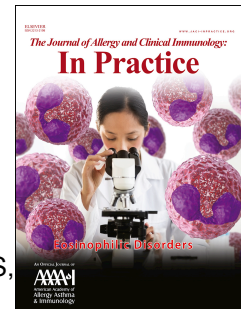


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Understanding Precautionary Allergen Labeling (PAL) Preferences Among Food Allergy Stakeholders

Ruchi Gupta, MD, MPH, Madeleine Kanaley, BA, Olivia Negriss, MA, Anita Roach, MS, Lucy Bilaver, PhD



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Title: Understanding Precautionary Allergen Labeling (PAL) Preferences Among Food Allergy Stakeholders

Ruchi Gupta MD, MPH^{1, 2}, Madeleine Kanaley BA¹, Olivia Negris MA¹, Anita Roach MS³, Lucy Bilaver PhD¹

Author Affiliations: ¹Northwestern University Feinberg School of Medicine, Institute for Public Health and Medicine, Center for Food Allergy & Asthma Research, Chicago, IL; ²Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL; ³Food Allergy Research & Education, McLean, VA

Corresponding Author: Ruchi Gupta MD, MPH, Northwestern University Feinberg School of Medicine, Institute for Public Health and Medicine, Center for Food Allergy & Asthma Research. 750 N Lakeshore Drive, Suite 680. Chicago IL, USA 60611. R-gupta@northwestern.edu, 312-523-3553

Author emails: r-gupta@northwestern.edu, madeleine.kanaley@northwestern.edu, olivia.negris@northwestern.edu, aroach@foodallergy.org, l-bilaver@northwestern.edu

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Abstract

Background: Food Allergy (FA) is an increasing public health concern in the United States, affecting approximately 8% of children and 11% of adults. The United States currently lacks clear requirements for the use of Precautionary Allergen Labeling (PAL) on packaged foods, such as “may contain” or “made on shared equipment”. This lack of specific governmental policy results in inconsistent labeling practices and confusion.

Objective: This study aimed to understand current knowledge and preferences for PAL statements among food allergy stakeholders.

Methods: A cross-sectional survey to FA stakeholders. Descriptive statistics and associations from logistic regressions were used to assess respondents’ knowledge of PAL policy, shopping habits, and preferences around PAL.

Results: Of 3,008 respondents, 24.2% were able to correctly answer four questions surrounding PAL policies. When asked about their shopping habits, the majority of respondents never purchase products with a “May Contain Traces of Allergen” label (85.5%) in comparison to never purchasing products with a “Good manufacturing practices used to segregate ingredients in a facility that also processes allergen” label (35.0%). Their top preferences for a PAL statement were “Not suitable for people with “blank” allergy” (29.3%) and “May contain” (22.1%). Healthcare provider discussions around PAL varied and were strongly associated with purchasing behaviors.

Conclusion: These results suggest FA consumers are not aware of PAL policies and make decisions based on the words in the PAL. They prefer having clearer, more specific, and consistent labeling on products, indicating explicit PAL policies are needed to allow customers to easily identify safe foods.

1. What is already known about this topic? (+31/35 words)

Food allergy (FA) prevalence is 7.6% and 10.8% among U.S. children and adults respectively. FA families must practice constant vigilance while shopping for foods, as precautionary allergen labeling (PAL) is voluntary.

2. What does this article add to our knowledge? (+35/35 words)

This study adds to literature on FA consumer’s understanding of PAL. Results suggest that FA consumers are largely unaware of PAL policies, purchase PAL based on specific wording, and prefer clear and consistent product labeling.

3. How does this study impact current management guidelines? (+35/35)

41 The U.S. lacks clear requirements for the use of PAL, which results in confusion and risk-taking
42 among FA consumers. Food manufacturers and government agencies need timely data from
43 stakeholders, researchers and allergists to make policy.

