NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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

[Docket No. 00P-1322] Food Safety and Food Labeling; Presence and Labeling of Allergens in Foods
66 FR 38591, July 25, 2001

[Docket No. 01D-0184] Compliance Policy Guide: "Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens;" Availability
66 FR 22240, May 3, 2001

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5900

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments on the docket referenced above.

NFPA is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks, and juices, or provide supplies and services to food manufacturers.

WASHINGTON, DC
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In these comments, NFPA will address the questions posed by FDA relative to Docket 00P-1322, focusing on perspectives that supplement those which NFPA provided in oral statements and responses to questions at the August 13, 2001 meeting. In addition, NFPA puts forward comments on Docket No. 01D-0184,

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with respect to FDA's related Compliance Policy Guide on food allergen controls and labeling.

As an overarching principle, NFPA supports the Food Allergen Labeling Guidelines developed by the Food Allergy Issues Alliance. NFPA is an active member and leader of the Alliance. These comments are consistent with, but expand upon, the Food Allergen Labeling Guidelines.

Source or Plain English Labeling

What plain English terms would be understandable for the eight most common food allergens?

NFPA supports the use of source or plain language labeling in association with ingredient declarations, to present information on the major food allergens in terms commonly understood by consumers. NFPA believes that plain language presentation options should not replace, but rather should augment, current labeling requirements. NFPA recommends that the terms used should be those that consumers commonly understand to represent the food allergen, when the commonly understood term differs from the common or usual name of the food.

The major food allergens, as currently defined by FDA, are not all single foods. Crustaceans, fish, and tree nuts represent classes of foods. NFPA recognizes that, within these classes of foods, current FDA regulations mandate that, as applicable, the statement of identity and the ingredient declaration must state the standardized name or the common or usual name of the individual food. For example, for crustaceans, crab (snow crab, king crab, etc.), crayfish, lobster, and shrimp, are the terms that would be required. For fish, the common or usual name of the fish species must be declared in the ingredient list. Both crustaceans and fish classes must follow the terminology set forth in FDA's Seafood List. Likewise, for the tree nut category, the individual common or usual names of nuts must be declared: almonds, Brazil nuts, cashews, chestnuts, filberts/hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts. At a minimum, declaration of these terms in the statement of identity and/or in the ingredient declaration will provide the consumer allergic to one or more foods in these classes with sufficient clear information to make informed purchase and consumption decisions. No change in current regulations is required to achieve this goal. Furthermore, NFPA believes that it would not be helpful to food allergic consumers to declare the class name, as it would not provide sufficient information for a consumer to make a clear purchase or consumption decision.

In many other foods, the plain language name of the major food allergen is part of the standardized name or common or usual name of the food. For example, hydrolyzed soy protein, buttermilk, peanut butter, cracked wheat, and milk chocolate all include the plain language names of major food allergens as part of their common or usual names or standardized names. No change in current regulations is needed for the continued presentation of this information.

When the plain language name of the food allergen is not declared in the statement of identity or the ingredient list, NFPA believes that food processors should ensure that the plain language term is present, in association with the ingredient list.

Some names of foods subject to standards of identity include plain language terminology, and other such names do not. For example, in the egg products standards, egg whites (21 CFR §160.140) specifies that "egg" is declared in the name. The name "dried yolks," however, as permitted by that standard (21 CFR §160.185), does not require the use of the term "egg." NFPA believes that the alternate permitted name, "dried egg yolks" should be declared, and could be shortened to "egg yolks" in an ingredient declaration, as provided in 21 CFR §101.4(b)(12). The standardized foods semolina, farina, durum flour, graham flour, and white flour – all standardized names in 21 CFR Part 137– should include the term "wheat."

The declaration of plain language terminology should also apply to foods without standards of identity, such as casein derived from milk, regardless of whether a non-dairy claim is made, as is provided for at 21 CFR §101.4(d).

What source or plain English labeling format or formats would be most informative to consumers?

NFPA believes that plain language terms for the major food allergens should appear within, at the end of, or in immediate proximity to, the ingredient declaration. Several presentations of plain language information may be useful to food allergic consumers. When plain language information is included as part of the common or usual name in the ingredient declaration, that presentation should provide sufficient information without the need for additional declarations. Other labeling approaches could provide plain language information on food allergens

where the plain language term is not a part of the common or usual name, and could reinforce the food allergen information already declared in the ingredient list. One option could be to place at the end of the ingredient declaration a statement such as "Contains peanuts." This statement could be prefixed by a phrase that highlights the focus on food allergic consumers, and not the general consumer. For example, the phrase "allergy information:" could precede "contains peanuts."

A further option could use a reference mark, such as an asterisk, next to the name of the ingredient whose common or usual name does not include the plain name of the allergen. Examples include "farina*" or "casein †." The reference mark then would refer to a corresponding statement at the end of, or in immediate proximity to, the ingredient declaration that states "* wheat," "† milk ingredient." This option takes up very little space, and could be useful for long ingredient declarations.

Another option would be to use, within the ingredient declaration, a parenthetical statement following the ingredient name that identifies allergens that are present in the ingredient, such as "farina (wheat)". The parentheses option could be very useful for a food that has a short list of ingredients or only a small number of major food allergens.

Any of these options could be presented with bold type or other highlighting, to draw attention to the information about the food allergens.

Are the formats from the Food Allergy Issues Alliance appropriate and sufficient?

NFPA believes the format options presented in the Food Allergen Labeling Guidelines of the Food Allergy Issues Alliance are clear, appropriate, and sufficient. The presentations discussed above are consistent with the Guidelines.

Are the recommendations in the petition from the attorneys general of nine States warranted and beneficial?

The Attorneys General petition would mandate a single plain language presentation "**Allergen Information:** This product contains soy and egg." Not only does this presentation contain words that are unnecessary to convey a clear message to food allergic consumers, such a requirement would be redundant in the case of foods that present plain language terminology in the common or usual name within the ingredient declaration. Nevertheless, the Attorneys General

petition example is consistent with one of the examples in the Food Allergen Labeling Guidelines.

The Attorneys General petition also would require a "circle-A" insignia on the front panels of foods that contain major food allergens. NFPA opposes such a use of the insignia. This symbol would provide no additional useful information to a food allergic consumer, as it would be necessary for the consumer to read the ingredient declaration to observe the information of concern, irrespective of the presence of any label insignia.

Additionally, the Attorneys General petition would present food allergen labeling rule as amendments to 21 CFR §101.17. This section of FDA's regulations addresses warning statements, and it is not an appropriate location for any rules on label statements that are not warnings. There is no need to warn an overwhelming majority of consumers about the presence of allergenic food ingredients, as for the overwhelming majority of consumers these substances are completely safe to consume. The petitioner, furthermore, explicitly references food allergen statements as information, appropriately provided to the specific sub-population that would be adversely affected. The ingredient declaration is already the best location for such information. Thus NFPA recommends that FDA decide that amendment to 21 CFR §101.17 is inappropriate for food allergen information labeling.

Are multiple formats confusing to consumers, and if so, is there a single format that would be preferable? If so, why?

NFPA believes that multiple format options for the presentation of plain language terminology should not confuse consumers, provided the food allergen information is always presented in association with the ingredient declaration. This is where food allergic consumers are instructed to look for information about the allergens in the food. Multiple formats can also accommodate the situation where plain language terminology is part of the common or usual name of the declared ingredient, thus necessitating no additional labeling.

Should source or plain English labeling be voluntary or mandatory for the eight most common food allergens?

Plain language labeling for food allergens should be permitted on a voluntary basis. Food processors should be encouraged to use such presentations, but they should not be required by regulation. NFPA believes that FDA should state publicly that such labeling is permitted, and that use of plain language in addition

to the common or usual name, within or in immediate proximity to the ingredient declaration, does not constitute violative intervening material among required label elements. NFPA also notes that, were FDA to require plain language ingredient labeling, the Agency would need to revise the labeling sections of each of the affected rules for standards of identity, in the same manner that the Agency was required to amend numerous standards, in addition to amending the general ingredient labeling rule, to incorporate mandatory declaration of all ingredients for standardized foods. A voluntary approach, clarified by FDA as acceptable, would require no amendments to standards of identity.

