American Bakers Association

Serving the Baking Industry Since 1897

October 29, 2001

Dockets Management Branch (HFA-305)
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)

Comments of the
American Bakers Association

These comments are submitted by the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. The Association's membership consists of approximately 300 bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. These comments focus on FDA's notice for a public meeting and for additional written comments on the various questions published to stimulate discussion and to obtain information to assist the agency in determining what additional action, if any, may be necessary to provide consumers with adequate information on product labels.

ABA Voluntary Allergen Labeling Guidance Document

ABA believes that a voluntary labeling approach should be implemented by the baking industry to address the "big eight" allergens. Voluntary guidelines for a comprehensive allergen management program have already been established for the baking industry (ABA Allergen Guidance Document, March 2000; document attached). This program serves the industry as a resource to provide guidance in the identification and management of potential food allergens, including use of good manufacturing practices (GMPs), strategies for operations, ingredients, packaging, sales/marketing, allergen awareness and consumer response. ABA posted this guidance document on its website last year to enable the entire baking industry to utilize it, and ABA has also worked with the American Institute of Baking (AIB) to circulate this approach further. In these comments, ABA will address additional labeling procedures for packaging that could be added to its current program and be used by the entire baking industry.

00P-1322 C469

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Source or Plain English Labeling

The American Bakers Association has concerns over a "plain English" language approach to labeling for several reasons. ABA believes that if "plain English" were to be used in place of proper ingredient names, that would be an encroachment of standards of identity/misbranding. Since accuracy of labeling has always been a priority, ABA questions whether such an approach would be beneficial.

If FDA proceeds with a "plain English" language approach that would lengthen existing ingredient legends, they would need to establish special allowances for small packaging that would have space constraints for some bakery products such as snack cakes, refrigerated dough, crackers, cookies and other sweet goods in small packages. ABA proposes that plain English labeling can be accomplished by means of a parenthetical statement accompanying the proper name of the ingredient. (For example: sodium caseinate would be coupled with the parenthetical "milk".) In recognition of the constraints on small packaging, as well as on all other types of bakery packaging, ABA believes that once a source is listed the first time, the parenthetical should not be required subsequently, since the first listing would confirm the inclusion of the allergen in the product and would alert the allergenic consumer to the presence of a specific allergen.

Advisory Labeling

ABA recommends a voluntary approach for advisory labeling. Despite adherence to GMPs that include allergen control strategies, such as separation and thorough cleaning, there are circumstances where it is not practical to conclude that all potential for cross contact has been eliminated, therefore in such situations, advisory labeling would be appropriate. In such cases, ABA believes that there is one critical criterion in determining if such a statement is needed: When good manufacturing practices (GMPs) including other allergen control strategies are being followed, and are not reliable in consistently eliminating the presence of a "big eight" food allergen. Currently, there is no established quantitative threshold regarding the amount of allergenic protein required to cause an allergic reaction. Therefore, manufacturers must assume that even a minute amount of allergenic protein could cause a reaction in certain highly sensitive, allergic consumers. Given these conditions, and the fact that the only method for a food allergic person to manage the allergy is to avoid the allergenic food, there will be situations in which a responsible manufacturer should use advisory labeling. ABA strongly believes that this is a concise, responsible and logical approach.

Such a supplemental statement should be located in close proximity to the ingredient legend. Further, ABA believes that the best statement to use in such cases would be "Made on shared equipment with (name specific allergen)". ABA bases this conclusion on data provided by the Food Allergen Network which indicated that 87% of their members favor this type of labeling because it provides the information that they seek regarding possible allergen cross-contact. Such a statement is factual, descriptive of the situation,

and provides food allergic consumers with the information that they need to make an informed food purchase decision.

Labeling of Ingredients Exempted from Labeling/Labeling of Incidental Additives

ABA believes that there should be a mandatory labeling policy for "big eight" allergens that are included in flavorings, spices and colors. There are no established thresholds that cause allergic reactions to food; therefore, if a "big eight" food allergen is present, it should be labeled. FDA should codify its policy to specifically state that incidental additives that are food allergens are not exempt from labeling and must be declared in the ingredient statement on the label. This policy should apply to ingredients, mixes, intermediate food products, processing aids and incidental additives alike, regardless of the amount of the allergen included in the formula. This policy change would require FDA to mandate suppliers to give accurate information to their customers on the "big eight" allergenic ingredients included in their proprietary formulas.