List of abbreviations:

FA = Food allergy

PAL = Precautionary Allergen Labeling

VITAL = Voluntary Incidental Trace Allergen Labelling

FARE = Food Allergy Research & Education

ORAB = Outcomes Research Advisory Board

REDCap = Research Electronic Data Capture

RFID = Radio Frequency Identification

FDA = Food and Drug Administration

RFR = Reportable Food Registry

GMP = Good Manufacturing Practices

INTRODUCTION

Food allergy (FA) is an increasingly prevalent public health concern, affecting approximately 8% of children and 11% of adults nationwide.(1, 2) Among children, almost 40% have experienced at least one severe life-threatening reaction, and these reactions can stem from even trace amounts of an allergen.(1) To avoid accidental ingestion or exposure to allergens, individuals and families living with FA must practice constant vigilance while shopping for packaged foods, often leading to added time, stress and an adversely impacted quality of life.(3)

Currently, a variety of allergen advisory regarding the potential presence of allergens appear on packaged foods to inform FA consumers. If top allergens are used as ingredients, then it is a requirement to label the food in accordance with the Food Allergen Labeling and Consumer Protection Act. (4) The law requires the names of the top eight allergens including peanut, tree nuts, milk, egg, wheat, soy, finfish and shellfish to be listed in English on ingredient labels. Recent data supports expanding this list to a top nine that includes sesame as well.(5) However, precautionary allergen labeling (PAL), such as “may contain” or “manufactured on shared equipment” are voluntarily placed by the food industry on their products.(6) There are no clear requirements for how to communicate the risk of potential presence of allergens in products. This lack of specific governmental policy results in inconsistent labeling practices and confusion among FA consumers and food manufacturers.

Several countries have made notable strides in managing and regulating the use of PAL. In Japan, it is illegal to label a food item with “may contain” and even minute quantities of allergens are to be included on product labels according to a system that began in 2001.(7) Japan recognizes that FA prevalence is dynamic due to changes in culture and diet; thus national

surveys are conducted every 3 years to monitor changes in FA.(8) Moreover, Australia has been the first country to establish industry standards for PAL. This standardized risk assessment system, Voluntary Incidental Trace Allergen Labelling (VITAL), was introduced in 2007 and roughly 19% of packaged foods were using VITAL by 2011.(9) Additionally, Canada released a recommendation to manufacturers in 2012 that only one PAL statement, “may contain” should be used.(6) Interestingly, despite this recommendation by Health Canada, a 2015 study by Brown et al. found that the majority of participants feel this statement is too vague as it offers no explanation as to why the product may contain the allergen.(10)

Unfortunately, in the United States, such attempts at unifying PAL legislation remain lacking. Therefore, this study aims to gain insights from FA stakeholders in the U.S. surrounding their understanding of current PAL practices and to identify clear and consistent preferences around this language.

METHODS

Survey development and design

This study was supported by the National Confectioners Association (NCA). Survey development began in July 2018 by researchers at Northwestern University in collaboration with the national FA advocacy organization, Food Allergy Research & Education (FARE). Institutional review board approval was granted by Lurie Children’s Hospital of Chicago and Northwestern University Feinberg School of Medicine. Individuals were invited to participate through FARE’s online email listerv and were eligible if they were at least 18 years of age, had FA, were the primary caregiver of a child with FA, had a partner or spouse with FA, or had another relationship with FA (teacher, babysitter, etc.).

To develop the survey instrument, the researchers first conducted a focus group with 12 FA stakeholders to better understand their grocery shopping experiences, current understanding of PAL, and preferences for labeling language, format, and placement on products. The focus group consisted of mothers of children with food allergy who were between 39-62 years of age and had mostly college or graduate level education. The aim of the focus group was to inform content to include in the survey.

The focus group data led to an initial survey draft, which was then tested and edited through a group discussion with FARE's Outcomes Research Advisory Board (ORAB), a committee consisting of 40 regional and 4 national representatives with expertise in FA research and care. The survey was programmed through REDCap, and was sent to 9 additional FA stakeholders who participated in 1-hour cognitive interviews to make final edits on readability and comprehension of the survey.

