

Soyfoods Association of North America

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

**Comments on Docket No. FDA-2012-N-0711
Request for Comments and Information on Initiating a Risk
Assessment for Establishing Food Allergen Thresholds**

Dear Docket Management Staff:

The Soyfoods Association of North America (SANA), which represents the interests of small and large soyfood manufacturers, soy processors, suppliers, soybean farmers, and other industry stakeholders, appreciates the opportunity to comment on Docket No. FDA-2012-N-0711- Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds.

SANA understands that “FDA convened a threshold working group to determine the best approach for estimating threshold levels for food allergens and it recommended the quantitative risk-assessment approach.” SANA agrees that establishing thresholds using the quantitative risk-assessment approach is both scientifically sound and also in the best interest of consumers with food allergies. Although SANA does not have current data on the quantitative level for soy protein associated with triggering an allergic reaction, SANA has collaborated with the Soy Nutrition Institute and the Food Allergy Research and Resource Program at University of Nebraska Lincoln to provide the quantitative data FDA needs to establish a regulatory threshold or action level for soy protein.

Avoidance of the allergenic protein remains the primary prevention against adverse reactions to food allergens. Consumers must reference the Ingredient List on the Product Information Panel to identify the source of food ingredients. Soy would appear in this list if intentionally used in the product formulation. Food companies take numerous precautions to avoid having adventitious ingredients, especially potential allergens, from appearing in a product and to assure customers that what is listed on the ingredient list is accurate.

Under current regulations for the Food Allergy Labeling and Consumer Protection Act (the Act), soy protein must be identified on all foods derived from soybeans, containing soy protein at any level. SANA recognizes that the Act provides mechanisms through which ingredients may become exempt from the major food allergen labeling requirement when scientific evidence demonstrates that an ingredient “does not cause an allergic response that poses a risk to human health.” This case-by-case basis requires each

ingredient be tested for its potential allergenicity, which is quite extensive versus an ingredient being tested for the presence of an allergen at or above a specific threshold that could cause an allergic response that poses a risk to human health. In this way, the consumer would best be able to identify the foods to avoid because they contain a known allergen at or above an established level associated with allergic reactions.

With the current rules for declaring any possibility of an allergen appearing in a food, consumers may select a food labeled as having a specific allergen to which they have an allergy, and then may not experience a reaction to that product. The consumer having not experience a reaction may become more casual in selecting other foods that are labeled as containing that specific allergen. For example, a product that contains soy lecithin would carry a label declaration about the potential presence of soy allergens. Since this ingredient has very little, if any, soy protein, consumers allergic to soy protein may not experience a negative reaction when consuming foods with soy lecithin. If consumers believe they have no allergy to soy, having consumed foods labeled with a soy allergen declaration because of lecithin or other soy ingredients with minimal soy protein content, they might then consume a soyfood with sufficient amounts of soy protein to cause a reaction.

The proposed rule would permit meaningful exemptions to the mandatory labeling of allergens, which could minimize consumer confusion. If a threshold were set for soy allergens, and tests showed the food did not contain that level of the allergen, allergen declarations might not have to be made. Manufacturers processing other foods in a plant that has also processed soyfoods, or vice versa, would have a clearer basis on which to make more prudent use of advisory labels.

SANA will respond to only four of the questions that FDA specifically asked in the call for comments and focus on soy protein allergens.

1. How should FDA define “an allergic response that poses a risk to human health?”

Allergic reactions to food can vary in severity and time of onset. SANA supports the suggested definition offered by the Food Allergy Research and Resource Program that “an allergic response that poses a risk to human health” involves an immune mediated reaction that causes the individual to seek medical attention, take pharmaceutical products or lose time from school, work, etc.

Symptoms of soy allergies vary widely, but the allergic reactions to ingested soy are rarely severe and life threatening. The prevalence of severe anaphylactic reactions to soy is quite low, compared to other food allergens.ⁱ There have been only a few reported cases of severe or fatal reactions to soy. Only one well-documented death from soy in the United States exists,ⁱⁱ but there are several in Europe. Over a three-year period, Swedish researchers reported four children with peanut allergies reacting fatally to soy protein as a component of hamburgers, meatballs, sausages and bread.ⁱⁱⁱ This high number of fatal soy-allergic reactions appears unusual; raising questions about other variables that may have been responsible for these reactions.

2. Which major food allergens are of greatest public health concern and what is the size of the at-risk population?

Based on the following data regarding the low level of public health threat and the limited size of the at-risk population, SANA suggests the FDA seek changes in the Act that would remove soy from the list of major food allergens.

The type of allergies changes with age. While adults tend to be allergic to fish, crustaceans, and tree nuts, children are most likely to have peanut (2%), milk (1.7%), shellfish (1.4%) allergies and the incidence of soy allergy was the lowest (0.4%)². A study of food-allergic children found that 58% reported food-allergic reactions in the past year, with 18% experiencing one or more reactions in school. While peanut allergy is estimated to be responsible for 50 to 100 deaths per year⁷, there has only ever been one recorded death in the U.S. due to soy allergy⁸.

Soy allergies account for a small fraction of the food allergies expressed in children. FDA considers soy as one of the eight major food allergens; yet, the prevalence of soy allergies in the pediatric population is estimated to be less than 1%, but this figure is not well substantiated, even among children with food allergy symptoms. In a population-based study in the United Kingdom, soy was reported as the least (0.3%) frequent cause of food intolerance among 16 foods/food types.^{iv} A study of food allergy/intolerance in a cohort of 480 neonates found only two (0.4%) developed a soy allergy as infants.^v In a Milan study, 148 out of 704 (21%) children age 1 month to 18 years with allergic symptoms tested positive to a soy skin prick test. Then only 6% of those with positive soy skin tests, or 1.2% of all the children with a history of food allergies, actually reacted positively when fed soy.^{vi} The prevalence would be much lower for the overall population in Milan.

