

Food Allergy Focus: Trends, Challenges and Opportunities

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“Most parents’ worst nightmare is a car accident, a bus accident; someone kidnaps your kid, something like that. My worst nightmare is simple. It’s a crumb.”





Our Mission

To ensure the safety and inclusion of individuals with food allergies, while relentlessly seeking a cure.





Our Work

- Provide evidence-based education and resources.
- Address public policy at all levels of government.
- Increase awareness of food allergies as a serious public health issue.
- Fund world-class research that advances treatment and understanding.



Food Allergy Platforms

- **Communications**
 - www.foodallergy.org
 - Weekly emails and quarterly newsletters
- **Awareness Programs**
 - FARE Walk for Food Allergy
 - Galas and Luncheons
 - Over The Edge
- **Education Resources**
 - Food Allergy Conferences
 - Teen Summit
 - Food Allergy Awareness Week
 - Educational Materials and Programs
 - Support Groups
- **Advocacy Campaigns**
 - School Epinephrine Campaign
 - Regulatory Reforms
 - Advocates Network

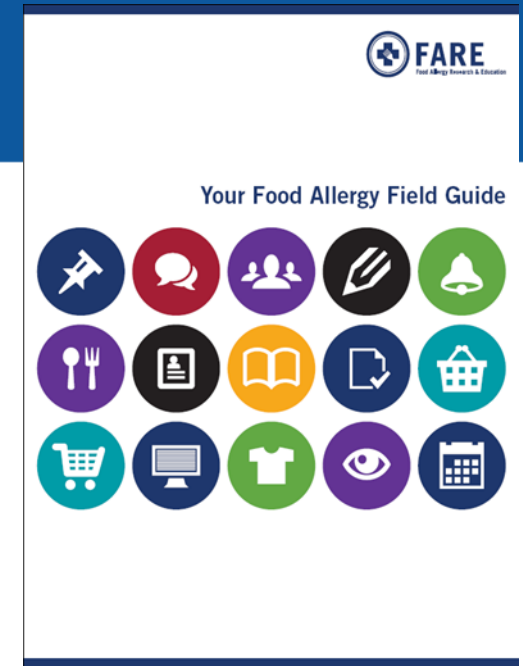




FARE Programs

■ Education Initiatives

- *Your Food Allergy Field Guide*
- National Food Allergy Conference (June 21-22, 2014 – Chicago)
- Monthly Webinar Series
- Teen Summit, Teen Advisory Group (TAG)
- College Food Allergy Program
- Grassroots Education (support groups, speakers, etc.)
- SafeFARE Restaurant Program





15 Million Reasons To Be Allergen Trained.

**15 million Americans with
food allergies dine with
family and friends where
they feel safe.**



**Get Started
Now.**



Food Allergy is a Serious & Growing Public Health Issue

15 million

Americans with food allergies

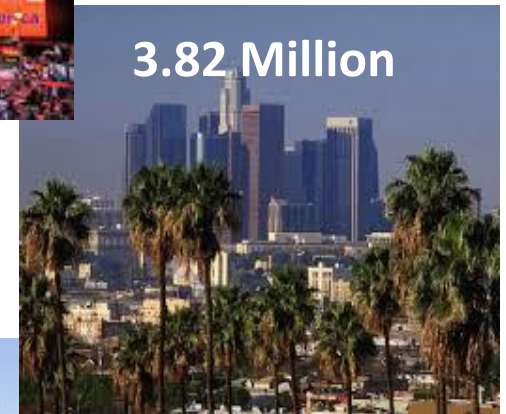
Including

6 million children



Putting It Into Perspective

- If the food allergy community were a state, it would be the **5th largest state in the U.S.** by population – right after California, Texas, New York and Florida.
- The number of people with food allergies in the U.S. is greater than the entire populations of New York City, Los Angeles and Chicago **combined.**





Food Allergy Is on the Rise

- According to a recent study by the Centers for Disease Control and Prevention, there has been an **50% increase** in food allergy between 1997 and 2011.
- In addition, more than **30 percent** of children with a food allergy (almost 1 in 3) have multiple food allergies.





Food Allergies Are Life-Threatening

- 40% of children with food allergies have experienced a severe or life-threatening reaction.
- A food allergy reaction sends someone to the emergency room every 3 minutes, resulting in 210,000 visits each year.
- Food allergy is the leading cause of anaphylaxis outside the hospital setting.





There Is Currently No Cure

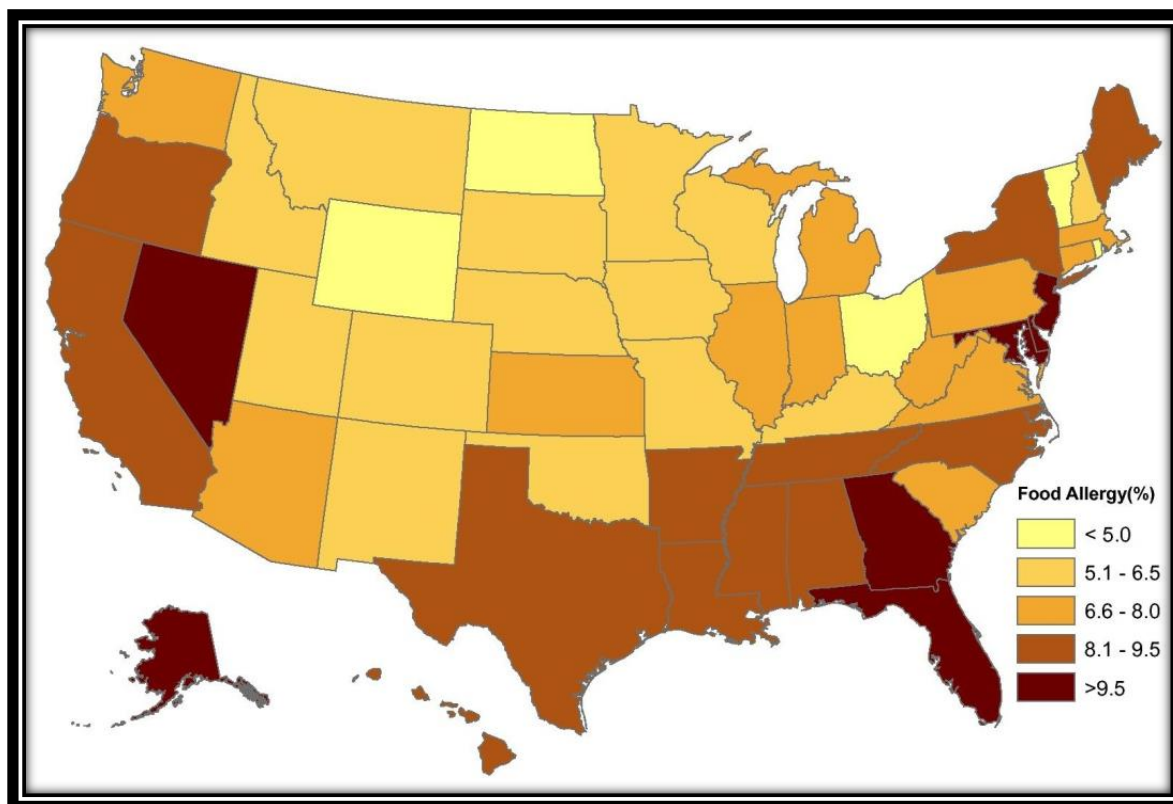
- Food allergy is the leading cause of anaphylaxis outside the hospital setting
- Fatalities associated with food-induced anaphylaxis are most commonly associated with peanut or tree nut ingestion
- FARE supports a number of clinical trials at prestigious institutions across the country that are exploring promising treatments, but these are still under study and not approved for use outside a research setting