Advisory or supplementary labeling (e.g., "May contain [allergen]")

Under what circumstances, if any, should advisory labeling statements be permitted, and what impact would those circumstances have on manufacturers and on consumers?

NFPA believes that there are limited circumstances in which advisory labeling – also called supplementary labeling – should be permitted. However, NFPA believes that the use of such labeling should be relatively rare and carefully controlled through responsible industry practices. NFPA also believes that discussion of food allergen control strategies in food processing operations is concomitant to a discussion of supplementary or advisory food allergen labeling. Episodes of inadvertent cross contact between foods that contain major allergens and foods that are not intended to contain those allergens, coupled with the resultant problem of undeclared allergens in the product where they are unintended, indicate that both production controls and labeling approaches must be considered.

Food processors that prepare foods that may be exposed to inadvertent contact with major food allergens acknowledge that labeling is not a substitute for good manufacturing practices (GMPs). Good manufacturing practices and their resultant controls must be considered before labeling approaches are considered. Processors should review the food plant environment, including storage conditions and production line architecture; should review the products, controls, and practices of their suppliers; should examine their own production operations, including separation, sanitation, and scheduling practices; and then should create optimum conditions for food allergen control, including employee training, as far as they are able. When this process is completed, if the risk that food allergens

may be present still exists, NFPA believes that advisory or supplementary food allergen labeling must be considered.

Supplementary or advisory labeling should be viewed as an approach of last resort, when the risk of presence of a food allergen cannot be avoided with absolute certainty. Supplementary or advisory labels should be relatively rare, not increasingly more common. Nevertheless, given the difficulties of achieving absolute certainty that there is no risk of presence of major food allergens in a variety of operational situations, supplementary or advisory labeling is necessary and should be permitted.

The food industry has taken numerous steps over the past several years to change manufacturing processes to reduce the potential for cross contact with Major Food Allergens. The NFPA Food Allergens Committee has been active over the past several years discussing ways to manage food allergens. These discussions resulted in NFPA's recent "Code of Practice on Managing Food Allergens," which NFPA is now elaborating into more detailed guidance for members.

The food industry recognizes that, in the spirit of existing GMP regulations, reasonable precautions must be taken to prevent cross contact with major allergenic proteins. In instances when the risk of cross contact cannot be avoided, even when complying with GMP regulations and best industry practices, food and ingredient manufacturers then should use labeling that informs the food allergic consumer of the possible presence of allergens in the food.

However, only supplementary or advisory label statements that are used in carefully controlled circumstances would provide a food allergic consumer with enough information to make a clear decision about whether or not a food is appropriate for them to eat.

Should the recommendations in the petition from the attorneys general of nine States be adopted?

The Attorneys General petition addresses some of the broad concepts of good manufacturing practices that need to be considered for optimal food allergen control, but is too prescriptive in its recommendations – the prohibition of rework,

for example, rather than accommodating rework on a "like into like" basis, or the apparent requirements for dedicated equipment or for testing of equipment and other food processing components. The Attorneys' General proposed labeling approach for such advisory labeling presents only one label statement option, when multiple options may be not only valid but necessary. In addition, under the Attorneys' General proposal, foods using advisory labeling also would be required to use a "circle-A" symbol on the principal display panel, which would not provide useful information to the food allergic consumer.

Do the criteria from the Food Allergy Issues Alliance form a reasonable basis for determining when a manufacturer may use advisory labeling on a particular product or should other criteria be used? Why?

The Food Allergen Labeling Guidelines of the Food Allergy Issues Alliance outlined four conditions that spell out the carefully controlled circumstances to govern responsible consideration of supplemental or advisory food allergen statements. The guidelines present a reasonable yet rigorous approach to the criteria for determining whether supplemental labeling statements should be used. These types of food allergen statements should be used judiciously only when all four of the following criteria are met:

First, the presence of a major food allergen is documented through visual examination or analytical testing of the processing line, equipment, ingredient or product, or other means;

Thus, the first step is to affirm that the major food allergen is in the environment. This affirmation can be accomplished through examination of the physical plant, processing procedure, analytical testing where available, or through documentation.