Most infants and toddlers outgrow their allergies early as their immune system matures. According to the National Institutes of Health, approximately 5 million or about 8% of children and 1-2% of adults have a documented food allergy.

For children with food allergies, less than 1% has allergic reactions to soy and these adverse reactions are generally a transient allergy of infancy and childhood. All of the allergic neonates in a cohort study became tolerant of soy by age 3.^{iv} Another study found two-thirds of children lost their soy allergy 2 years after a positive oral challenge.^{vii} About 5% of Danish children with a cow's milk allergy demonstrated adverse reactions to soy in infancy, but all children lost this soy sensitivity by the age of 3 years.^{viii}

6. What data or other information exists on current levels of exposure associated with the consumption of undeclared major food allergens in packaged foods?

Although SANA does not have specific information on current levels of exposure associated with consumption of soy protein, the soyfood manufacturers have implemented many precautionary practices to avoid introduction of an unintended major food allergen in a food package. Shared manufacturing equipment can introduce food allergens into previously non-allergen containing foods.^{ix} To prevent cross-contact with other food allergens, soyfoods manufacturers follow good manufacturing processes, including thorough cleaning, adequate testing, and dedicated equipment.

7. What other information or data should we consider in establishing regulatory thresholds for major food allergens?

SANA supports the Soy Nutrition Institute's recommendation that each allergen should have a unique threshold based on published clinical data and/or unpublished clinical records, as reported in the Allergen Bureau's Summary of the VITAL Scientific Expert Panel Recommendations¹⁰. The prevalence and severity of the allergic reaction should be considered when establishing thresholds for each allergen.

SANA's position is in harmony with a recent guidance piece from Health Canada on the adventitious presence of soy in cereal grains. "Health Canada would like to inform Canadians with soy allergies that cereal grains, such as wheat, oats or barley, may contain low levels of soy because of the way these grains are grown, harvested, transported and stored. This cross contamination, or adventitious presence, is not a new issue, but rather has always been present as part of normal agricultural practices. The possibility of this adventitious presence is reflected in cereal grain quality grading standards.

"Based on the low levels of soy that have been detected in grain-based foods, Health Canada has determined that exposure is not likely to represent a health risk for soy allergic individuals. As such, the department has advised the food industry that the use of food allergen precautionary labeling, in cases where low levels of soy present in grain-based foods has been determined to be due to adventitious presence, is not considered to be the best approach, and would not benefit the interests of soy allergic consumers as it would potentially limit food choices."

Conclusion

SANA strongly supports FDA's initiative to establish thresholds for food allergens. Thresholds would allow FDA to make appropriate judgments about source labeling exemptions such as for processing aid uses of soy lecithin or other practices that may lead to soy protein levels well below the threshold. The implementation of thresholds could also give useful guidance to industry on appropriate uses of advisory labeling. It is important that consumers receive more meaningful information about the potential presence of a food allergen that poses a true risk to human health, instead of the current excessive number of warning labels that suggest the presence of an allergen when the allergen is either absent or the amount of the allergen present is too low to trigger an allergic reaction. The Soyfoods Association of North America (SANA) would be glad to supply FDA guidance for manufacturing practices to avoid cross contact with soy and other food allergens. SANA is happy to assist FDA in any manner and encourages FDA to contact our office with any requests, questions, or concerns related to soyfoods, soy ingredients, and soy allergies.

Sincerely,



Nancy Chapman, R.D., M.P.H.
Executive Director

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- ¹ Sicherer SH, Sampson HA. Peanut and soy allergy: a clinical and therapeutic dilemma. *Allergy*. 2000;55:515-521.
- ² Yunginger JW, Nelson DR, Squillace DL, Jones RT, Holley KE, Hyma BA, Biedrzycki L, Sweeney KG, Sturner WQ, Schwartz LB. Laboratory investigation of deaths due to anaphylaxis. *Journal of Forensic Science* 1991; 36: 857-65.
- ³ Foucard T, Malmheden Yamn I. A study on severe food reactions in Sweden-is soy protein an underestimated cause of food anaphylaxis? *Allergy*. 1999;54:261-265.
- ⁴ Young E, Stoneham MD, Petruckevitch A, Barton J, Rona R. A population study of food intolerance. *Lancet*. 1994;343:1127-1130.
- ⁵ Bock SA. Prospective appraisal of complaints of adverse reactions to food in children during the first 3 years of life. *Pediatrics*. 1987;79:683-688.
- ⁶ Magnolfi CF, Zani G, Lacava L, Patria MF, Bardare M. Soy allergy in atopic children. *Ann Allergy Asthma Immunol*. 1996;77:197-201.
- ⁷ Sampson HA, McCaskill CC. Food hypersensitivity and atopic dermatitis: evaluation of 113 patients. *J Pediatr*. 1995;107:669-675.
- ⁸ Host A, Halken S. A prospective study of cow milk allergy in Danish infants during the first 3 years of life. *Allergy*. 1990;45:587-596.
- ⁹ Vierk K, Faldi K, Wolyniak C, Klontz KC. Recalls of foods containing undeclared allergens reported to the US Food and Drug Administration, fiscal year 1999. *J Allergy Clin Immunol* 2002;109:1022-6.