Geographic Variability

Geographic distribution of childhood food allergy in the United States (N = 38,465)

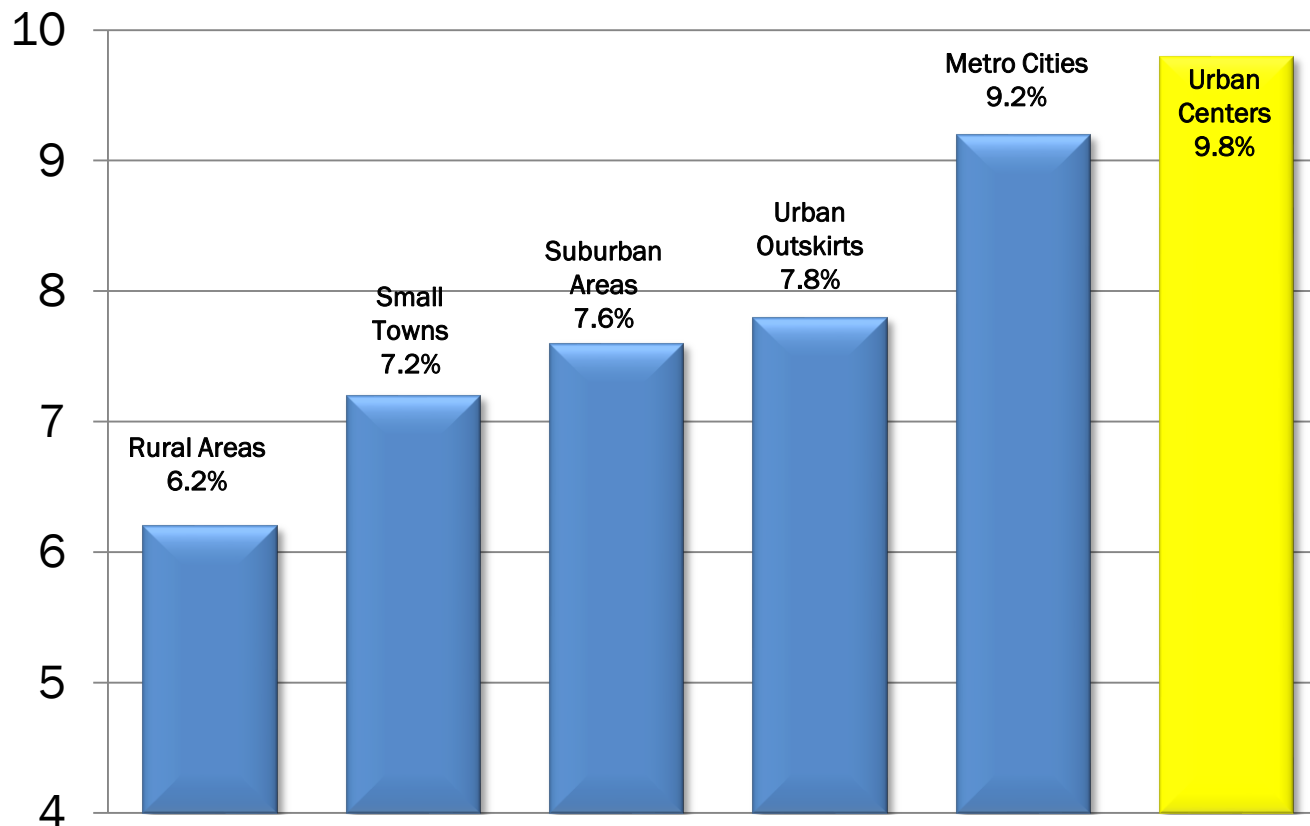


Gupta RS, Springston EE, Zhang XY, Smith B, Warrier MR, Pongracic J, Holl JK. Geographic variability of childhood food allergy in the United States. Clin Pediatr 2012, May 17. [Epub ahead of print].



Geographic Variability

Population density corresponds with food allergy prevalence ($P < 0.0001$)



Gupta RS, Springston EE, Zhang XY, Smith B, Warrier MR, Pongracic J, Holl JK. Geographic variability of childhood food allergy in the United States. Clin Pediatr 2012, May 17. [Epub ahead of print].



Advocacy Agenda - Social Impact

- ✓ Restaurants
- ✓ Elementary Schools
- ✓ Colleges
- ✓ Emergency Services
- ✓ Airlines
- ✓ Grocery Shopping





Advocacy Agenda

School Access to Emergency Epinephrine Act



The Food Allergy Customer





The Average Food Allergy Family

- Fierce loyalty to brands that they trust.
- Spend \$1.7B annually on safe foods
- Information about trusted brands is often passed through word of mouth.
- Has one or more family members with a food allergy - many are managing multiple allergies
- Tends to have higher than average family income.





Food Allergy Customer - Restaurants

15,000,000 People With Food Allergies
X \$2,505 Average Spend on Dining Out

\$37,575,000,000

6,000,000 Children With Food Allergies
X \$2,505 Average Spend on Dining Out

\$15,030,000,000

X4 (Average Family Size)

\$60,120,000,000



Laws and Guidelines

- FALCPA (Food Allergy Labeling Consumer Protection Act 2004)
 - Requires labeling of top eight food allergies
 - Advisory statements; “may contain”, “trace amounts”, “cross contact” are voluntary

- Future of labeling ---- thresholds?
 - Gluten-free – 20 parts per million
 - Enforced beginning August (manufacturers, restaurants, etc.)
 - Issues with allergens
 - How do we determine what amount is safe?