Food Allergy Issues Alliance Allergen Labeling Guidelines

The Food Allergy Issues Alliance finalized its Food Allergen Labeling Guidelines and submitted it to FDA at the end of May 2001. This plan attempts to provide voluntary guidelines that will result in consistency in labeling of food allergens to address the needs of allergic consumers. The document features five plain English labeling options for manufacturers and discusses a set of criteria for determining the need for supplemental labeling language.

Even though ABA was an Alliance member and participated in the drafting of the document, ABA could not endorse the final document. While ABA believes that there is merit to the foundation of the Alliance's plan, which has similarities to the ABA Allergen Guidance Document, ABA members strongly believe that the five labeling options presented in the Alliance plan would be overwhelming and confusing to consumers and manufacturers alike. Further, ABA members believe that the criteria for supplemental labeling are repetitious and would be confusing to manufacturers. ABA supports a simple and concise plan that would best serve consumers, industry and government. ABA strongly believes that clear and concise ingredient labeling is the most accurate and simple way to provide information to the consumer. It is ABA's hope that the comments we have included in this document will assist the agency in streamlining ingredient listings and provide full allergen disclosure on the label for the consumer.

Petition Filed by the Attorneys General of Nine States

The petition filed by the attorneys general of nine States asserts that advisory labeling should only be permitted if the manufacturer has followed certain required procedures in the production process. The petition specifies procedures that include dedicating facilities and production lines solely to products that do not contain allergenic

substances. These overly burdensome requirements would impose enormous costs for the baking industry. Both large and small manufacturers alike would be severely impacted and could be forced to discontinue a variety of product lines.

Additionally, despite the fact that technology for allergen testing of all "big eight" food allergens and allergen standards are not complete in development, the attorneys general petition suggests periodic testing for migration of allergenic substances. Existing GMPs already require that manufacturers take reasonable precautions to prevent cross contact with "big eight" allergenic substances. In addition, in the absence of known thresholds that trigger allergic reactions and in the absence of test kits available to all "big eight" food allergens – it is unclear how such testing would be fully conclusive.

Also, ABA notes that the nine attorneys general proposed that FDA mandate two label notices: "Allergen Information: This products contains _____ " and "Allergen Information: May contain _____." ABA believes that the combination of these two notices may be confusing to consumers, and may create consumer doubt regarding the integrity of the product's ingredient statement. For these reasons listed above, ABA urges FDA not to adopt the proposals as written by the nine attorneys general.

FDA Allergen Compliance Document

ABA would also like to take this opportunity to share our concerns regarding language in the FDA Allergen Compliance document regarding allergen consideration beyond the "big eight" during plant inspections. ABA is concerned that there is not a definitive, clear list and one that has been published by the agency for the information of industry so that we can address these issues.

ABA appreciates this opportunity to comment on this notice which is of great interest to the wholesale baking industry. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,

Paul C. Abenante
President & CEO
American Bakers Association

Attachment

American Bakers Association

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ABA Allergen Usage Guidelines

Food Allergens

A food allergen is a product or ingredient containing certain proteins that can potentially cause a severe (occasionally fatal) reaction in a food allergic person. There are currently over 170 food allergens identified. The most prevalent in the U.S. have been identified as peanuts, tree nuts, crustacea (shellfish), fish, eggs, dairy products, wheat, and soy. Other countries may use variations of this list.

ABA Allergen Goal

The goal is to provide guidance to all bakers in the identification and management of potential food allergens, including strategies for operations, ingredients, packaging, sales/marketing, awareness, and consumer response.

The attached audit forms have been compiled to help each plant assess their risk by production line. The usage guidelines offer suggestions on ways to reduce the risk of producing finished product containing unlabeled allergens.

Cleaning, product protection, and operational practices must be adequately designed and implemented to avoid allergen contamination. Effective implementation of GMP's is essential. After an allergen product run, all process system components that have been in contact with allergens should be *Allergen Clean* before start-up of another product that does not declare that allergen on the label.

Allergen Clean

Allergen Clean is generally accepted to mean that all food contact surfaces in the production system (including the packaging area) are visibly clean. There should be no visible product found after the cleaning process. Any product contact surface not inspected can not be assumed to be Allergen Clean. A validated procedure can be developed to substantiate elimination of visible product in those areas. Areas around or above the production system should be free of visible allergen containing product or dust that may possibly fall into or come in contact with a product.