The final cross-sectional survey was disseminated through FARE's membership listserv in September 2019 and was open for responses until October 2019.

Data Analysis

Descriptive statistics were used to describe PAL survey responses and respondent characteristics. Respondents provided demographic characteristics including gender, race/ethnicity, level of education, household income, and living location (urban, rural, suburban). FA related characteristics include the respondent's relationship to FA), type of FA in the household, number of FA (single versus multiple), severe reaction history (ever visited the emergency department or

used epinephrine), and PAL knowledge. Survey domains that were assessed as outcomes include shopping habits, frequency of purchasing products with PAL, PAL preferences (statement, format, and placement), confidence when purchasing PAL, and PAL discussions with healthcare providers. Logistic regression was used to assess associations between respondent characteristics and key PAL outcomes. All analysis was done using STATA version 15.1.

RESULTS

Of recipients who received the link to the electronic survey, 25,208 opened the email, and 3,541 of these recipients began the survey (14%). After removing incomplete surveys and respondents who indicated that they lived outside of the United States, we analyzed a final analytic sample of 3,008 respondents.

Characteristics of respondents:

Demographic characteristics of the 3,008 respondents are presented in **Table I**. Respondents were predominantly female (84.7%), primary caregivers of someone with FA (77.0%), Non-Hispanic White (78.4%), had a graduate degree (40.6%), and had an annual household income of over \$100K (48.5%). Respondents most commonly reported avoiding the following allergens in their household: peanut (69.4%), tree nuts (68.1%), egg (29.9%), cow's milk (27.6%), sesame (22.8%), shellfish (20.9%), wheat (12.7%), soy (11.2%), and fin fish (10.6%). Most respondents (78%) reported multiple food allergies, and more than half (65.7%) reported a severe reaction history. When asked four knowledge questions about current policies surrounding allergen labeling, [eg. 1. US law requires food labels identify food source names of all major food allergens used to make the food. (T or F), 2. PAL is mandated by law. (T or F), 3. PAL is based

on specific amounts of allergen present in the foods. (T or F), and 4, PAL differs depending on the quantity of allergen that is present in the product (T or F)], only 24.2% of respondents answered all 4 questions correctly.

Current Shopping Practices:

Current shopping practices of respondents are summarized in **Table II**. Of respondents, 27.4% indicated that they or a family member had experienced an allergic reaction from a product that contained a PAL statement. Among the 2,765 respondents who primarily do the grocery shopping, most (94.0%) shop at a supermarket, specialty food store (52.5%), or online (30.7%). The majority indicated they check labels every time they purchase a grocery item (70.9%) or cosmetic (53.1%). Most respondents were unfamiliar with “SmartLabel®” (82.4%), the online system that can be used to access detailed product information. Additionally, when asked how they feel about current labeling practices, over half (53.1%) noted that it is a significant problem that interferes with their everyday lives.

Frequency of Purchasing Products by PAL

The frequency of purchasing products varied by the PAL statement listed (**Table III**). For instance, 85.5% of consumers indicated they currently never purchase products with “*May Contain Traces of Allergen*,” in comparison to those who indicated they currently never purchase products with the label “*Good manufacturing practices used to segregate ingredients in a facility that also processes allergen*” (35.0%). When asked why they sometimes, frequently, or always purchase foods with certain PAL statements, 1,983 respondents most frequently listed the following reasons: “I have purchased a product with this PAL in the past and I/my family

member with FA have not experienced a reaction” (45.9%), and “The PAL made me feel confident that this option was safe for me/my family member with FA” (35.8%).