Survey of Food Allergy Community

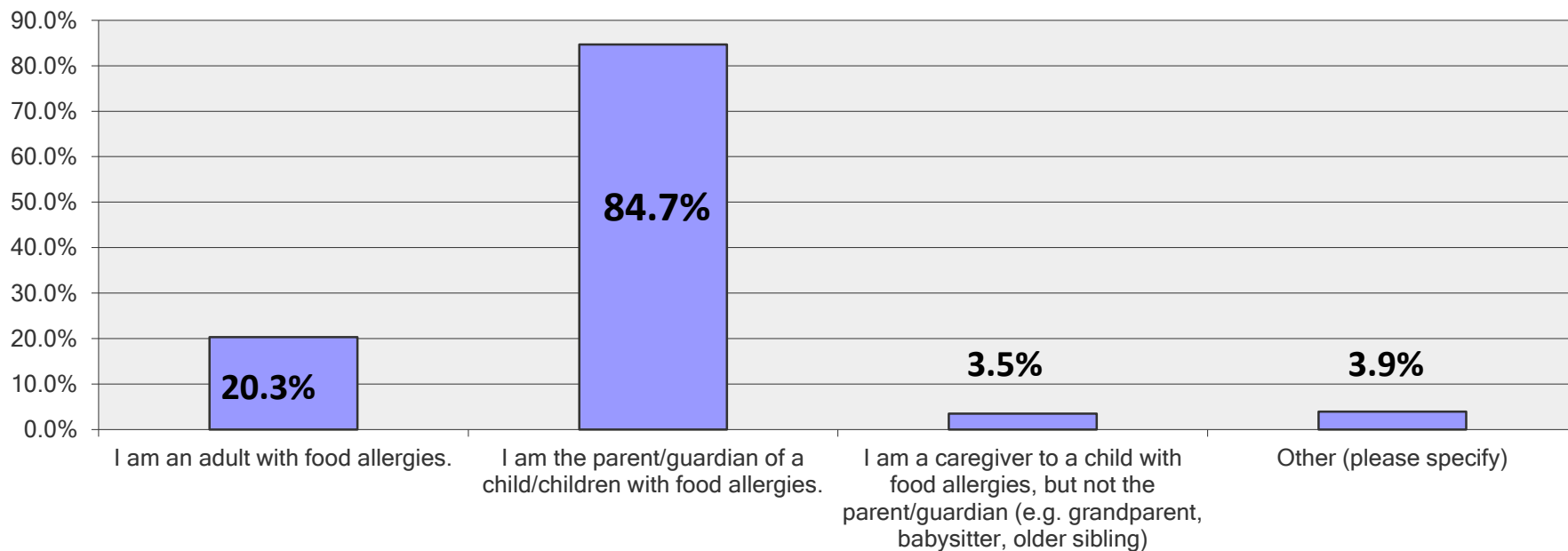
- February 2013
- 18 questions (using Survey Monkey)
- Survey link was distributed electronically via email and social media
- 5,578 members of the food allergy community participated in the survey
- Survey results can be found at: www.foodallergy.org/laws-and-regulations/current-issues