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Operations Strategies

1. Allergenic ingredients should be uniquely identified (colored stickers/containers, etc.) and stored in an isolated area. Utilize the bottom storage racks to avoid potential cross contact of other ingredients.
2. Clearly identify all ingredient containers used. Consider color coding of allergen containers and dedicated utensils (scoops, scrapers, etc.). Containers not dedicated should be verified as Allergen Clean prior to use for non-allergen material.
3. Try to schedule allergenic products just prior to end of shifts followed by major clean ups. Minimize changeovers whenever possible. If unavoidable, be sure to allow enough time between changeovers to clean effectively.
4. Where possible dedicate processing, personnel, and packaging lines to specific allergenic products.
5. When switching from an allergenic to non-allergenic ingredient, dust socks inside collectors and other absorbent materials in contact with allergen material should be changed or cleaned to be considered Allergen Clean.
6. Physical barriers, such as shield covers, catch pans, etc. should be placed to prevent spillage and cross contact.
7. Equipment should be designed (and reviewed prior to installation) for easy cleaning access with dead spots, rough surfaces, void areas, etc. minimized.
8. Equipment crossovers and conveyors provide potential contamination opportunities. Evaluate individual lines for risk levels.
9. Minimize or avoid cleaning allergen areas with blown air. This offers the potential to spread the allergen to other areas.
10. If using rework containing an allergen, "like into like" is the expected practice. Rework containing allergens should be allowed only during the current production run of that product, and should not be moved from that production line. All rework containers should be properly identified by allergen and Allergen Clean if used for more than one product. Consider the use of plastic liners.
11. "Work in Process" (in-between stages of production) containing allergens should be properly labeled and stored. Example: Store icing containing cream cheese in a clearly labeled sealed container where there is no potential for cross contact.
12. Include a review of all formula changes and synchronize manufacturing with proper label changes as part of the plant food safety program.
13. Identify all equipment, conveyors, and food contact surfaces requiring cleaning after an allergenic product run.
14. Develop procedures specific to product lines, equipment, and formulations to effectively remove visible allergenic product.
15. Be sure to include splash zones, indirect product contact surfaces, and utensils on the cleaning program.
16. Create checksheets reflecting cleaning requirements to be completed upon each cleaning.
17. Validate the cleaning procedure with a quality audit or audit the procedures to ensure effectiveness.

Ingredient Strategies

1. Evaluate ingredients and suppliers (**see Appendixes I and IV**) to assess potential allergen risk and effective allergen management. A questionnaire to each supplier can be used to perform a hazard assessment and determine if further follow up is needed. An actual supplier audit may be required. If a supplier/ingredient represents a high risk, an alternate source/ingredient should be identified.
2. It is recommended that the Receiving Department physically identify/mark each package of incoming allergen containing ingredients as it is received (see Operations Strategies #1).
3. Where possible use ingredients that are already included in other products.
4. Evaluate the use of allergenic ingredients when formulating new/reformulated products. Do not add or substitute ingredients containing allergens, as they may not be included in the label ingredient statement on the finished product packaging.
5. Establish and follow a Label Development Process (with appropriate checks and balances) to ensure that all necessary steps are completed to produce accurate ingredient statements.
6. Identify all ingredients with a unique lot # (often assigned by the supplier and present on ingredient labels) and record this number when ingredients are received.
7. Track this number through use from receipt to delivery, and link ingredient lot #'s to finished product batches.

Packaging Strategies

1. Where possible, include ingredient labels on all products containing allergenic ingredients, such as: promotional products, small packages, food service, etc.
2. Consider systems to assure that the correct product is packed into the correct secondary package (carton). Example Toaster Pastries. Barcode readers are sometimes used for this purpose.
3. Be aware of the potential of "foreign" packages, which may come from "gang printing" at the packaging supplier. Consider the use of coding on cartons (such as stripes) visible from the sides when stacked.
4. When reformulating products, all supplies of old packaging material should be discarded if they fail to accurately declare the ingredients.
5. Similar products (with different formulations) should have packaging with differentiating colors, graphics, etc. for unique identification.
6. Label any of the "Big 8"* allergens (see page 5) when contained within the product formulation, even if present only in sub-components of ingredients or processing aids.
7. Be aware that other countries may have different regulations regarding labeling of food allergens.
8. Utilize checksheets to verify labeling at receipt and point of use.