Improving confidence in shopping for products with PAL

When asked what would make them feel more confident about purchasing foods with PAL present, the majority of respondents (73.5%) indicated they would like a declarative statement on products designating that the manufacturers use an allergen free LINE (with specific allergens listed) or allergen free FACILITY (with specific allergens listed). **(Figure 1).**

FA Consumer preferences surrounding PAL:

Regarding top preference for PAL statement, respondents were most likely to choose “*Not suitable for people with (blank) allergy*” (29.3%), followed by “*May Contain (Allergen)*” (22.1%) **(Table IV)**. For format, respondents were most likely to indicate they’d like a PAL statement designating specific allergens present vs. a category of allergens (32.1%) (eg. Noting that the product contains walnuts instead of tree nuts) .Finally, regarding placement of PAL on products, most respondents wanted the statement on the front of the package and immediately following the ingredient list (39.5%).

Diagnosis and Healthcare Provider Discussions

Food allergy diagnosis and discussions with healthcare providers surrounding PAL are summarized in **Table E1**. The majority of respondents noted they or their child was diagnosed by an allergist (89.6% and 70.7% respectively). When asked if they discussed PAL with their healthcare provider, 32% of individuals with FA were instructed to avoid while 44.5% did not

discuss. Of parents with children with FA, 50.5% were instructed to avoid all PAL labels and 29% did not discuss PAL labeling management.

Associations

We examined the adjusted association of several respondent characteristics with key PAL responses including: previous reaction to food with PAL and sometimes, frequently or always purchases products with PAL (**Table V**). The analysis sample was limited to child or adult respondents diagnosed by a healthcare provider. Respondents with a child with FA were consistently less likely to report a previous reaction to food with PAL and less likely to purchase products with PAL. In contrast, Asian respondents were consistently more likely to report a previous reaction and more likely to report purchasing products with PAL. Greater labeling knowledge was consistently associated with a lower odds of purchasing PAL. Having a discussion with a healthcare provider about PAL was also consistently associated with PAL purchasing. Specifically, respondents who were told by a healthcare provider to avoid all PAL were 59% less likely to purchase products with any of the PAL described in the survey compared with respondents who did not discuss PAL with their healthcare provider (OR 0.41, $p<0.001$). In contrast, respondents who reported that they were told they could eat products with PAL or could continue eating products they have eaten in the past were more likely to purchase foods with any PAL compared with those who did not discuss PAL with their healthcare provider (OR 2.16, $p=0.007$; OR 1.82, $p=0.0016$, respectively). Education, income, and past severe reaction were not consistently associated with past PAL reactions or purchasing behaviors.

DISCUSSION

Many misconceptions surrounding PAL exist among FA stakeholders, and they would prefer clearer, more consistent labeling practices to enable more confident decision making around PAL. When asked questions about current labeling practices and policies, less than a quarter of respondents were able to answer all questions correctly. Respondents are currently purchasing products with certain PAL statements more regularly than others despite the fact that no single PAL statement is regulated in the U.S., and over a quarter of these respondents have experienced allergic reactions to a product containing a PAL statement. Healthcare provider discussions about PAL management were strongly associated with purchasing behavior. Over half have noted that current labeling practices interfere with their daily life, and they would like to know more about manufacturer's use of an allergen free line or facility to more confidently purchase products with PAL.

Prior research among FA consumers in the U.S. and Canada found patterns of PAL knowledge similar to the current study. When asked questions about current policy, 28.8% of their respondents incorrectly believed that PAL is required by law, and 16.9% admitted they didn't know the answer. Moreover, over 37% of respondents answered incorrectly when asked if advisory labels were based on the amount of allergen present in the product.⁽⁶⁾ Despite being highly educated (40.6%) and motivated to take the survey as a FA advocacy group member, the majority of current respondents are still unaware of current PAL policies, indicating further education is needed to help consumers.

In addition to current misunderstanding of PAL policies, results also showed that many individuals with FA are not discussing PAL with their healthcare providers (39.6%), or are told

to avoid PAL labels entirely (47.6%). These discussions were strongly associated with purchasing behavior. Regardless of the PAL, respondents who were instructed to avoid all PAL were much less likely to purchase products with PAL while those that were advised to include PAL products in their diet were much more likely to purchase products with PAL compared with those who did not discuss PAL management with their healthcare provider. Despite the lack of PAL regulation, the advice of healthcare providers was highly associated with purchasing behavior. Patients listen to their providers around purchasing PAL and only with consistent definitions and labeling regulation will they be able to have more effective discussions on this challenging topic.