Survey Respondents



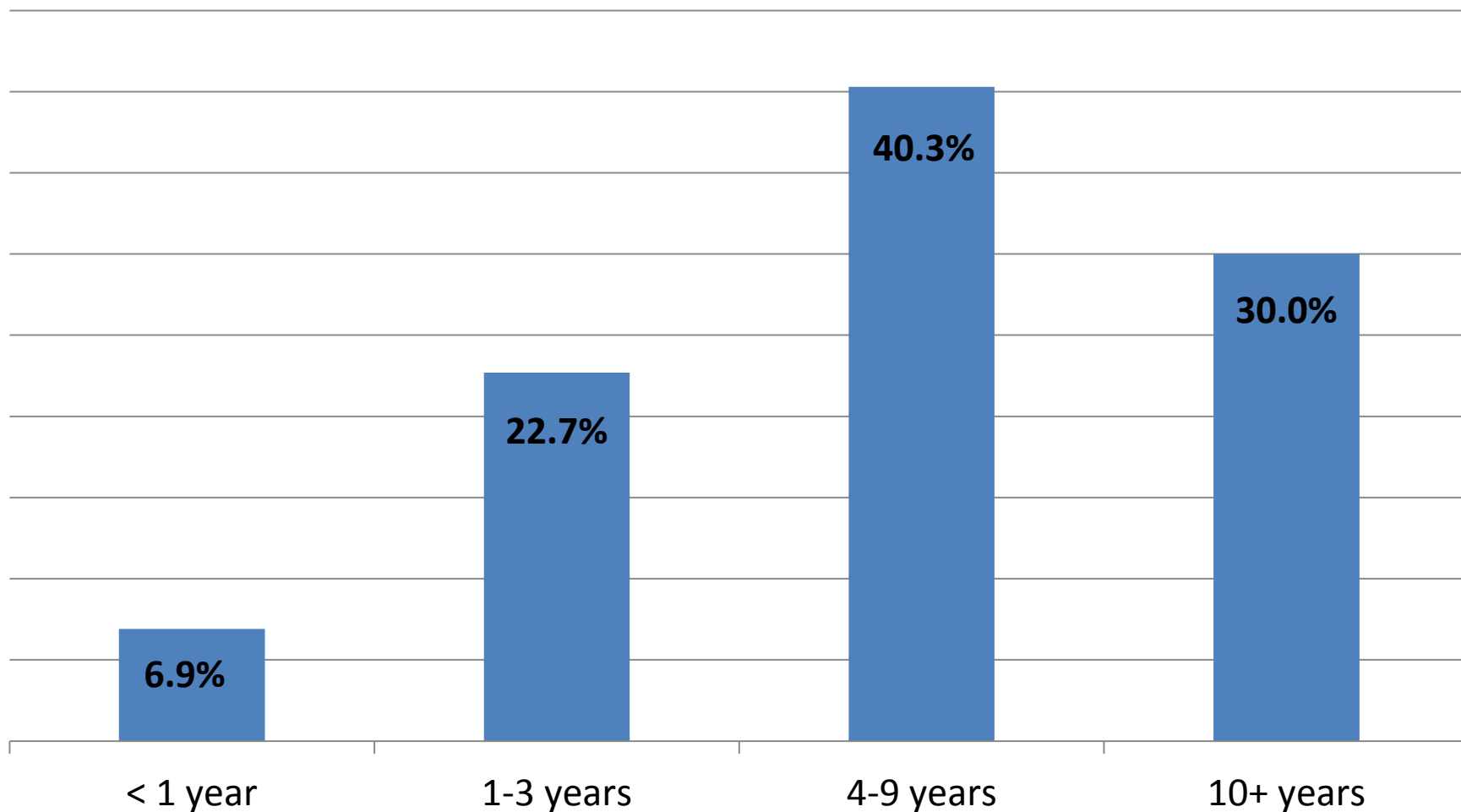


Tell Us About Yourself





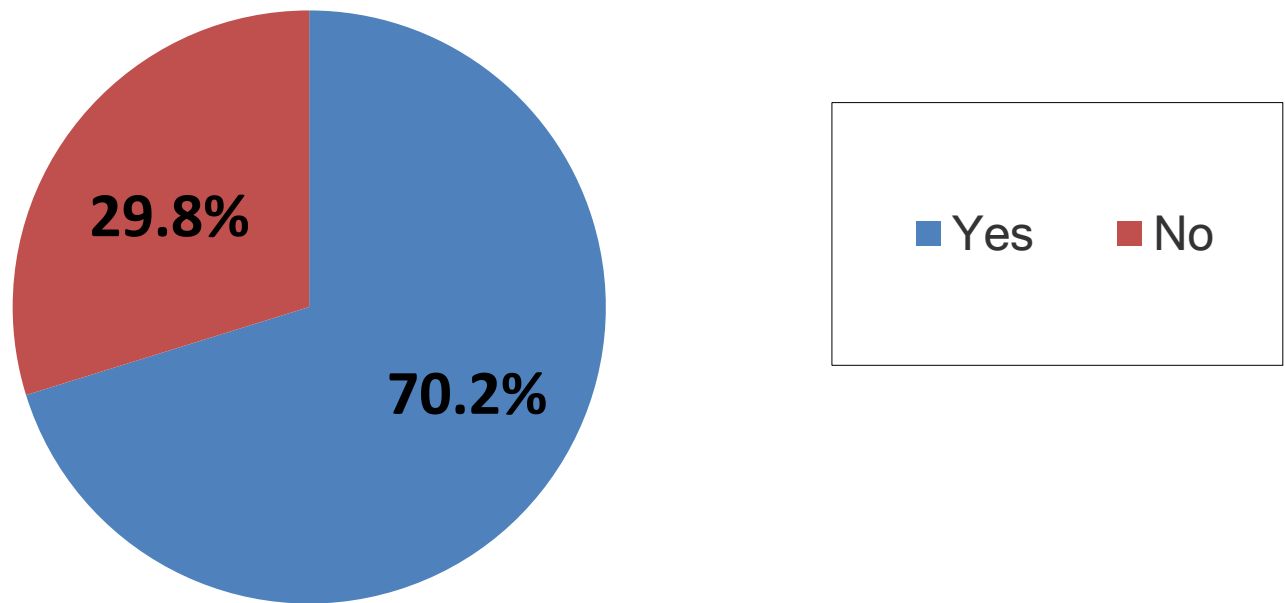
How long ago was the food allergy diagnosed?





Experience with Severe Reactions

Has anyone in your household ever experienced a severe food allergy reaction, such as anaphylaxis; difficulty breathing; a drop in blood pressure; swelling of the tongue, lips, face or throat; loss of consciousness; or shock?



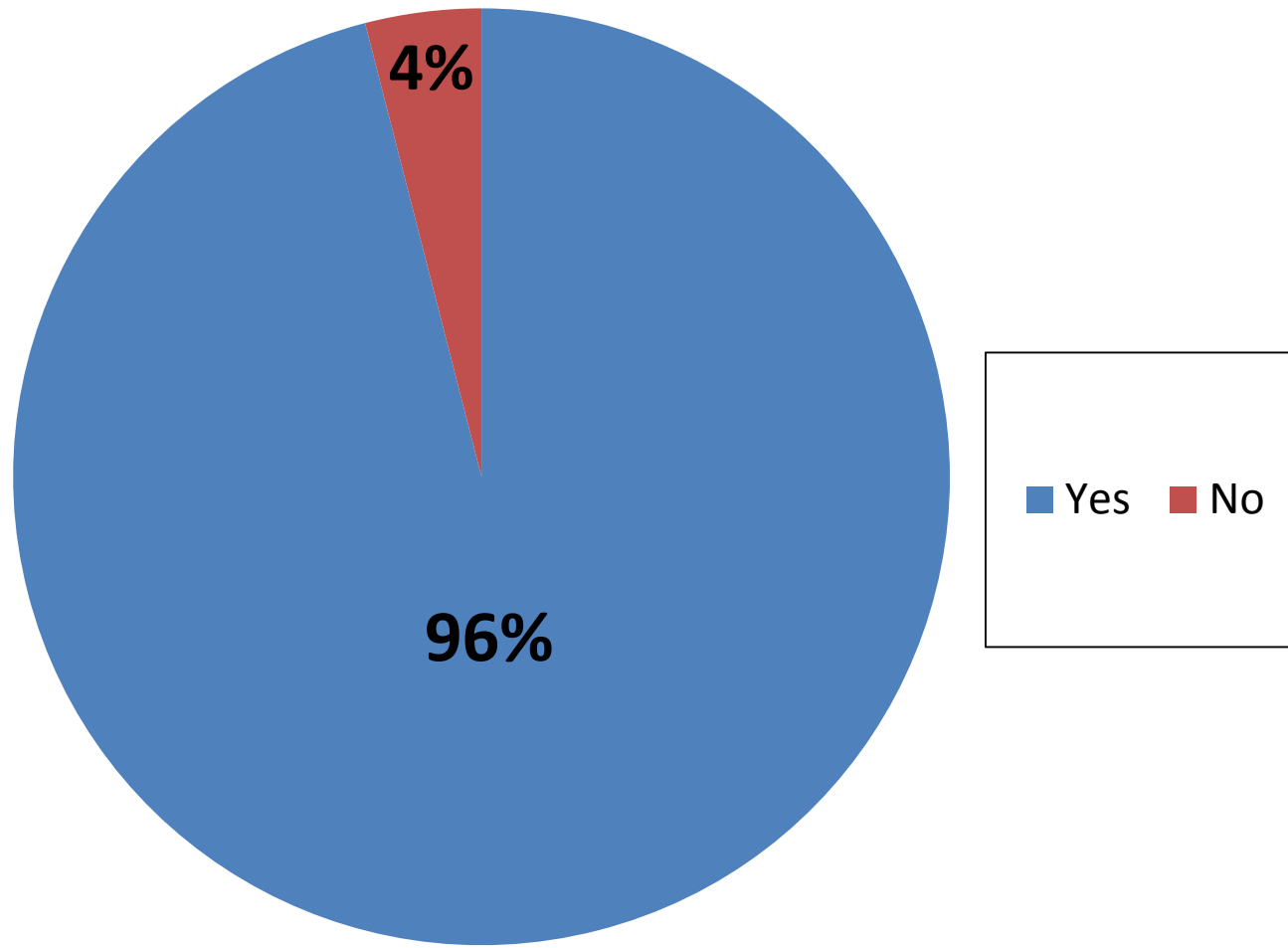
Note: 97% of respondents said someone in their household had experienced an allergic reaction to food (positive skin test alone excluded).