Sales/Marketing Strategies

1. Consider the discontinuation of marginal products with high allergenic potential.
2. Be aware of the potential allergenicity of new and/or reformulated products.
3. Be aware of allergen risks associated with consumer testing, product promotions, and product sampling as inserts.
4. For in-store demonstrations, prominently display the ingredient statement. It is not advisable to provide product to unaccompanied children.
5. Consider strategies for alerting consumers if a currently marketed product will be reformulated to include an allergen. Typical strategies include package bursts, sell sheets, PR campaigns, or notifications/mailers to appropriate consumer/trade groups.

Awareness Strategies

1. Provide allergen awareness training to all plant personnel which identifies allergens and their potential risks. The training should include a description of the responsibilities of each employee when dealing with allergenic materials.
2. Training should be provided as part of employee orientation. Temporary or part time employees should also be trained.
3. Verification of training should be documented for each employee.
4. Annual refresher training is expected.
5. Training material should be reviewed annually to incorporate new information or changes in strategies.

Consumer Response Strategies

Following is the recommended procedure and information to include in a response to consumers.

1. Identify the product(s) the consumer is asking about.
2. Maintain an updated database of ingredient listings cross-referencing product/formula/market area. Read the ingredient statement to determine if any of the allergen(s) in question is listed.
3. If not, research the formula to identify the ingredients used. Ingredient sub-components (such as in mixes, flavorings, etc.) should also be investigated as they may also contain allergens. The ingredient vendor or product developer should be able to assist with identifying allergens in ingredient sub-components.
4. When responding to the consumer, recommend that they always read the ingredient statements of all food products.
5. Indicate that by formulation, the product does or does not contain the allergen in question. However, also point out that an allergen may be used in other products manufactured within the plant or an ingredient may be exposed to an allergen in the ingredient supply chain outside of the plant. Therefore, do not say with 100% certainty that absolutely none of the allergen would ever be contained in the product.

6. Do not provide a "safe list" of products to consumers. Suppliers and formulas may change.

- If you discover an allergen in the basic formula and that allergen is not listed within the ingredient statement, IT IS VERY IMPORTANT that you alert the appropriate individual so corrective action can be implemented if necessary.

***Big 8 Allergens of public health importance as recognized by FDA** (see Appendix V)

Peanuts (such as peanuts, peanut butter and peanut flour)
Tree Nuts (such as almonds, walnuts, pecans, hazelnuts/filberts, cashews, Brazil nuts, pistachios, hickory nuts, pine nuts, chestnuts, and macadamia nuts)
Dairy Products (such as milk, whey, casein, caseinates, yogurt, cheese and butter)
Eggs (such as egg whites, yolks, and albumen)
Soy (such as textured soy vegetable protein, tofu, and soy sauce)
Wheat (such as bran, germ, gluten, starch, and flour)
Crustacea (such as lobster, crab, crayfish, and shrimp)
Fish (all species should be considered as potential allergens)

Consider other potential food allergens – especially where cross contact is possible or unavoidable. New food allergens may be added to this list as their public health importance becomes recognized. There are some test kits available (and more in development) to quantify residual allergen protein. For more complete information and an up to date listing of allergens contact the following organizations:

Food Allergy Network
http://www.foodallergy.org
Phone: 800-929-4040

Food Allergy Research and Resource Program
http://foodsci.unl.edu/farrp
Phone: 402-472-2839

Allergen Survey - Instructions for Use

Ingredients with Potential Allergens (Appendix I)

1. Record the name of the plant location.
2. Record the date of the survey.
3. Identify the ingredient name and manufacturer.
4. Indicate which allergens are contained in the ingredient. Identify tree nuts by name to avoid mixing pecans with walnuts, etc.
5. Record the name of the person(s) who prepared the survey.

Formulas with Potential Allergens (Appendix II)

1. Record the name of the plant location.
2. Record the date of the survey.
3. Identify the product name and formula number for all products manufactured at the site.
4. Indicate how many ingredients of each allergen are contained in each formula. Your spreadsheet can be set up to automatically calculate totals. Identify tree nuts by name to avoid mixing formulas with pecans with those containing walnuts, etc.
5. The total number of allergenic ingredients used should help indicate the amount of potential allergen risk. Peanuts, eggs, dairy products, and tree nuts are the most common causes of severe allergic reactions in the U.S.
6. Record the name of the person(s) who prepared the survey. Past experience has found it was beneficial to audit in teams and reach consensus on the ratings.