In addition to provider discussions, other respondent characteristics were consistently associated with PAL purchasing behavior. Greater labeling knowledge was associated with a lower odds of purchasing products with PAL after controlling for healthcare provider discussions, respondent type, race/ethnicity, education, income, and history of severe reaction. These results demonstrate that consumers who understand the lack of meaning behind PAL in the U.S. avoid purchasing these products. Another respondent characteristic that was consistently associated with a higher odds of previous PAL reactions and PAL purchasing was Asian race. We had a very small number of Asian respondents (n=150) in our study. It is unclear why these respondents were much more likely to purchase products with PAL. Future research with a more representative group of Asian individuals affected by FA is needed to explore the meaning of this finding.

Consistent with previous literature, our results demonstrated that the frequency of purchasing products varied according to the consumer's perceived risk of the PAL, with "may contain" statements being most deterrent.(11) Respondents who report purchasing products with PAL noted they do so because they have purchased them in the past without a reaction or it made them feel confident it was a safe option for them or their family. Due to the preventative measures they must take, FA stakeholders often experience additional stress and adverse quality of life in addition to increased time spent purchasing food items.(3) Of our sample, 53.1% noted that current PAL practices are a significant problem that interferes with their everyday lives. Inconsistent communication from PAL can cause stress and insecurity,(12) which may lead to increased risk-taking by disregarding all PAL.(6, 13) The high frequency of PAL use in the marketplace may explain why certain PAL statements are being selected less frequently. For example, FA consumers were less likely to heed advisory labeling in 2006 (75%) compared to 2003 (85%).(11) Further, evidence that PAL is frequently misused was shown in a 2007 study that revealed clinically significant levels of peanut were detected in only 6.5% of examined foods containing PAL.(11) The undue burden that current PAL practices place on FA consumers could be mitigated by standardized PAL.

The majority of respondents (82.4%) were unfamiliar with SmartLabel[®],(14) an online system created by the Trading Partner Alliance to give consumers instant access to detailed product information. Consumers with FA are currently making their own choices surrounding allergen labeling based on the language used, noting reasons for doing so such as: the PAL has not given them an allergic reaction in the past (45.9%), the wording made them feel confident the product was safe (35.8%), or they called the manufacturer and felt the product was safe (26.6%). Mobile

apps like this could assist consumers in quickly finding relevant information about products before purchasing them could help consumers make safe purchasing decisions. Additionally, other novel information and communication technology approaches, such as Radio Frequency Identification (RFID) on foods, (15) can allow consumers to scan product barcodes that take them to complete manufacturing and allergen lists. Such technology could improve informed decision-making among consumers, and should be more widely tested to determine the optimal route of communication of PAL.

When asked to choose one PAL option for all packaged products, respondents were most likely to choose “*Not suitable for people with BLANK allergy* (29.3%)” or “*May Contain Allergen*” (22.1%). While “Not suitable for those with BLANK allergy” is less commonly utilized in the U.S., this phrase clearly deters consumers with certain FA from purchasing products. In a similar Canadian study conducted in 2012, 80.2% of participants noted “not suitable” was the most effective in deterring purchasing of a product.(16) These results suggest that a clear phrase like “not suitable” may help consumers quickly make a decision about the safety of the product. However, there are also other risk-factors to consider while using this language. For example, in a 2015 study conducted in Canada, “not suitable for” as a PAL statement was excluded when considering the possibility of other potential allergen cross-contamination.(10) Unfortunately, until we have scientific agreement and regulatory guidance on thresholds of allergenic foods, “not suitable” labels are not possible. While it is clear consumers want a straightforward label, ensuring all potential allergen risks are appropriately communicated is imperative when coming to consensus around one label.