Purchasing Habits



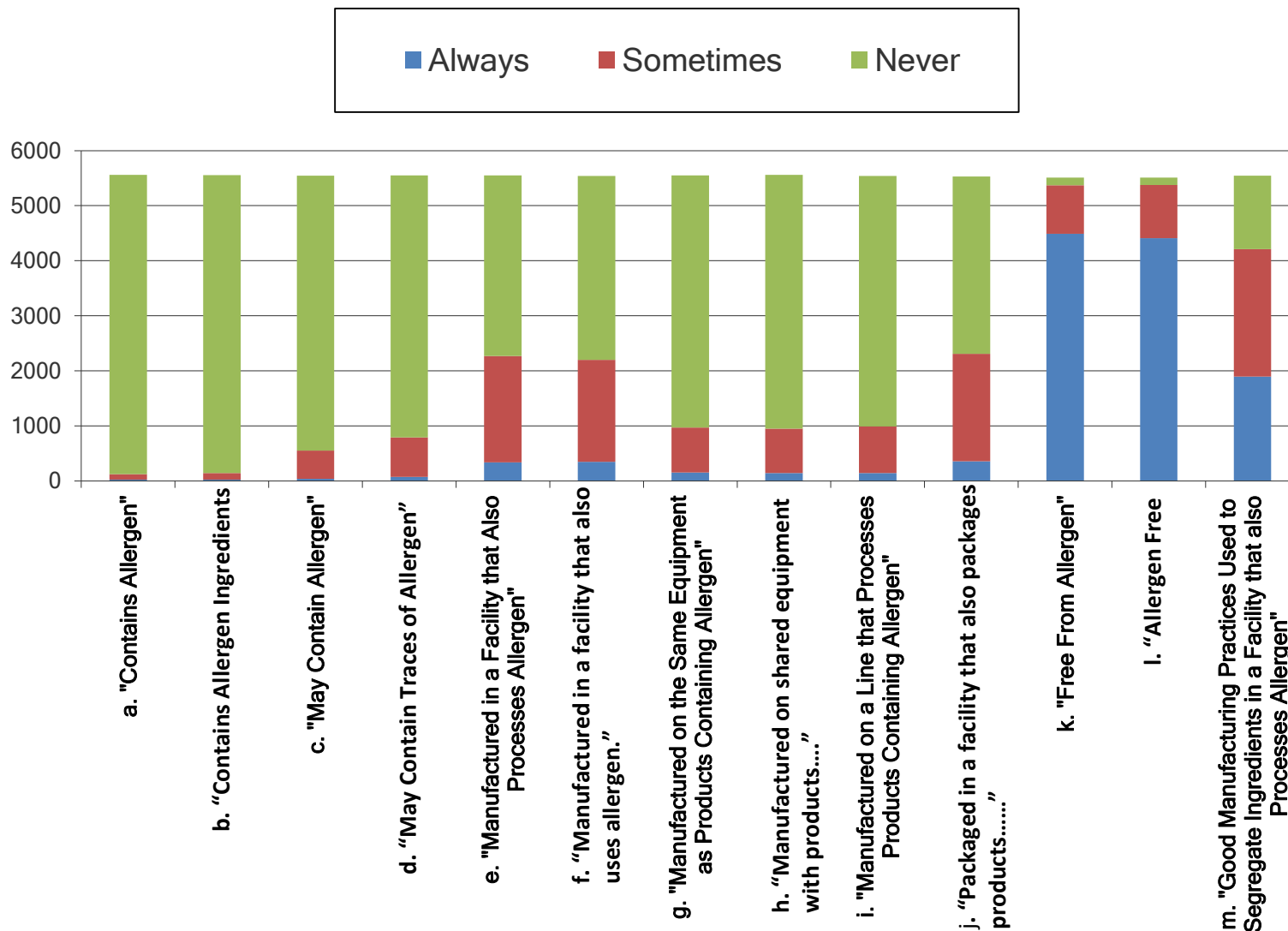


Do you purchase pre-assembled or processed foods, such as crackers, cookies, mixes, etc.?





How often would you purchase a product intended for a family member with food allergy if the label contained the phrases below?



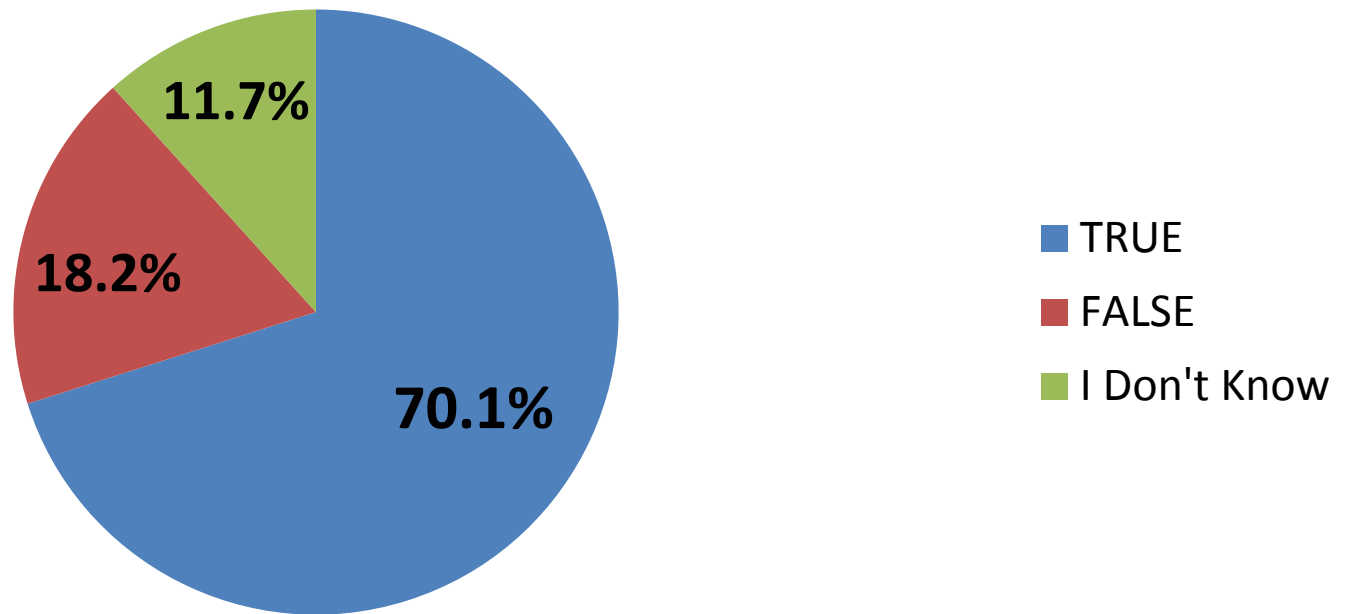
Knowledge of Thresholds & Labeling Requirements





