Barley Snyder

Should Sesame Join the Big 8 Allergens?

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The "Big 9"?

While sesame has never in the United States been declared a major allergen that must be listed on food labeling if it is included in the ingredients -- even if it has in other countries -- new data from the federal Food and Drug Administration suggests it somewhat easily could someday force its way onto the list.

The data, which is now part of <u>new draft guidance from the FDA</u>, show that 0.2% of both children and adults suffer from a sesame allergy, just less than the rate of the Big 8 allergens. However, the data report shows that two-thirds of a sesame allergy reaction in children requires an emergency room visit - more than most other allergens.

Based on the data gathered, the FDA has concluded that severe allergic reactions have occurred because consumers may not know things like hummus and tahini may have sesame as one of their "flavorings." The new FDA guidance suggests the industry disclose when a spice or flavoring contains sesame, such as an ingredient statement with a sesame-containing component that should now look more like "spices (including sesame)" or "tahini (sesame)."

Even when the final version is published, the <u>Voluntary Disclosure of Sesame as an Allergen: Guidance for</u> <u>Industry</u> is not binding, but rather reflects the agency's current thinking on this issue. The FDA encourages interested parties to submit comments to the draft version of this guidance within 60 days.

However, while not required, the draft guidance and subsequent final guidance may be treated as a standard of care or industry standard in a product liability setting. If you have sesame products you should confer with your insurer and counsel about labeling.

If you have any questions about whether your company's labeling is compliant with the most up-to-date labeling requirements and guidance, or if you would like assistance with comments on the draft guidance, please <u>contact me</u> or anyone in the <u>Barley Snyder Food & Agribusiness Industry Group</u>.

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