Second, the risk of the presence of a major food allergen is not unavoidable, even when current good manufacturing practices are followed. This criterion signifies that all the feasible operational issues that can be addressed have been addressed, with respect to control of major food allergens, yet, even under those conditions, there is not a complete certainty that one can avoid the risk that the allergen could be present.

Third, the major food allergen is present in some, but not all, of the product in question. Clearly, if this criterion is not met, "may contain" type label statements could not apply – the product *does* contain the allergen. The occasional or sporadic presence of an allergen may provide additional information that allows the food processor to diagnose a situation with a supplier, the plant environment, a piece of equipment, or a processing procedure. This information would then trigger a review of the second criterion, and any remediation that is possible. If one can identify a feature that would enable the processor to control further the risk of presence of an allergen, then steps should be taken to exert additional controls.

This third criterion highlights that the review of allergen control procedures is not static, but dynamic. Review of the criteria for supplemental or advisory labeling should be undertaken whenever there is a change to one of the operating variables, such as ingredients, suppliers, equipment, or processing techniques.

The fourth criterion is that the presence of the major food allergen is potentially hazardous. At the present time, scientists are uncertain whether there is a condition under which the presence of the major food allergen is not potentially hazardous, so this criterion currently would apply.

If some, but not all, of these criteria are met, food and ingredient manufacturers should consider food allergen control and/or labeling strategies other than supplemental or advisory allergen statements. Meeting all four criteria will ensure that supplementary or advisory label statements are considered only after due diligence. Meeting all the criteria also ensures that labeling statements are not used capriciously or as a theoretical precaution.

For food processors, adhering to these criteria undoubtedly will have associated costs – for reviews, self-inspections, audits, documentation of procedures, post-sanitation testing, personnel, and sometimes new equipment or facilities. However, failure to be vigilant with GMPs, or such widespread use of supplemental or advisory labeling that food allergic consumers no longer believe the statements, can have consequences that are not only expensive, but also tragic. If supplemental allergen labeling is used responsibly, the likelihood is that food allergic consumers will believe the statements, and avoid eating those products containing allergens to which they are sensitive.

Are there better alternatives for advisory labeling than the type of wording that currently exists (e.g., "May contain [allergen]," "Made on shared equipment with [allergen]," "Manufactured in a facility that also processes [allergen]")?

These wording alternatives for advisory or supplementary labeling communicate to food allergic consumers information to assist them in making clear decisions on whether to purchase or consume a food product. Any statement used must be truthful and non-misleading.

Do such statements adequately inform consumers of possible cross-contact with allergenic materials?

NFPA believes that these statements are informative to food allergic consumers and provide them with information with which to make appropriate purchase and consumption decisions.

How do consumers interpret the wording of such labeling?

NFPA recommends that FDA should conduct research to assess such consumer understanding, especially as the Agency contemplates any recommendations on the use of such statements. The goal of any supplemental or advisory food allergen statement should be to prompt food allergic consumers to draw the conclusion that they should not consume the product.

Should advisory labeling statements be prescriptive (i.e., one or more specific statements) or flexible?

As the circumstances regarding the possible presence of major food allergens are likely to vary from one food production situation to another, food allergen advisory or supplemental statements should be sufficiently flexible to accommodate the range of advice. Provided the advisory statements are true, and are understood by food allergic consumers, prescribed language is not needed.

Where should advisory labeling statements be located on the food label?

NFPA believes that advisory or supplementary label statements regarding food allergens should be presented on the information panel, in proximity to the ingredient declaration, as this is the location where food allergic consumers are instructed to examine for information relative to food allergens. NFPA believes that FDA should state publicly that such labeling is permitted, and that use of supplementary or advisory labeling, in immediate proximity to the ingredient

declaration, used in appropriate conditions, does not constitute violative intervening material among required label elements.