Allergen Labeling

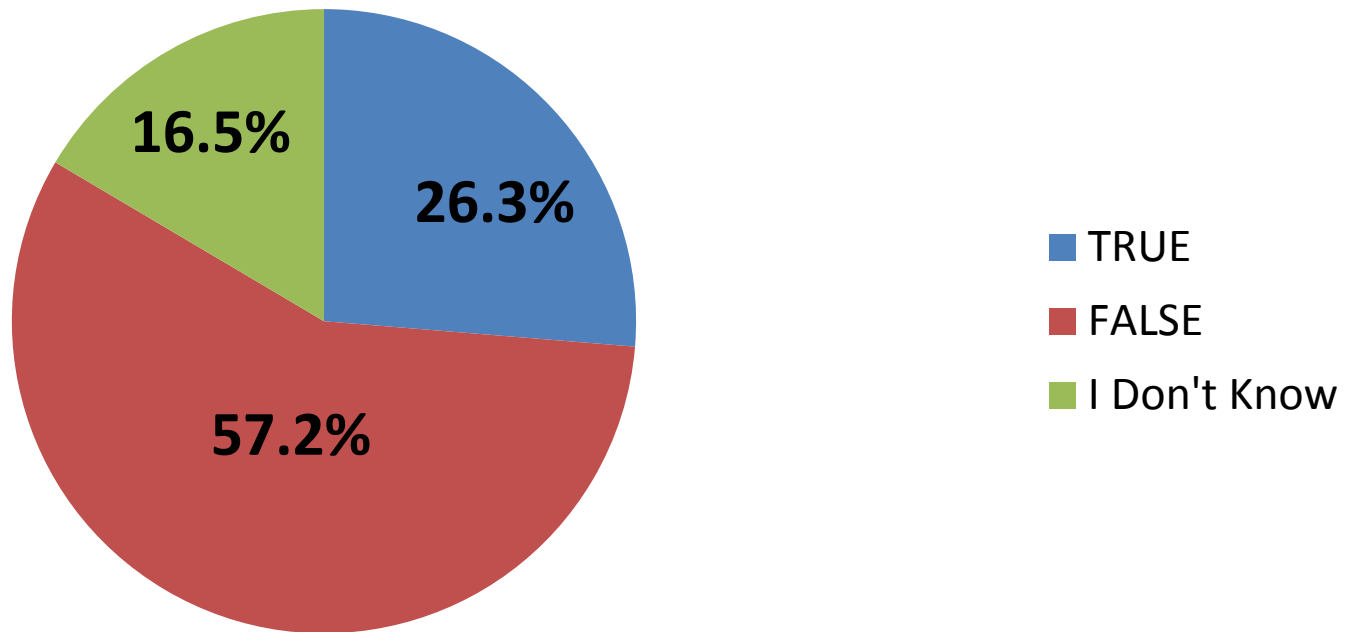
TRUE or FALSE: Current law requires that food labels identify the food source names of all major allergens used to make the food.





Advisory/“May Contain” Labeling

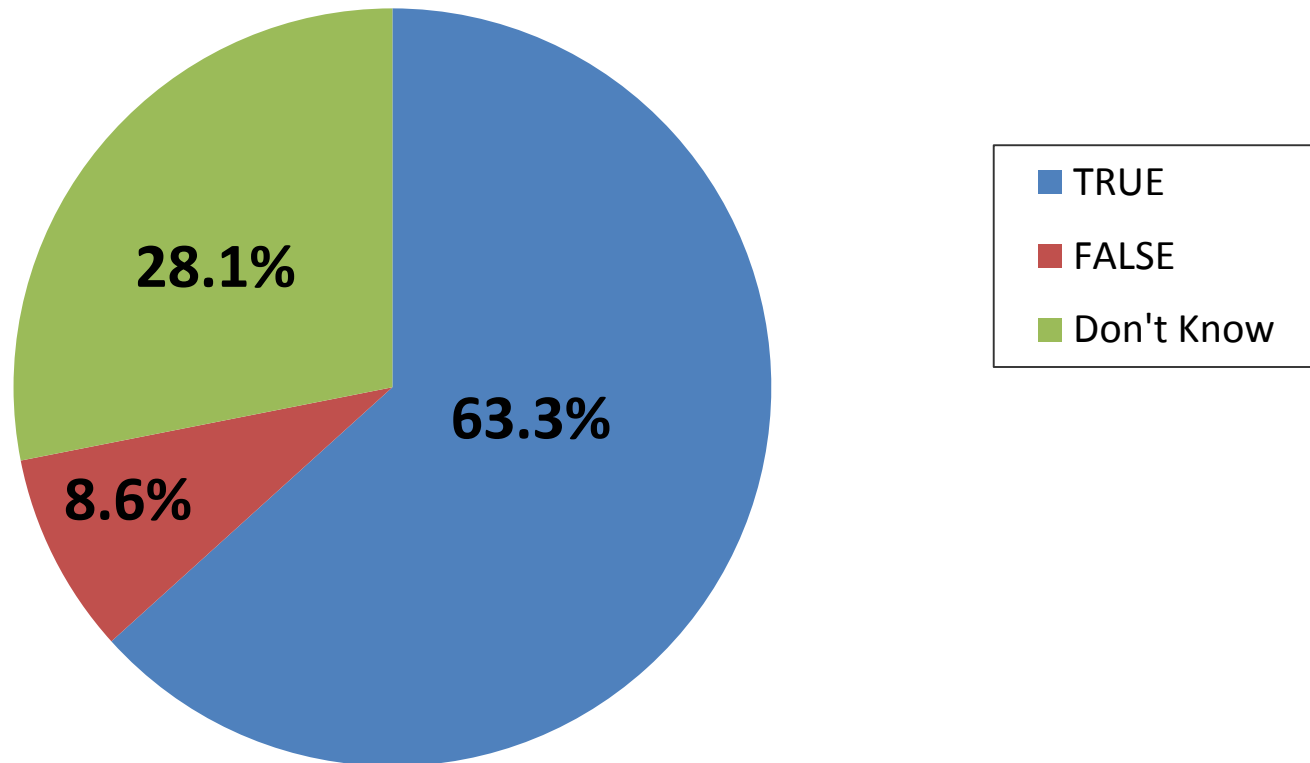
TRUE or FALSE: Advisory labeling such as "may contain soy" or "this product is produced on equipment shared with tree nut products" is mandated by law.





