

**Conference for Food Protection
2016 Issue Form**

Issue: 2016 I-029

Council Recommendation: Accepted as Submitted _____ Accepted as Amended _____ No Action _____

Delegate Action: Accepted _____ Rejected _____

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Issue History:

This is a brand new Issue.

Title:

Labeling for Food Allergen Cross-Contact

Issue you would like the Conference to consider:

Adding an addendum to the 2013 FDA Food Code subparagraph 3-602.11(B)(5) to include a statement on a product's label, when applicable, that cross-contact with specifically named allergens is possible.

Public Health Significance:

Consumers assume that delis, bakeries, grocery stores, restaurants, and other venues that sell pre-packaged foods (i.e., foods NOT produced and packaged in manufacturing plants that fall under the provisions of the Food Allergen Labeling and Consumer Protection Act, FALCPA) are labeled as stringently for the presence of allergens as manufactured products, and also assume that these venues practice strict allergen control. Because the labels seldom indicate the potential presence of allergens due to cross-contact, reactions have occurred, including food anaphylaxis deaths.

Recommended Solution: The Conference recommends...:

that a letter be sent to the FDA requesting that subparagraph 3-601.11(B)(5) of the 2013 Food Code be amended as follows (language to add is underlined):

3-601.11 Food Labels.

(B) Label information shall include:

(5) The name of the FOOD source for each MAJOR FOOD ALLERGEN contained in the FOOD unless the FOOD source is already part of the common or usual name of the respective ingredient.^{Pf} When applicable, all pre-packaged items will have a label stating that the food may have been in contact with allergens specifically named by the venue preparing and/or packaging the product.

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Supporting Attachments:

- "Suit in Allergy Death: Should Store Bakeries Have to Label? (redacted)"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Suit in Allergy Death: Should Store Bakeries Have to Label?

Posted By *Ishani Nath* On 2015/07/08 @ 9:10 am In Food Allergy

A lawsuit in the death of an Alabama boy, who suffered fatal anaphylaxis from eating a cookie, could have broad implications for supermarket bakeries and food-allergic consumers.

The family of 11-year-old Derek “Landon” Wood filed the lawsuit, in which a crucial aspect is whether a grocery store’s bakery should be required to label all of its products, since many of them are made, either entirely or mostly, off the bakery premises.

██████████, which sold the cookie, takes issue with that interpretation of the U.S. food allergen labeling law, known as FALCPA ([Food Allergen Labeling and Consumer Protection Act](#)^[2]). It had filed a motion to get the case dismissed.

But on June 11, 2015, a U.S. district judge denied that motion, finding that the family’s case has sufficient merit, and allowing the case to proceed.

One thing that no one disputes is that Landon’s death was a tragedy and a traumatic experience. The boy, who had multiple food allergies and asthma, and his mother Beth Cline were visiting family in Clarksville, Tennessee on June 3, 2014 when, along with his aunt and cousin, they stopped at a ██████████ store.

In the bakery section, Landon asked his mother to buy him an unlabeled, ready-to-eat “Chocolate Chew” cookie. In the lawsuit, Cline says she spoke to the bakery employee and was assured that the cookie did not contain tree nuts – one of Landon’s allergens. (In its legal response, ██████████ denies a bakery employee would have told Cline this.) Cline says it is based on this information that she bought her son the cookie, and a sugar cookie for his cousin.

After returning to the aunt’s house, the suit says that Landon had three bites of the cookie, and began saying that his mouth was burning. His mother gave him Benadryl, but the symptoms progressed, with Landon finding it harder to breathe, and his face turning red. His mother administered his epinephrine auto-injector as her sister called an ambulance.

The boy’s condition improved briefly during the ambulance ride, but in hospital, even with further medication, his breathing worsened, and he suffered extreme swelling and plummeting blood pressure. Landon was airlifted to Vanderbilt Children’s Hospital in Nashville, but his condition could not be stabilized; he died at 10:19 that evening.

The family's lawsuit against the grocery chain calls for "compensation for [REDACTED]'s negligence and to raise awareness of potential fatal food allergies in American children."

[REDACTED], for its part, denies the negligence claims. The grocery chain has yet to either agree or deny that a conversation took place between Cline and one its bakery employees. But [REDACTED] does say that the Chocolate Chew cookies were known by staff to contain tree nuts as an ingredient, and it denies that a bakery employee would have told Cline that these cookies were free of nuts.

As the case moves forward, a key element is the legal interpretation of [FALCPA](#) ^[2], which requires manufacturers to list the Top 8 allergens on the labels of packaged foods, but **exempts foods that are placed in a wrapper or container or prepared on a made-to-order basis** – like a deli sandwich. Further, FALCPA does not cover foods "served in restaurants or other establishments in which food is served for immediate human consumption".

In Landon's death, however, the family argues that these exemptions should not apply, since the [REDACTED] supermarket that sold the cookie makes most of its finished baked goods at a regional facility, and products are then shipped to in-store bakeries. ([REDACTED] has not yet answered how Landon's specific cookie was prepared.)

In its response, [REDACTED] contends that the Chocolate Chew Cookie does not require ingredient labeling because it is "prepared and displayed in a bakery setting and then placed in a wrapper or similar package in response to a consumer's order."

U.S. District Court Judge Aleta Trauger noted that, in attempting to have the family's case dismissed, [REDACTED] had argued that the cookies that were sold fell within this exception in FALCPA as well as within a similar "immediate consumption" clause in the federal Food, Drug and Cosmetic Act. The judge summarized that the supermarket chain also suggested that the cookie could be considered "made-to-order", making it exempt from labeling requirements.

"[REDACTED] appears to contend that, because products sold from behind the display case are not packaged and can be sold individually, the products are indistinguishable from cookies sold at a mall cookie counter or a muffin sold at a coffee cart," Trauger wrote.

But in denying the [REDACTED] motion, she found that, because the cookie did not appear to be served for immediate consumption, nor prepared fresh such as from a food truck, **"the plaintiffs (the family) have sufficiently alleged that the [REDACTED] bakery was subject to the labeling requirements"**.

"From my perspective, [REDACTED] the retail store is not operating a bakery," Eddie Schmidt, the attorney representing Landon's family, told Allergic Living. "It's simply a

section of the grocery store.” ██████████ would not comment directly to Allergic Living on the continuing lawsuit.

“Part of this lawsuit seeks a declaratory judgment from a federal court that ██████████ cannot use this FDA-interpreted exception to bakeries for not labeling its bakery products,” Schmidt said. “If that is accomplished, that will require ██████████, as well as all other grocery stores who are selling bakery products, to identify the food allergens within its products.”

Donna Rosenbaum, a consultant with Food Safety Partners, has given the plaintiffs some advice in this suit. She views the in-store bakery labeling issue as an example of how FALCPA has “eroded and evolved over time”.

“I would love to see movement from within the industry, and not just from the consumer base; I would love to see people come together on this,” she said. “Stores don’t want to get sued and consumers certainly don’t want to get sick from store products, so it should be a win-win.”

She acknowledges, however, that any significant changes will take time. For now, she says the allergic community should look at grocery store bakery products with an added layer of suspicion, and she encourages parents to raise these concerns with grocery store managers, to let them know it’s an important issue.

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URLs in this post:

[1] Image: <http://allergicliving.com/wp-content/uploads/2015/03/d8b41ce6-9ac5-4d69-aa47-d30db88d49af.jpg>

[2] Food Allergen Labeling and Consumer Protection Act:
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm>