

## Not-So-Sweet Surprises for Allergy Sufferers

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"How much is too much?"

This is a question asked fairly often in the context of allergen cross-contamination. We know that a Nutella is made from hazelnuts (these delicious morsels also go by the name "filbert"), so it's no surprise to see the required "Contains hazelnuts" statement on the label. But when is it appropriate to say "may contain peanuts" or "manufactured on equipment that also processes soy"? And which of these statements may be required?

As a general rule, if one of the "[Big Eight](#)" allergens is included in a food as an ingredient, the U.S. Food and Drug Administration (FDA) requires a warning statement on the food's package that begins with the word "Contains," and states which allergen is present in the product. Food manufacturers know that avoiding allergen cross contamination is a part of Current Good Manufacturing Practice (cGMP). Yet, even the most comprehensive cleanout procedures may leave dangerous levels of residue behind. The FDA doesn't have any requirements for statements - called "advisory statements" - intended to alert customers to some level of unintentional allergen residue resulting from cross-contamination.

Does the FDA tell us where to draw the line between warning statements and advisory statements? How much is too much? As it stands today, FDA doesn't provide any quantitative guidance here for the Big Eight.

For now.

The agency [recently published a study](#) of a sampling of dark chocolate manufactured and sold in the U.S. bearing "dairy free" or similar claims, and found a number of products (approximately 10%) containing what FDA refers to as "potentially hazardous levels of undeclared milk." It seems that there is a threshold level of allergen - at least for milk - that the FDA considers to be hazardous. However, the agency has yet to publish any "action level" or, conversely, "tolerance level," leaving manufacturers ruminating over how best to label products that *may* contain an allergen.

The FDA has indicated its intent to continue to monitor the food industry for allergen levels in "allergen-free" products, and we will continue to monitor any action the FDA may take, including the possible establishment of tolerance levels.

If you have questions about how to label your food product, or any questions related to food manufacturing and sales, please [contact me](#) or anyone in the Barley Snyder [Food & Agribusiness Industry Group](#) for guidance.

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