Interestingly, the second most common answer provided by respondents was “may contain”. This phrase is not as clear as “not suitable for” but is often seen on products throughout the U.S., despite being vague and not corresponding with risk levels different from any other label. Since 2012, Health Canada recommends that manufacturers only use “may contain” on products. Although U.S. manufacturers are under no obligation to use any particular PAL at this time, there is evidence that they would prefer a single label, which ever it may be. A 2017 study by Gupta et al. found that the manufacturing industry supports unifying PAL as 78% of survey respondents reported that a single option for PAL would improve their industry.(17) The evidence from this study provides an important next step toward making a single PAL a reality.

Regarding PAL format and placement preferences, the answers most frequently chosen were PAL statements that specify the allergens that may be at risk for cross contact, rather than a category of allergens (ex. Hazelnut vs. tree nuts), and statements placed both on the front and back of products. Previous research also found that participants with allergy to tree nuts expressed a desire for labels that list individual allergens, rather than broader category.(18) Moreover, previous research has also shown that consumers believe ingredients lists often contain too much information (‘information overload’) as well as unfamiliar terms, which can lead to difficulty for adults, children, and for those who may not speak English as their first language.(15) More specific and consistent formats for labels should be further evaluated, as this is a persisting desire among FA consumers.

Limitations

Limitations of this study should be noted. Because we relied on a convenience sample of individuals on FARE's listserv, our sample is not representative of the population of consumers affected by FA. Respondents involved in the advocacy group are overwhelmingly white, highly educated women with high annual household income and a child with FA. According to the U.S. Census, 14.9% of US citizens earn in the \$100,000-149,999 income bracket a year and 13.1% have earned an advanced degree.(19, 20) In this context, the racial and ethnic associations that we found with key PAL responses may not be representative of a larger group of minority consumers affected by FA. Furthermore, we were unable to offer financial incentives for survey completion, which likely contributed to a low overall response rate. Balancing these limitations is the size of our sample, which yields narrow confidence intervals around estimated survey responses.

CONCLUSION

In a large sample of FA consumers, this study revealed widespread lack of awareness of PAL policies and decision making based on the words in the PAL. Consumers preferred having clearer, more specific, and consistent labeling on products, highlighting the need for explicit PAL policies to allow customers to easily identify safe foods. Allergists play a significant role as we found that consumers follow their advice when purchasing PAL. However, this is complex because there is no clear PAL management guidance. The support of consumers and food manufacturers for a single PAL is a crucial first step toward improving labeling policy for individuals and families with food allergy. This is just the beginning of this journey with the need for thresholds on packaging and threshold testing for patients next, to provide accurate advice to patients on their ability to purchase and consume food with PAL labeling.

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Figure I: Respondent's Confidence when Purchasing Products with PAL

Respondents were asked to select from a list of options what would make them feel more confident about purchasing foods with PAL present. The responses are presented in percentages and are stratified by those having multiple FAs versus a single FA, as well as overall response.

Table Legend

Table I: Characteristics of Labeling Respondents

Basic demographic information as well as relevant FA information was provided by survey respondents. Respondents were also asked to attempt to answer four policy questions related to current food labeling practices. The responses are presented in overall numbers and percentages.

Table II: Shopping Habits of Labeling Survey Respondents

All respondents were asked about accidental allergen exposures due to PAL. Additional questions were asked of respondents who actually do the shopping for foods and cosmetics. The responses are presented in overall numbers and percentages.

Table III: Frequency of Purchasing Products by PAL

Respondents were asked how often they purchase products with PAL, and then asked for their reasons for deciding to make these purchases. The responses are presented in percentages.

Table IV: Top Choice of PAL Statement, Format, and Placement by Labeling Respondents

Participants were asked to provide information on their top choices for various aspects of PAL. Preferences for language used in the statement itself, format of the label, and location of placement on the product were collected. The responses are presented in overall numbers and percentages.

Table V: Adjusted associations with Key PAL Responses

Logistic regressions control for respondent type (parent of child with FA, own FA, both, or other), gender, highest level of respondent’s education, current living location (urban, rural, suburban, other), and history of severe reaction in addition to the variables presented above. Observations with missing gender, education, and current living location were excluded from the logistic regression.

