ConAgra Foods[®]

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

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

Dear Sir/Madam:

ConAgra Foods appreciates the opportunity to comment on the Food and Drug Administration's (FDA) announcement of a public meeting and request for written comments on the presence and labeling of allergens in foods, published in the *Federal Register* on July 25, 2001.

ConAgra Foods is one of North America's largest foodservice manufacturers and retail food suppliers, with annualized sales in excess of \$27 billion. ConAgra Foods' consumer brands include: Hunt's tomato products, Healthy Choice, Banquet meals, Armour meats, Bumble Bee tuna, Louis Kemp seafood, La Choy, Chun King, Lunch Makers, Wesson, Country Pride, Blue Bonnet, Kid Cuisine, Parkay, Reddi-wip, Marie Callender's, Cook's ham, Butterball, Act II, Slim Jim, Decker, Chef Boyardee, Orville Redenbacher's, PAM Cooking Spray, Snack Pack puddings, Van Camp's, Peter Pan, Hebrew National, Gulden's mustard, Pemmican Jerky, Swift Brown 'n Serve Sausages, Swiss Miss, and many others.

Understanding that food allergic consumers depend on food labels to avoid foods that might result in an allergic reaction, ConAgra Foods takes seriously its responsibility to provide consumers with clear, accurate and complete information on major food allergens.

ConAgra Foods is a member of several of the trade associations that comprise the Food Allergy Issues Alliance and we supported the development of the Food Allergy Labeling Guidelines issued in May, 2001. Following the release of the guidelines and with the benefit of the input provided from the participants in the FDA's August 13, 2001 public

00P-1322

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meeting on food allergens, ConAgra decided to take the additional step of establishing its own food allergy labeling policy. The policy was adopted earlier this month and will be phased in by all of ConAgra's operating companies as label changes are made.

ConAgra Foods believes this voluntary approach to allergen labeling is the best way to provide consumers with allergen information. Since there is no need to go through a notice and comment period, voluntary action allows for a much swifter rollout of allergen labeling and provides companies with the flexibility to revise their labels should new information be developed about emerging allergens.

The ConAgra Foods allergen labeling policy addresses the three issues raised by FDA in the *Federal Register* notice, source or plain English labeling, advisory (or supplemental) labeling and labeling of ingredients exempted from declaration.

Source or Plain English Labeling

Recognizing that the common or usual names for ingredients listed in the ingredient statement may not be understood by consumers to be derived from food allergens, the *Federal Register* notice asks several questions regarding plain English labeling

ConAgra Foods allergen labeling policy calls for plain English labeling of nine major food allergens: milk, eggs, peanuts, tree nuts, fish, shellfish/crustaceans, wheat, soy and sesame. With the exception of tree nuts and shellfish/crustaceans, the plain English terms of the major food allergen categories are sufficiently clear to provide food allergic consumers with the information they need to avoid certain foods. In the case of tree nuts, ConAgra believes the actual name of the nut should be listed as the plain English term (walnut, almond, hazelnut, etc.). In the case of shellfish/crustaceans, the species should be listed as the plain English term (clam, lobster, shrimp, etc.)

The ConAgra Foods policy adds sesame to the action was taken because we understand sesame is considered by allergists to be the "ninth" major food allergen and both Canada and the E.U. list sesame on their respective major food allergen list. In addition to providing consumers with accurate and complete information on major food allergens, ConAgra Foods believes the addition of sesame to the major food allergen list makes sense as we strive for uniformity between the U.S. and Canada on product labeling.

Regarding the format for plain English labeling, ConAgra has adopted a single format to be utilized by all of our finished retail and foodservice product labels. We believe consumers will be well-served by the uniformity and predictability of this approach. Specifically, ConAgra's policy requires:

Information pertaining to the presence of the major food allergens to be listed on the finished product label directly below the ingredient statement. The allergen content is to be presented in bold type, capital letters, and a size equal to that of the ingredient statement. A sample statement is presented below:

CONTAINS: MILK, PEANUTS, SOY, AND WALNUTS.

The FDA has asked if plain English labeling should be voluntary or mandatory for the eight most common food allergens. As stated previously, ConAgra believes that allergen labeling should be voluntary, in order to provide the highest degree of flexibility to respond to new data regarding allergens.

Advisory Labeling (e.g. "May contain [name of food allergen]")

ConAgra Foods agrees with the FDA's statement that advisory labeling statements such as "may contain peanuts" should not be used in lieu of good manufacturing practices. Such statements should not be the norm and we are striving to eliminate the presence of allergenic ingredients that are not intentionally added to a specific food product. Moreover, we are asking our suppliers to minimize their use of advisory labeling which would have to be carried through to a final product.

ConAgra's labeling policy establishes clear criteria outlining when advisory labeling statements may be used. The policy states:

The use of supplemental allergen information on the labels of ingredient or product components entering ConAgra Foods facilities is not allowed. ConAgra Foods will attempt to obtain written verification from all suppliers indicating their ingredients do not contain any undeclared major food allergen(s).

Supplemental food allergen labeling statements on ConAgra Foods finished product labels are only acceptable when undeclared allergen(s) are potentially

following conditions have been satisfied:

- a. The infrequent presence of the allergen must be verified by analysis (if routine, then the allergen must be declared as an ingredient).
- b. Rationale and documentation that provides evidence as to why the infrequent presence of the undeclared allergen is unavoidable must be kept on record.

The FDA has asked where advisory labeling statements should be located on the food label. ConAgra believes all information pertaining to major food allergen content should be consistently placed in the same area to assist food allergic consumers. Therefore, ConAgra's allergen labeling policy states:

Information pertaining to the potential presence of an undeclared major food allergen(s) is to be listed on the finished product label directly below the

ingredient statement. The allergen content is to be presented in bold type, capital letters, and a size equal to that of the ingredient statement. A sample statement is presented below:

MAY CONTAIN: PEANUTS AND SOY

Finally, the FDA has asked if there are better alternatives for the wording of advisory labels than currently exist ("may contain," "made on shared equipment," "manufactured in a facility that also processes...,").

ConAgra was deeply concerned with the survey results shared by the Food Allergy and Anaphylaxis Network (FAAN) at the August 13 public meeting that indicated food allergic consumers interpret differing statements with different degrees of risk. Again, food allergic consumers are served by uniformity, thus our policy limits the use of advisory statements to the term "may contain." Food allergic consumers should not be encouraged to make risk management decisions regarding which foods are safe for them to eat based on the advisory statement. If an allergen advisory statement is included on a ConAgra Foods label, it is there to alert the food allergic consumer to avoid the product.

Labeling of Ingredients Exempted From Declaration

ConAgra Foods believes that the presence of a major food allergen, regardless of whether or not it is subject to a labeling exemption for flavorings, spices and colors or incidental additives, must be disclosed on the finished product label. Gathering this information from suppliers is a massive undertaking and is currently underway.

Separately, whenever feasible, ConAgra will be demanding that its suppliers minimize or eliminate major food allergens from ingredients if they do not serve a functional role.

rulemaking process is labor intensive and time consuming. Thus, ConAgra does not support the development of a mandatory allergen labeling regulation for flavors, spices or colors but rather believes the FDA should make clear in the *Compliance Policy Guide*, as it has with incidental additives, that major food allergens be declared in the ingredient list.

Thank you for the opportunity to share our views on allergen labeling.

Sincerely,

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Vice President, Government Affairs