How prominent should advisory labeling statements be on the label?

Supplementary or advisory label statements should be at least as prominent as the ingredient declaration. Food processors that wish to provide additional prominence through bold type, highlighting, or other approaches, should be encouraged to do so.

Should the location and prominence of advisory labeling statements be prescribed?

As NFPA believes that advisory or supplementary labeling statements should be permitted under appropriate circumstances, on a voluntary basis, we also believe that location and prominence should not be prescribed. Presentation of such labeling statements in proximity to the ingredient declaration is consistent with the approach in the Food Allergen Labeling Guidelines of the Food Allergy Issues Alliance.

Labeling of ingredients exempted from declaration (common or usual names of flavorings, spices, and colors; incidental additives).

Should the agency continue to address the labeling of individual allergenic flavorings, spices, and colors on a case-by-case basis, or should there be a generally applicable policy?

It is important to note that the major food allergens are proteins. There are numerous components in flavors, colors and incidental additives that are not proteins. Often, these components include alcohols or oils that may be derived from the major food allergens, but are so highly refined that they do not contain protein. Bleached, deodorized and refined soybean oil that may be used as a carrier for flavor or color, or a component in a food additive, in some food applications, is an example of the type of product that should be considered not to contain allergenic protein. Furthermore, there is no spice included among the list of the eight major food allergens.

For these reasons, FDA should continue to address the labeling of allergenic components in flavors, colors, and spices on a case-by-case basis. Creating a generally applicable policy most likely would encompass substances that are not at issue for labeling of food allergens.

While food processing firms are responsible for obtaining information regarding their ingredients, NFPA believes it is equally the responsibility of ingredient suppliers to provide information on the allergenic components present in flavors, colors, spices and additives. NFPA believes that suppliers should always volunteer this information to their food processor customers, with the understanding that food companies are not interested in learning the formulation of the flavor, color, spice, or additive, but simply need to know which allergenic proteins are present. NFPA also is of the view that food processors should carry forward to their own labels information on the presence, or possible presence, of those major food allergens in flavors, colors, spices, and incidental additives.

Should the information on allergenic components of flavorings, spices, and colors be included in the ingredient list? Is there a better location or format for this information? Explain.

NFPA believes it is appropriate to present plain language information on the allergenic components of flavors, colors, spices, and incidental additives in association with the ingredient declaration of the finished food. This information should be in the ingredient list, where the flavor is declared, or at the end of the ingredient list, as appropriate to the food and the flavor. The presentation options discussed in the section on plain language all are valid presentations, as would be any plain language representation of the name of the allergen in the common or usual name of the flavor.

For individual flavorings, spices, or colors that contain one of the eight most common allergens, should listing the common or usual name of the individual flavoring, spice, or color on the product labeling be voluntary or mandatory?

NFPA believes that the food industry should declare, on a voluntary basis, the plain language terms for major food allergen components in flavors, colors, or spices. Many NFPA members already declare information on these allergenic components on a voluntary basis. NFPA believes that food processors should obtain this information from their suppliers and carry it forward to finished product labeling. Many NFPA members use check lists and other techniques to ensure that they have received this information from their suppliers.

It important to note that the information on the allergen present may be different from the common or usual name of the flavor, or color. Because some of the major food allergens are common in the food supply – milk, wheat, egg, and soy, for instance – food companies do not limit their information collection to the obvious or major ingredients. Egg protein that may be a component, but not a characterizing flavor, of a flavor formulation is a good illustration of concept. The

food processor that uses the flavor in the formulation of a food should obtain information that egg protein is present, and carry that information forward to the label of the finished food.

What, if any, minor ingredients would manufacturers be unlikely to recognize as containing food allergens and therefore not include on the label, and what kinds of manufacturing processes would manufacturers be unlikely to recognize as inadvertently introducing food allergens?

NFPA believes that it is a predicate of food processing that producers fully understand the applicable laws, regulations and policies in order to produce foods that are in compliance. NFPA believes that it is the responsibility of food processors to have full knowledge of their ingredients and understand how their processes may inadvertently introduce any ingredients into food products. It is the responsibility of food processors to request, and to ensure they receive, all relevant information from their suppliers.