Variable	N	% of Total	95% CI
Total	3008	100	100
Relationship with Food Allergy (FA)			
Own FA	745	24.8	(23.3-26.3)
Child with FA	2316	77	(75.5-78.5)
Partner or Spouse with FA	128	4.3	(3.6-5)
Other Relationship with FA	296	9.8	(8.8-11)
Gender			
Male	236	7.8	(6.9-8.9)
Female	2547	84.7	(83.3-85.9)
Other	4	0.1	(0-0.4)
Missing	221	7.3	(6.5-8.3)
Race/ethnicity			
White, non-Hispanic	2359	78.4	(76.9-79.9)
Black	57	1.9	(1.5-2.4)
Hispanic/Latino	106	3.5	(2.9-4.2)
Asian	150	5	(4.3-5.8)
Other	48	1.6	(1.2-2.1)
Prefer not to answer or Missing	288	9.6	(8.6-10.7)
Highest Level of Education			
High school diploma or Less	94	3.1	(2.6-3.8)
Some college or College Degree	1466	48.7	(47-50.5)
Master's, professional, or doctoral degree	1222	40.6	(38.9-42.4)
Other or Prefer not to Answer	11	0.4	(0.2-0.7)
Missing	215	7.1	(6.3-8.1)

<\$100K	622	20.7	(19.3-22.2)
\$100K or over	1460	48.5	(46.8-50.3)
Unknown or prefer not to answer or other	27	0.9	(0.6-1.3)
Missing	899	29.9	(28.3-31.5)
Current living location			
Urban location	510	17	(15.7-18.3)
Rural location	294	9.8	(8.8-10.9)
Suburban location	2010	66.8	(65.1-68.5)
Other	8	0.3	(0.1-0.5)
Missing	186	6.2	(5.4-7.1)
Types of FA in Household			
Peanut allergy	2089	69.4	(67.8-71.1)
Tree nut allergy	2048	68.1	(66.4-69.7)
Cow's milk allergy	831	27.6	(26.1-29.3)
Egg allergy	898	29.9	(28.2-31.5)
Shellfish allergy	628	20.9	(19.5-22.4)
Fin fish allergy	319	10.6	(9.6-11.8)
Soy allergy	338	11.2	(10.2-12.4)
Wheat allergy	381	12.7	(11.5-13.9)
Sesame allergy	687	22.8	(21.4-24.4)
Number of allergies			
Single allergy	656	21.8	(20.4-23.3)
Multiple allergy	2352	78.2	(76.7-79.6)
Severe Reaction History (ED Visit or Epinephrine Use)			
Yes	1976	65.7	(64-67.4)
No	826	27.5	(25.9-29.1)
Missing	206	6.8	(6-7.8)

Current U.S. law requires that food labels identify the food source names of all major food allergens (ex. peanuts, tree nuts, milk, egg, soy, fin fish, shellfish, wheat) used to make the food. (True)	2071	68.8	(67.2-70.5)
Precautionary Allergen Labeling (PAL) such as "may contain milk" or "this product is produced on equipment shared with tree nut products" is mandated by law. (False)	1675	55.7	(53.9-57.5)
Precautionary Allergen Labeling (PAL) is based on specific amounts of the allergen present in the foods. (False)	1322	43.9	(42.2-45.7)
Precautionary Allergen Labeling (PAL) language differs depending on the quantity of allergen that is present in the product. (Ex. "May contain traces of allergen" has a smaller amount of allergen present than "May contain allergen") (False)	1218	40.5	(38.7-42.3)
Percent with 4 correct answers	729	24.2	(22.7-25.8)

