

## Implementing Changes to FDA’s Updated Allergen Guidance<sup>1</sup>

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The United States Food and Drug Administration (FDA) recently issued [Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act \(Edition 5\)](#). In late March 2025, FDA released [Frequently Asked Questions: Food Allergen Labeling Guidance for Industry](#), which provides further guidance and offers insight into the new administration’s thinking on allergen labeling. This summary provides a recap of the changes in FDA’s approach to major food allergens and information to guide the industry’s implementation of the changes.

### What Foods Are No Longer Considered Major Allergens?

The FDA’s recent guidance provides a list of 12 tree nuts that FDA considers major food allergens, stating, “[o]nly the tree nuts listed... are considered major food allergens.” The following table compares FDA’s 2025 list to the list previously incorporated in FDA’s 2022 draft guidance:

Tree nuts, according to the 2025 Final Guidance	Additional tree nuts, according to the 2022 Draft <i>(no longer tree nuts, according to 2025 Final Guidance)</i>
<ul style="list-style-type: none"> <li>• Almond</li> <li>• Black walnut</li> <li>• Brazil nut</li> <li>• California walnut</li> <li>• Cashew</li> <li>• Filbert/Hazelnut</li> <li>• Heartnut/Japanese walnut</li> <li>• Macadamia nut/Bush nut</li> <li>• Pecan</li> <li>• Pine nut/Pinon nut</li> <li>• Pistachio</li> <li>• Walnut (English, Persian)</li> </ul>	<ul style="list-style-type: none"> <li>• Beech nut</li> <li>• Butternut</li> <li>• Chestnut</li> <li>• Chinquapin</li> <li>• Coconut</li> <li>• Cola/kola nut</li> <li>• Ginkgo nut</li> <li>• Hickory nut</li> <li>• Palm nut</li> <li>• Pili nut</li> <li>• Shea nut</li> <li>• Any other tree nut, as defined by the manufacturer</li> </ul>

### What Additional Foods Are Now Considered Major Allergens?

FDA’s recent guidance expands the list of foods that are considered “milk” and “egg” for purposes of declaring major allergens.

**Milk** now includes milk from “goats, sheep or other ruminants,” as well as cows.<sup>2</sup> Milk from animals other than cows should be indicated as such (e.g., “Contains goat milk”).<sup>3</sup>

**Egg** now includes eggs from “ducks, geese, quail and other fowl,” as well as chickens.<sup>4</sup> Eggs from birds other than chickens also should include the name of the bird source (e.g., “Contains duck eggs”).<sup>5</sup>

<sup>1</sup> Prepared by Suzie Trigg and Carleigh Lenz as of February 3, 2025; updated April 8, 2025. See FDA, [Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act \(Edition 5\)](#) (Jan. 6, 2025) (“**2025 Final Guidance**”); FDA, [Frequently Asked Questions: Food Allergen Labeling Guidance for Industry](#) (March 26, 2025) (“**March FAQs**”).

<sup>2</sup> 2025 Final Guidance at 13.

<sup>3</sup> March FAQs, [Milk and Eggs Question 3](#).

<sup>4</sup> 2025 Final Guidance at 13.

<sup>5</sup> March FAQs, [Milk and Eggs Question 4](#).

## When is Compliance Required?

The March 2025 FAQs confirm that the FDA's recent guidance is currently effective.<sup>6</sup> FDA acknowledges the "implications" of requiring label changes and indicates it will allow companies an informal grace period. The FDA's statements indicate that it believes that *adding* the new milk and egg allergens to "Contains" statements is more of a public health concern—and therefore more time sensitive—than *removing* coconut and other nuts that are no longer considered "tree nuts" from the "Contains" statements.

### ***How long will companies have to update labels that currently list coconut (or other nuts no longer considered "tree nuts") in the "Contains" statement?***

*"... FDA recognizes that product labels might be corrected the next time they are printed. Alternatively, the firm may choose to use a sticker to cover the outdated labeling."<sup>7</sup> As part of its answer to a related question, FDA also states that, "[t]here will be a transitional period before firms remove coconut from the 'Contains' statement. In addition, some packaged foods can have a long shelf life, and you may continue to see products declaring coconut in the 'Contains' statement for a few years."<sup>8</sup>*

### ***If I use duck eggs and goat milk as ingredients in my packaged food, but I do not label them as major food allergens in the "Contains" statement adjacent to my ingredient statement, can I continue to use these labels?***

*"In this case, if the duck eggs and goat milk ingredients are labeled in the ingredient statement and a 'Contains' statement is also used, firms must make necessary labeling updates by adding duck eggs and goat milk in the 'Contains' statement. While firms must be in compliance with major food allergen requirements of the FD&C Act, we understand the implications of making label changes and that firms have been relying on previous guidance. However, these are significant public health concerns for those consumers who are allergic to these products and therefore we recommend label changes as soon as practicable. Alternatively, the firm may choose to use a sticker to cover the outdated labeling. FDA's compliance approach is generally risk-based and FDA evaluates compliance actions on a case-by-case basis. If a firm has questions, we encourage the firm to contact FDA's Food and Cosmetic Information Center."<sup>9</sup>*

Impacted stakeholders should seek guidance specific to their products prior to implementing changes and regarding specific timing.

## What Else Do Food Manufacturers Need to Do?

Companies that manufacture, process, pack or hold human food should update their allergen cross-contact preventative controls, hazard analysis and critical control point (HACCP) plans, as applicable, to reflect these changes in what foods are considered major allergens. In contrast to label changes, FDA does not indicate whether it plans to afford manufacturers a grace period to make these changes.<sup>10</sup>

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<sup>6</sup> March FAQs, [Compliance Question 4](#) (the uniform compliance date does not apply).

<sup>7</sup> March FAQs, [Compliance Question 6](#).

<sup>8</sup> March FAQs, [Consumer Question 1](#).

<sup>9</sup> March FAQs, [Compliance Question 5](#).

<sup>10</sup> March FAQs, [Compliance Question 2](#) and [3](#).