When products that contain food allergens will be further processed or repacked, is food allergen labeling sufficient on such intermediate products or is it necessary to have clearer labeling on intermediate products to ensure that food allergens are appropriately declared on the retail packaging of the final product?

NFPA believes that it is not necessary for such information to be present on a label, provided that the provisions of 21 CFR 101.100(d) are followed.

Should the agency 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?

Regarding major food allergens that are components of additives that might qualify for the incidental additives declaration exemption, NFPA believes that FDA has already made its views very clear that such allergenic components are not exempt from declaration. NFPA advises its members in a manner consistent with FDA's policy interpretation. Consequently, NFPA believes that it is not necessary for FDA to codify its views into regulations.

Criteria for the Major Food Allergens

In 1992, as part of its Statement of Policy: Foods Derived From New Plant Varieties (57 FR 22984, May 29, 1992), FDA advised that "Examples of foods that commonly

cause an allergenic response are milk, eggs, fish, crustacea, molluscs, tree nuts, wheat, and legumes (particularly peanuts and soybeans)."

This year, FDA published its Compliance Policy Guide (CPG) "Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens." (66 FR 22240, May 3, 2001). In this Compliance Policy Guide, FDA states that "FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies: peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, wheat."

NFPA notes that there are differences between these lists of major food allergens published by FDA. However, FDA has not to date discussed its criteria for deciding which foods should be included on the list of major food allergens. NFPA recommends that FDA engage in a dialogue with respect to the criteria regarding this list of foods of public health importance.

Furthermore, in the 2001 CPG, FDA notes that "For other foods that may cause an allergic response in certain individuals, the FDA district office should contact CFSAN/Office of Field Programs for guidance." This statement suggests that FDA maintains a prioritized list of other food allergens. NFPA recommends that FDA's discussion of its decision-making criteria elaborate on the differentiation of foods that are on the "major" list, which addresses more than 90% of food allergic reactions, and lists of other food allergens.

Both the food industry and FDA recognize that food allergy is an important public health situation, supported by a wealth of scientific discussion and research. As this issue is also a regulatory matter, however, the food industry believes it is an unsatisfactory situation to operate largely in the dark with respect to the decisions of the regulatory agency as to the basis of investigations and enforcement actions. We believe that the processes of FDA should be open and transparent, and for this reason we request that FDA engage in a dialogue regarding how it determines food allergens of concern.

Furthermore, in the CPG, FDA outlines criteria for recommending legal action:

"The following represents the criteria for recommending legal action to CFSAN/Office of Field Programs/Division of Enforcement and Programs (HFS-605):

1. The food contains an undeclared allergenic ingredient that is a derivative of one of the eight (8) ingredients listed in this guide.

2. The food contains an undeclared allergenic ingredient that was used as a processing aid in the manufacture of the product.

3. The food contains an undeclared allergenic ingredient, but the ingredient is not one of the eight (8) allergens listed in this guide.

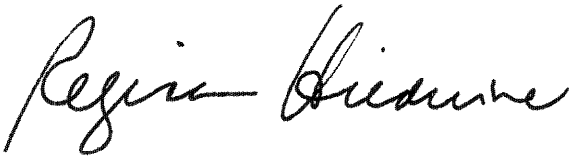
4. The food is not labeled as containing an allergen, but inspection of the firm shows that it was manufactured under conditions whereby the food may have become contaminated with an allergen.

5. The inspection of the firm was conducted consistent with the Guide To Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients."

The list does not make clear whether the criteria are to be met in a conjunctive manner, with "and" understood between each term, or in a disjunctive ("or") modality. As independent criteria, the final item would appear to ensure that all inspected firms would be recommended for legal action. NFPA recommends that FDA clarify this point at its earliest opportunity.

Thank you for the opportunity to comment on this important issue.

Sincerely,



Regina Hildwine
Senior Director, Food Labeling and Standards