



AMERICAN SPICE TRADE ASSOCIATION, INC.

1101 17th Street, N.W. • Suite 700
Washington, DC 20036 USA
Tel: 202-331-2460 • Fax: 202-463-8998
E-mail: info@astaspice.org
Web: www.astaspice.org

Via Electronic Transmission

December 31, 2018

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

Re: Food and Drug Administration [Docket No. FDA-2018-N-3809] Sesame as an Allergen in Foods, request for comment, 83 Fed. Reg 54594 (October 30, 2018)

To Whom it May Concern:

On behalf of the American Spice Trade Association (ASTA), we appreciate the opportunity to submit comments in response to the U.S. Food and Drug Administration (FDA) Request for Comment on Sesame as an Allergen in Foods.

Introduction

ASTA was established in 1907 and is the voice of the U.S. spice industry in the global market. Our members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the wholesale and retail levels. We represent our members' U.S. interests by supporting regulatory compliance and maintaining relationships with U.S. agencies.

ASTA shares FDA's commitment to food safety. Our highest priority is ensuring the supply of clean, safe spices to American consumers. Additionally, we have consistently advocated to ensure that FDA is adequately resourced and are a member of the Alliance for a Stronger FDA.

Many of our members import and process sesame seeds. We support science-based policies pertaining to allergens and believe that the FDA should base decisions to identify major food allergens strictly on the best available science. If credible research identifies sesame as a major allergen in the United States, we would support the disclosure of sesame on food labels.

ASTA has a long history of working with food regulatory authorities and we are pleased to provide the following information in response to the questions in FDA's request for comment on sesame as an allergen in foods. Additionally, we are collaborating with the Food Allergy Research & Resource Program (FARRP) to solicit responses to their survey about sesame labeling and cross-contact from our members.

Responses to Questions in the FDA's Request for Comments

Question B.1 What are examples of products or product categories that contain sesame as a spice, flavor, color, or incidental additive and that do not list "sesame" on the product labeling?

The FDA Compliance Policy Guide Sec. 525.750 for Spices¹ states that sesame seeds "are not considered to be spices. When used as an ingredient in foods they should be declared on the label by common or usual name[.]" The practical implication of this FDA policy guide is that sesame seeds are already currently labeled as such on food products and are not listed under spices on labels.

There are scenarios in which a sesame-containing ingredient, or a food such as tahini, may be used to formulate or manufacture a flavoring that may be added to a spice or seasoning blend. In this instance the ingredient or food would be declared on the bulk flavor label consistent with the regulations at 21 CFR 101.22(g), and if the material is a constituent of a flavoring added to a spice or seasoning blend then it may be labeled consistent with the regulations at 21 CFR 101.22(h). As such, there are instances under current law where sesame ingredients would not be required to be declared on the label.

Question C.1 What would the costs be if we established disclosure requirements for sesame? We are interested in any costs, specifically those to manufacturers for labeling changes to reflect sesame as an ingredient, spice, flavor, color, or incidental additive.

Labeling changes would require finishing (or discarding) the current stock of labels and updating products with new labels. Estimates from our members indicate that this would cost a one-time fee of approximately \$3,000-4,000 dollars per impacted SKU. Providing adequate lead time to implement the change would help to alleviate the cost and burden to the industry.

Additionally, consideration must be given to products currently in the stream of commerce that may not comply with any new allergen labeling requirements that may be established for sesame. Spices generally have a long shelf life, often up to three-years. ASTA requests that any new labeling requirements would not be applied to products already in the stream of commerce and that a minimum of one year be provided for new product labels to be updated.

Several jurisdictions including the European Union, Australia, New Zealand and Canada regulate and require labeling for sesame as an allergen. As such, some multi-national companies currently label sesame as an allergen.

Question C.2 What would the costs be to manufacturers to control allergen cross-contact from sesame and what would the costs be of educating food managers at retail or food establishments to control for sesame as an allergen?

Under current law and policy, companies are not required to perform a full allergen cleaning between a product with sesame and another product that is produced on the same line or in the same factory. We are aware of companies that currently produce non-sesame products after sesame products on the same equipment without conducting an allergen changeover. If FDA requires that sesame be regulated in a manner similar to the major food allergens, manufacturers will need to implement new allergen changeover procedures. The cost of an allergen changeover and the number required per year varies by company. One ASTA member estimates that each new allergen changeover for sesame products would cost approximately \$3,000 annually. Members that process sesame have reported sesame changeovers ranging from just a few to dozens.

¹ <https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074468.htm>

Question C3 What steps have manufacturers taken to eliminate or reduce cross-contact from sesame and/or sesame-containing ingredients?

Multinational companies that sell into markets that currently regulate sesame as an allergen have changeover procedures in place to control for sesame cross-contact. However, since sesame is not currently considered an allergen in the United States, companies do not typically execute allergen changeovers for products sold into the U.S. market.

Conclusion

ASTA supports science-based policy. If credible scientific evidence determines that sesame is a major allergen, we would support allergen labeling for sesame. However, the industry would need sufficient time to implement new labeling requirements and we request that any new labeling regulations do not impact product already in the stream of commerce.

ASTA appreciates the opportunity to comment on the FDA request for comments on Sesame as an Allergen in Foods.

Sincerely,

A handwritten signature in cursive script that reads "Laura Shumow". The signature is written in black ink and includes a long horizontal flourish at the end.

Laura Shumow
Executive Director
American Spice Trade Association