Contamination with Potential Allergens (Appendix III)

To be used to access the probability of occurrence for potential contamination

1. Record the name of the plant location.
2. Record the production line name or number being surveyed.
3. Record the date the survey was performed.
4. Record the name of the person(s) who performed the survey.
5. Basic process steps have been listed. Additional steps may be added or others deleted as needed. Modify the form to fit the needs of the individual line.
6. A comment section is available to record observations and comments for future discussion.
7. The ratings assigned should be based on observation, experience, and knowledge of the plant/process/history. The scale is based on the likelihood that contamination with potential allergens could occur. The number values are described on the form.
8. Indicate if the plant has a policy/procedure to prevent contamination. Describe the existing policy/procedure.

INGREDIENT ALLERGEN SURVEY - APPENDIX I

Ingredients with Potential Allergens - indicate the presence of ingredients in each category

	Ingredient Name/Manufacturer	Wheat	Identify Tree Nuts	Egg	Peanuts	Soy	Crustacea Fish	Dairy Products	Total
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
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33									
34									
35									
36									
37									
38									
39									
40									
	Totals:								

Plant: _____ Prepared By: _____ Date: _____

FORMULA ALLERGEN SURVEY - APPENDIX II

Formulas with Potential Allergens - indicate the presence of ingredients in each category

	Product Name/Formula #	Wheat	Identify Tree Nuts	Egg	Peanuts	Soy	Crustacea Fish	Dairy Products	Total
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
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34									
35									
36									
37									
38									
39									
40									
	Totals:								

Plant: _____ Prepared By: _____ Date: _____

ALLERGEN SURVEY - APPENDIX III

Plant: _____ Date: _____
Line ID: _____ Prepared By: _____

Contamination with Potential Allergens

Process Steps	Rating	Comments
Receiving		
Storage & Handling		
Staging		
Scaling		
Mixing		
Make Up		
Proofing/Boiling/Retarding		
Topping		
Baking/Frying		
Topping		
DePanning/Cleaning		
Cooling		
Conveying		
Slicing		
Packaging		
Total Rating	0	

Rating Scale (Likeliness to Occur)

100%	High	5
75%	Moderately High	4
50%	Medium	3
25%	Moderately Low	2
< 25%	Low	1

Is there a policy/procedure to prevent allergen contamination? Yes _____ No _____
Describe policy/procedure: _____

SUPPLIER EVALUATION FORM - APPENDIX IV

COMPANY/LOCATION:_____

CONTACT/TELEPHONE NUMBER:_____

PREPARED BY:_____ **DATE:**_____

PLEASE ATTACH A LIST OF PRODUCTS OR INGREDIENTS YOU PRODUCE

SUPPLIER EVALUATION FORM
Do you use or store peanuts, peanut butter, tree nuts, soy-based ingredients, crustacea/shellfish, or fish, dairy products, or eggs as an ingredient for any item you produce at this location?
IF YES, do you have specific procedures to eliminate the risk of contamination with any product which does not contain these items in your finished product label statement? **Attach a listing of these items.**
Do you have an HACCP (Hazard Analysis Critical Control Point) plan in place and documented? Does it address allergens as a risk area and detail controls? **Please attach this plan.**
Do you use a chemical clean-up between allergen-potential products and non-allergens? **Attach this cleaning procedure.**
Do you schedule allergen-potential products after non-allergen products? How do you schedule allergen potential versus non-allergen products?
How are you assured that controls for allergen management are in place and effective?
What are your lot coding procedures? **Please provide an example of your coding practices.**
How do you guarantee that the correct label matches the finished product packaged formula?

FDA ALLERGEN WARNING LETTER - APPENDIX V

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition

June 10, 1996

NOTICE TO MANUFACTURERS

Label Declaration of Allergenic Substances in Foods

This letter is to make you aware of the Food and Drug Administration's (FDA's) concerns regarding the labeling of foods that contain allergenic substances. Recently, FDA has received a number of reports concerning consumers who experienced adverse reactions following exposure to an allergenic substance in foods. These exposures occurred because the presence of the allergenic substance in the food was not declared on the food label.

The Food, Drug, and Cosmetic Act (the act) requires, in virtually all cases, a complete listing of all the ingredients of a food. Two of the very narrow exemptions from ingredient labeling requirements appear to have been involved in a number of the recent incidents, however. First, section 403(i) of the act provides that spices, flavorings, and colorings may be declared collectively without naming each one. Secondly, FDA regulations (21 CFR 101.100(a)(3)) exempt from ingredient declaration incidental additives, such as processing aids, that are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food.

