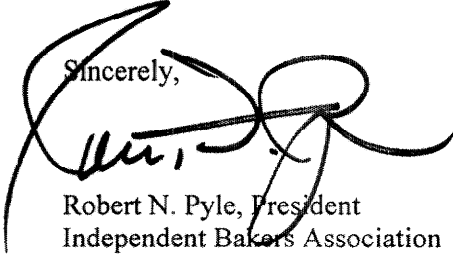
³ The nine attorneys general have proposed that FDA mandate two separate label notices: "ALLERGEN INFORMATION: This product contains _____" and "ALLERGEN INFORMATION: May contain _____." As discussed below, in our view this format may confuse consumers and we do not support it.

recommendation would be extremely costly for the food industry, and we do not believe it would provide any significant benefit to the food-allergic consumer.

In considering the "circle A" idea, it is important to keep in mind that most packaged foods contain one or more major allergens. Thus, most packages would bear the "circle A" insignia, and it is hard to see how this notice would provide useful information to the food-allergic consumer. The consumer would still have to read the ingredient label to know which allergens are involved. IBA therefore opposes that recommendation.

IBA appreciates the opportunity to comment on these issues, which are of great importance to our members. Our members share FDA's commitment to food safety and to accurate and informative food labels.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Pyle", written over the word "Sincerely,".

Robert N. Pyle, President
Independent Bakers Association

cc: CFSAN Nutrition Labeling Office