Advisory Labels & Thresholds

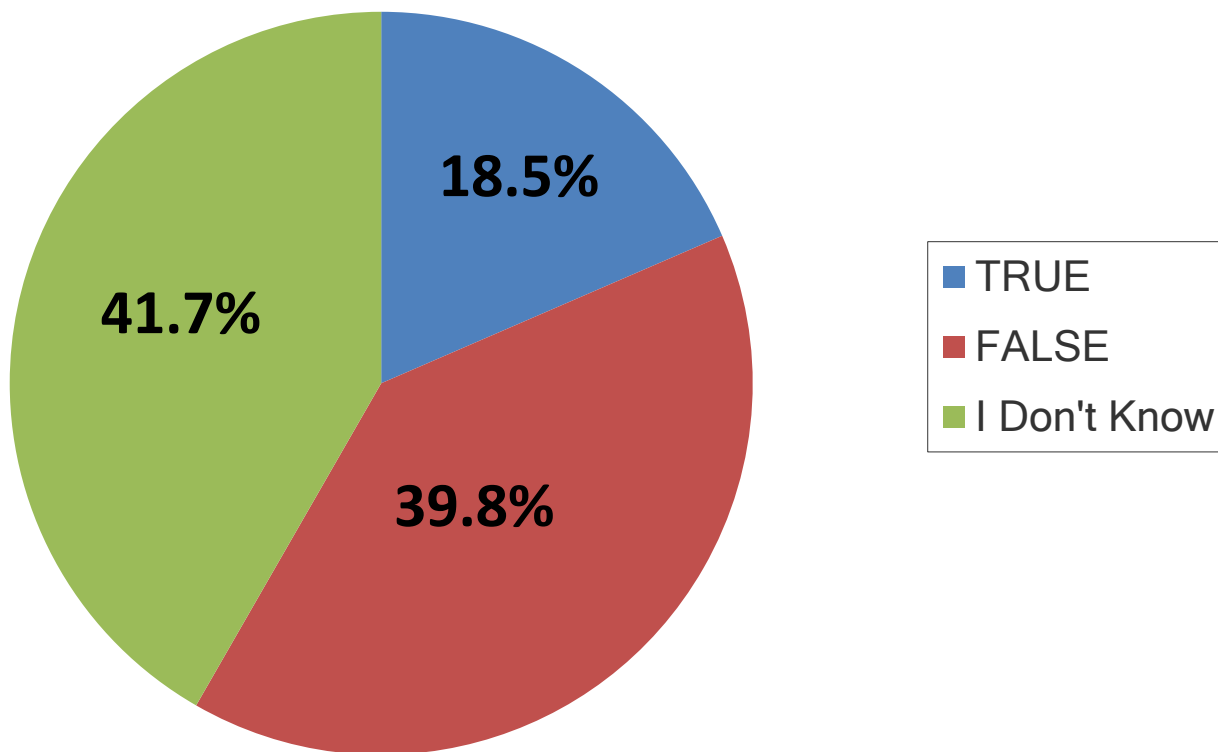
TRUE or FALSE: Advisory labeling is not based on the specific amounts of the allergen present in the foods.





Do scientific thresholds exist?

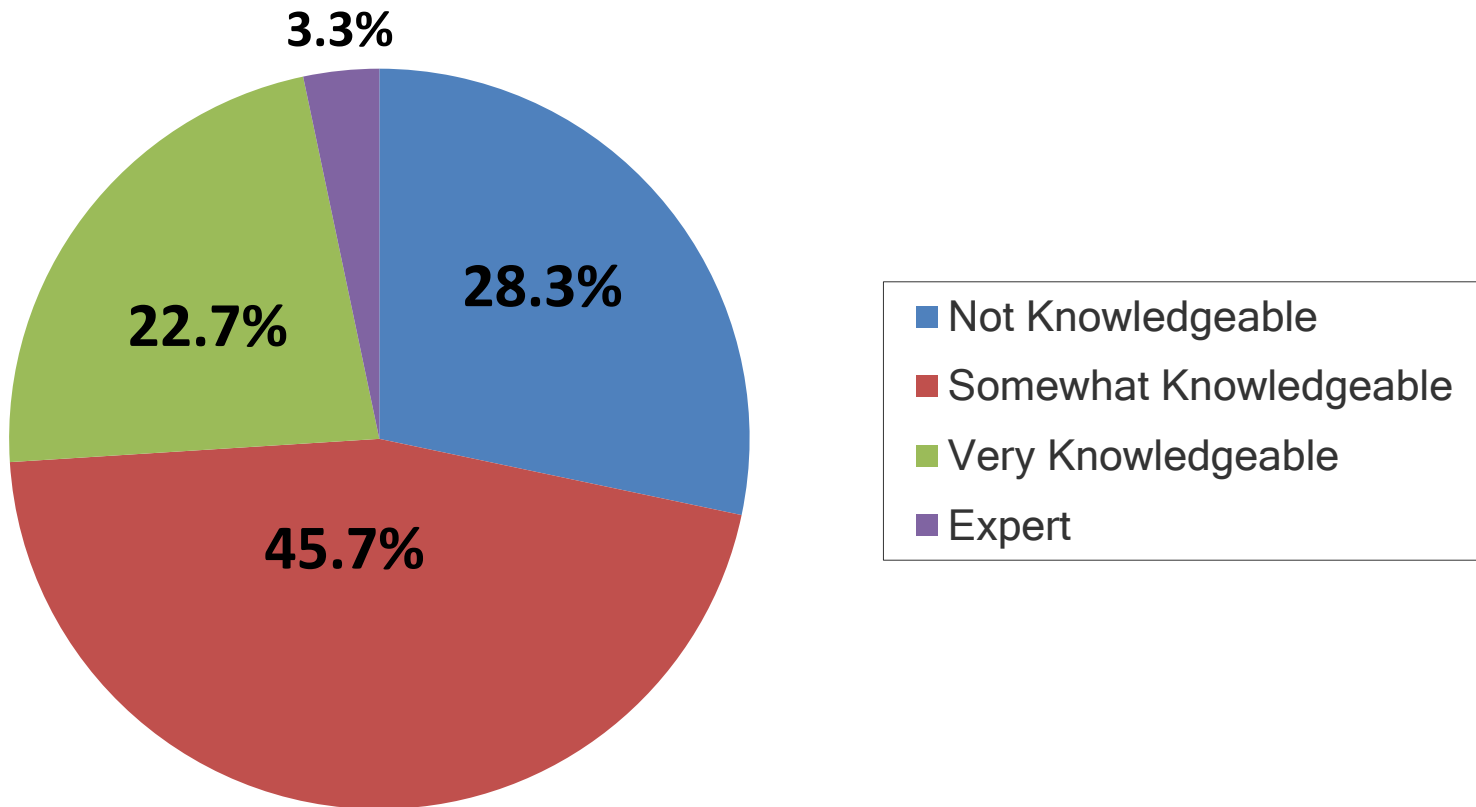
TRUE or FALSE: Scientific thresholds exist to determine how much food would cause an allergic reactions.





How knowledgeable do you think you are about allergen thresholds?

71.7% say they are at least somewhat knowledgeable





Based on what you know about allergen thresholds, how do you feel about them?

