

Tuesday, August 16, 2022

Submitted electronically via regulations.gov

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



Re: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act; Docket No.: [FDA-2021-N-0553](#)

Soy Nutrition Institute Global (SNI Global) thanks the Food and Drug Administration (FDA or the Agency) for the opportunity to comment on the guidance entitled, *“Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.”* SNI Global is the leading voice representing soy industry producers, suppliers, and users up and down the soy value chain involved with soybeans or soy ingredients intended for human use.

SNI Global supports transparency and providing consumers - particularly those with food allergies - with critical information about food allergens in soy products. That is why our members are committed to disclosing the presence of soy and the other major allergens on the labels of soy products. We also use our communications platform to inform individuals who are allergic to soy that they need to avoid soyfoods while also informing these individuals they can safely consume highly refined soybean oil, which is an important source of both essential fatty acids.

SNI Global appreciates the draft approach the Agency intends to take when evaluating the public health importance of food allergens that are not one of the 9 major food allergens. We were pleased to see a detailed background section explaining the current regulatory framework for allergens, the data the FDA would consider the most relevant for consideration of potential allergens, and discussion of the lowest eliciting dose for an allergen. However, SNI Global members are concerned the draft guidance establishes the framework and process that the Agency plans to follow for future evaluations of non-listed food allergens but does not identify the scientific or legal standards that would be applied. Our members believe the Agency should provide clear levels at which a food allergen will be considered prevalent, severe, and potent in the U.S. population. For example, for potency, FDA should clearly outline a level below which it is unlikely a food allergic individual would experience an adverse effect when exposed.

Soy is on the Big 9 major allergens list, which also includes milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and sesame. However, the prevalence of soy allergy is low in comparison to the other foods on the list. This point is made very clear by a paper recently published in the journal *Nutrition Today*, which reviewed four North American surveys of the prevalence of food allergies. This review found that the prevalence of soy allergies is far lower

than all but one of the other major allergens (sesame allergy is less prevalent than soy allergy). In fact, the surveys show that 1, 1.6, 3.5 and 6.0 out of every 1,000 adults are allergic to soy. If one simply averages the results of the 4 surveys, then the evidence suggests about 3 out of every 1,000 adults are allergic to soy.¹

We offer this information understanding that the Agency intends to evaluate the public health importance of food allergens that are not currently one of the major food allergens. If a food has a higher prevalence than any one of the Big 9, does the agency believe this demonstrates the need for its addition? By outlining prevalence level parameters across the criteria FDA uses in the draft guidance, questions such as this one can be addressed. Moreover, it can help us more effectively evaluate the public health importance of all food allergens and, most importantly, protect those who suffer from food allergies.

We look forward to ongoing dialogue with FDA and moving forward on issues related to the future of the Food Allergen Labeling and Consumer Protection Act (FALCPA) that provide clarity and certainty to manufacturers and consumers. Should you have any questions about this letter, please contact me.

Sincerely,

Julie Ohmen
Chief Executive Officer
SNI Global

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1. Messina, Mark, Carina Venter. Recent Surveys on Food Allergy Prevalence. *Nutrition Today* 2020; 55:22-29.