

August 17, 2022

VIA ELECTRONIC SUBMISSION

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

Docket No. FDA-2021-N-0553 (April 18, 2022)

RE: Comment Request on Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act; Draft Guidance for FDA Staff and Stakeholders

The Institute of Shortening and Edible Oils (ISEO) appreciates the opportunity to provide comments to the U.S. Food and Drug Administration (FDA) on its draft guidance titled *“Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.”* We applaud FDA for taking this action as it works to define a transparent, science-based process when evaluating the public health importance of a non-listed food allergen. ISEO looks forward to being a resource and partner to you as you move forward.

Introduction

ISEO submits these comments on behalf of U.S. refiners who produce 95 percent of domestic edible fats and oils from the following commodities: U.S. grown soybean, U.S. grown corn, U.S. grown cottonseed, U.S. grown canola, U.S. grown rice, U.S. grown sunflower, U.S. grown safflower, U.S. produced lard, tallow, and wheat germ, as well as imported commodities such: olive, palm, palm kernel, coconut, canola and sunflower) used for baking, frying, cooking and also as ingredients in a wide variety of foods and personal care products from confections to cosmetics.

Background on the Allergenicity of Edible Oils in the U.S.

As noted by Susan L. Hefle, Ph.D. with Food Allergy Research and Resource Program (FARRP) at the University of Nebraska in a white paper titled: [Allergenicity of Edible Oils](#), food allergies are caused by proteins in food. These naturally occurring proteins are referred to as allergens, and the vast majority of them are resistant to heat and digestion.

In contrast, edible oils processed by typical U.S. procedures are highly refined and contain no detectable protein. Because these highly refined oils are virtually free of allergenic protein, these oils are generally safe for allergic individuals to eat. These refined oils are most often used in the production of salad dressings, margarine, and many other food products.

The vast preponderance of edible oils consumed in the U.S. are highly refined and processed to the extent that allergenic proteins are not present in detectable amounts. The majority of well-

designed and performed scientific studies indicate that refined oils are safe for the food-allergic population to consume.

For these reasons, and per the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) “the term ‘major food allergen’ means (among other definitions) “A food ingredient that contains protein derived from a food”, “except any highly refined oil derived from a food and any ingredient derived from such highly refined oil”.

Finally, the National Bioengineered Food Disclosure Standard (NBFDS or the Standard) by the U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS) requires food manufacturers, importers, and other entities that label foods for retail sale to disclose information about bioengineered (BE) food and BE food ingredients to provide a mandatory uniform national standard for disclosure of information to consumers about the BE status of foods. As part of the implementation of the Standard, USDA AMS concluded that the Standard “defines bioengineered foods as those that contain detectable genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature” and therefore “highly refined foods or ingredients (such as edible oils) that do not contain detectable modified genetic material are not bioengineered foods”.

ISEO continues to follow the science on this topic work closely with Food Allergy Research and Resource Program (FARRP) to ensure it has the latest information and science on the allergenicity of edible oils. In the event the science evolves on this topic as it relates to refined edible oils, ISEO is pleased to share additional information with FDA in this regard.

ISEO Recommendations on Draft Guidance

Overall, we appreciate that FDA’s general draft framework follows the criteria of evidence of IgE-mediation, prevalence, potency and severity which were also the agreed upon criteria of the ad hoc FAO/WHO joint expert consultation on food allergen risk assessment. However, there are some key recommendations we believe FDA should include in its final version as discussed below:

- 1.) Support Public Rulemaking and the Publication of a Full Risk Assessment for Listing a New Food Allergen

It is most appropriate to address the listing of future food allergens through notice-and-comment rulemaking in conjunction with the publication of a full risk assessment for public comment.

This process allows an opportunity for meaningful stakeholder engagement and solicitation of critically important data and information. Once finalized, a rule would establish mandatory, enforceable requirements, consistency in industry and consumer expectations, and a clear timeline for implementation.

- 2.) Support a Clear Regulatory Process and Framework for Identifying New Allergens and Removing Allergens that are No Longer a Concern

ISEO generally supports the direction FDA is taking to use a scientific criteria for identifying and evaluating new food allergens beyond the major allergens. We believe assessing the evidence of IgE-mediation, prevalence in the U.S. population, severity, and potency of a potential allergen serves as a strong science-based framework that can be supported by both industry and consumers. In addition to identifying and evaluating new food allergens, we request that FDA explain whether the same scientific criteria could be used to remove allergens that are no longer of public health importance due to changing science and risk. As FDA proceeds, we encourage you to continue to use ISEO as a resource, and engage with experts in the food allergen space such as Food Allergy Research & Education (FARE), FAARP, and the Asthma and Allergy Foundation of America (AAFA) to inform its work.

Conclusion

Thank you for your consideration of these comments. ISEO stands ready to be a resource and a partner to FDA as it works to finalize a transparent, science-based process when evaluating the public health importance of a non-listed food allergen.

Sincerely,

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