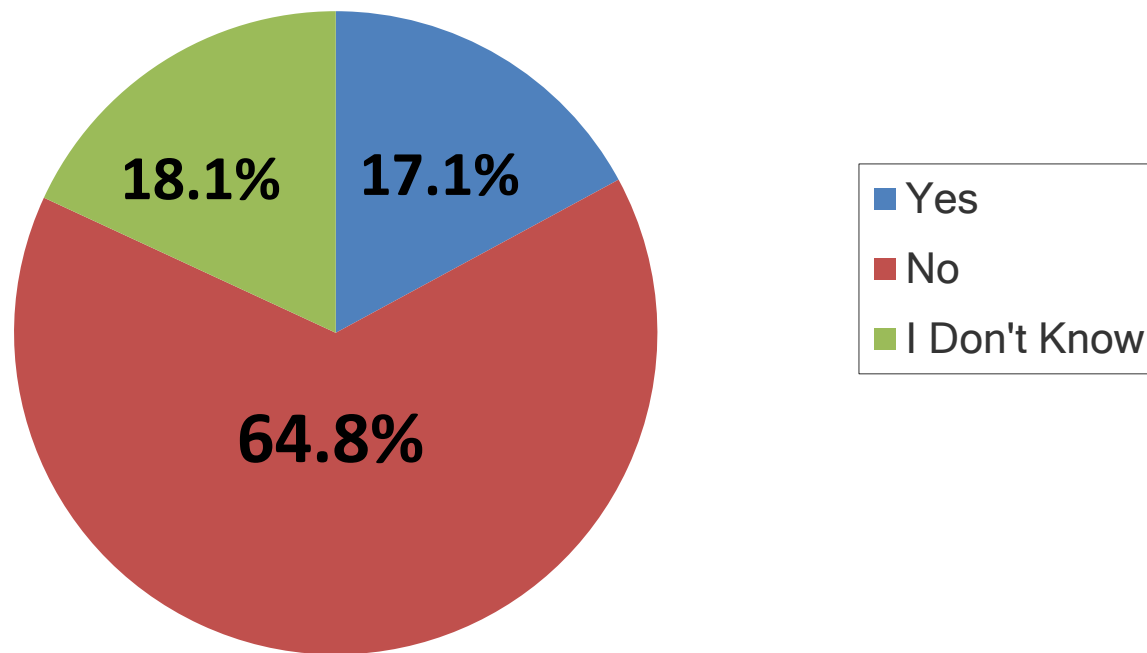
Excerpts from open responses:

- “It all makes me nervous.”
- “There is no acceptable threshold to be considered safe, because for some people it is NOT safe. Majority can't rule when it jeopardizes even one child's life.”
- “I strongly feel that using a threshold for labeling purposes provides a false sense of security that the food is allergen free. Knowing that the exposure of even a microgram of the allergen could be life-threatening, I would advocate for the right to be fully informed on the products that I choose as a consumer and a parent.”
- “Concerned that they could be inaccurate, but also don't like that the voluntary labels are over-reaching.”



Thresholds & Purchasing Behavior

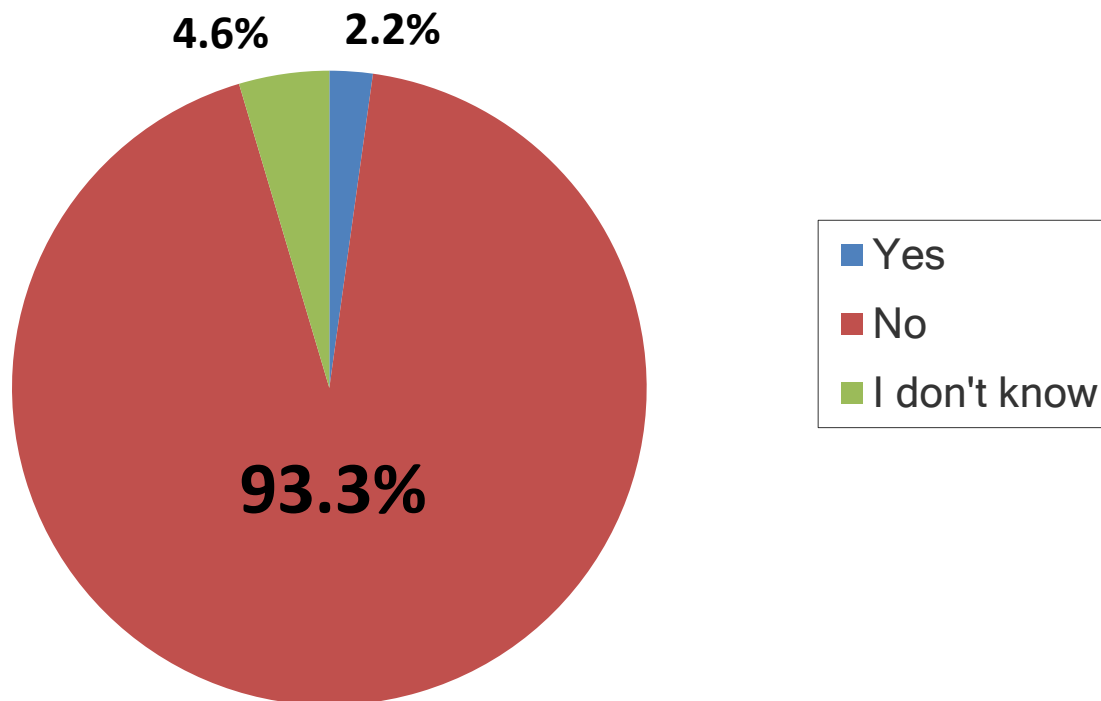
Would you purchase a food that contains the allergen(s) you are avoiding if you could be assured that the amount of that allergen present in the food is not capable of triggering an allergic reaction?





Thresholds & Purchasing Behavior

Would you purchase a food that contains the allergen(s) you are avoiding if you could be assured that the amount of that allergen present in the food is only capable of triggering a mild allergic reaction, such as tingly lips or an itchy throat?





RESPONSE – Risk Assessment on Thresholds

- FDA should not establish a threshold for any food allergen unless FDA is in possession of both reliable scientific data and reliable analytical method for determining compliance with the threshold that can be easily used by food companies and FDA.
- FARE supports further efforts to: (a) obtain and evaluate the scientific data needed to determine whether it would be possible to establish thresholds, (b) answer the questions FDA has asked, and (c) develop reliable methods of analysis to determine compliance with any thresholds that might be established in the future.
- If FDA decides to use quantitative risk assessment or any other method to establish thresholds, FARE urges FDA to first engage in outreach to the food allergy community to explain how thresholds would affect families who live with food allergies, and then engage in notice and comment rulemaking to establish any thresholds.



FSMA – Preventive Controls

- FSMA Pending Rule on Preventive Controls
 - Encourages the FDA to specify what constitutes a hazard and what procedures need to be implemented.
 - Develop better analytical methods to monitor and verify.
 - Comprehensive FDA awareness campaign to consumers & industry.
- What Are the Implications for Labeling?





The Future?

- Research Progress
- Regulatory Advances
 - Labeling
 - Transportation
 - Schools
 - Restaurants
- Civil Rights
- Social Acknowledgement



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