In some of the instances of adverse reactions, failure to declare an ingredient appears to have been the result of a misinterpretation of the exemption from ingredient declaration provided for incidental additives in 101.100(a)(3). FDA reminds manufacturers that to qualify for the exemption from ingredient declaration provided for incidental additives and processing aids, a substance must meet both of the requirements of 101.100(a)(3), i.e., it must be present in the food at an insignificant level, and it must not have any technical or functional effect in the finished food. Thus, incidental additives may include substances that are present in a food by virtue of their incorporation as an ingredient in another food. However, when an ingredient added to another food continues to have an effect in the finished food (e.g., egg white as a binder in breading used on a breaded fish product), the ingredient is not an incidental additive, and its use must be declared on the label.

The recent adverse reaction reports indicate that some manufacturers have also incorrectly interpreted what constitutes an insignificant level of a substance. Clearly, an amount of a substance that may cause an adverse reaction is not insignificant. Because evidence suggests that some allergenic substances can cause serious allergic responses in some individuals upon ingestion of very small amounts of the substance, it is unlikely that such an allergen, when it is present in a food, can be present at an insignificant level. Thus, it follows that the requirements of 101.100(a)(3) can not be met under such circumstances.

FDA is considering whether it is necessary to clarify its regulations to ensure that manufacturers fully understand the circumstances in which allergenic food ingredients must be declared and to ensure that sensitive individuals are protected by appropriate labeling.

We have also received reports of adverse reactions to foods in which likely allergenic substances were used as flavors, and not declared by name. Therefore, in addition to the exemption in 101.100(a)(3), the agency is also considering whether an allergenic ingredient in a spice, flavor, or color should be required to be declared, 403(i) not withstanding. On a substance-by-substance basis, the agency has required ingredients covered by the exemption in section 403(i) to be declared when necessary to protect individuals who experience adverse reactions to the substance, e.g., FD&C Yellow No. 5. The agency is open to suggestions on how to best address this problem.

While FDA has not formally defined "allergens," it provided examples of foods that are among the most commonly known to cause serious allergenic responses, i.e., milk, eggs, fish, crustacea, mollusks, tree nuts, wheat, and legumes (particularly peanuts and soybeans), in a policy statement dealing with foods derived from new plant varieties published in the FEDERAL REGISTER of May 29, 1992 (57 FR 22984 at 22987).

FDA advises that the issue of declaring allergenic ingredients in food is being discussed on an international level. Several individual governments and the Codex Alimentarius Commission have begun to formulate policy for the labeling of foods containing allergenic ingredients to ensure that consumers are provided sufficient information to avoid substances to which they are allergic. While packaged foods sold in the U.S. are among the most comprehensively labeled foods in the world (some countries provide broader exemptions from ingredient declaration), FDA is studying its labeling requirements, and considering whether rulemaking is necessary, for the labeling of allergenic ingredients.

While the agency does so, FDA asks manufacturers to examine their product formulations for ingredients and processing aids that contain known allergens that they may have considered to be exempt from declaration as incidental additives under 101.100(a)(3), and to declare the presence of such ingredients in the ingredient statement. Where appropriate, the name of the ingredient may be accompanied by a parenthetical statement such as "(processing aid)" for clarity.

The voluntary declaration of an allergenic ingredient of a color, flavor, or spice could be accomplished by simply naming the allergenic ingredient in the ingredient list. Because such ingredients are normally present at very low levels, the name of the ingredient could generally be placed at the end of the ingredient list and be consistent with its descending order of predominance by weight. Other, non-allergenic ingredients t hat are exempt from declaration would remain unlisted.

Another area of concern is the potential, inadvertent introduction of an allergenic ingredient to a food (e.g., in a bakery that is manufacturing two food products on one production line, one product with peanuts and one without, where traces of peanuts, or peanut products, may end up in the product that does not normally contain peanuts). FDA is considering options for providing consumers with information about the possible presence of allergens in these foods.

The agency is aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (insert name of allergenic ingredient)." FDA advises that, because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMP. The agency urges manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of the identified food. The agency is open to suggestions on how best to address this issue.

Sincerely,

Fred R. Shank, Ph.D.
Director, Center for Food Safety and Applied Nutrition

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