	N	% of Total	95% CI
All Respondents	2765	100.0	100.0
Have you, a family member, or someone you cared for with FA ever experienced an allergic reaction from a product that included PAL? (ex. "may contain", "manufactured in a facility that also processes", etc.)?			
Yes	758	27.4	(25.8-29.1)
No	1486	53.7	(51.9-55.6)
Not Sure	521	18.8	(17.4-20.3)
Number of Respondents Who Shop for Groceries	2718	100.0	100.0
Where do you typically shop?			
Supermarket	2556	94	(93.1-94.9)
Convenience Store	185	6.8	(5.9-7.8)
Specialty Food Store	1427	52.5	(50.6-54.4)
Online	835	30.7	(29-32.5)
Other	99	3.6	(3-4.4)
When do you check food labels?			
Every time	1928	70.9	(69.2-72.6)
Only for new items	655	24.1	(22.5-25.7)
Not every single time	116	4.3	(3.6-5.1)
Do not read labels	0	0	0
Other	19	0.7	(0.4-1.1)
How do you feel about labeling practices?			
Significant problem that interferes with daily life	1444	53.1	(51.2-55)
Problem but do not interfere with daily life	1020	37.5	(35.7-39.4)
Not a problem	254	9.3	(8.3-10.5)
SmartLabel use			

No	310	11.4	(10.3-12.7)
Do not know what SmartLabel is	2240	82.4	(80.9-83.8)
Number of Respondents Who Shop for Cosmetics	2463	100.0	100.0
Every time	1332	54.1	(52.1-56)
Only new products	640	26	(24.3-27.8)
Not with regularity	307	12.5	(11.2-13.8)
Do not read labels	167	6.8	(5.9-7.8)
Other	17	0.7	(0.4-1.1)

	% of Respondents			
How often do you purchase products when a label contains the following phrase: (n=2729)	Never	Sometimes	Frequently	Always
"May contain Allergen"	80.8	14.3	3.5	1.4
"Manufactured in a facility that also processes Allergen"	47.7	34.7	13.2	4.4
"Manufactured on a line that processes products containing Allergen"	78.5	14.8	4.7	1.9
"Good manufacturing practices used to segregate ingredients in a facility that also processes Allergen"	35.0	37.0	17.8	10.1
"May contain traces of Allergen"	85.5	10.4	2.5	1.7
"Made on shared equipment that also processes Allergen"	77.5	15.6	5.1	1.8
"Packaged in a facility that Also packages products containing Allergen"	48.4	35.0	12.1	4.5
"Manufactured on same equipment with products containing allergen"	79.9	13.6	4.5	1.9
Reasons for PAL purchases (among those sometimes, frequently or always purchasing PAL, n=1983)	% of Respondents Purchasing PAL			
I didn't have enough time to find an alternative when shopping	4.3			
I believe there is no alternative	14.5			
I believe this labeling has very small quantities of the allergen that would not affect me.	20.3			
It made me feel confident that this option was safe for me/my family member with FA.	35.8			
The product was cheaper than competing brands with clearer labeling practices.	1.4			
I have purchased this product in the past and I/my family member with FA and have not experienced a reaction	45.9			
I believe PALs don't really mean anything. They are included by manufacturers to protect themselves from liability.	17.7			
I cannot avoid purchasing products with PALs in order to have enough options for my family.	20.4			

Journal Pre-proof	
I called the manufacturers of the product before purchasing and felt confident the product was safe.	26.6
Other	7.9

Table 1. Top choice of PAL statement, format, and placement by choosing respondents

Percent of Respondents Choosing Top PAL Statement (n=2810)	N	% of Respondents	95% CI
"May contain Allergen"	621	22.1	(20.6-23.7)
"Manufactured in a FACILITY that also processes Allergen"	259	9.2	(8.2-10.3)
"Manufactured on a LINE that processes products containing Allergen"	171	6.1	(5.3-7)
"Good manufacturing practices used to segregate ingredients in a facility that also processes Allergen."	352	12.5	(11.4-13.8)
"May contain traces of Allergen"	152	5.4	(4.6-6.3)
"Made on shared equipment that also processes Allergen"	152	5.4	(4.6-6.3)
"Not suitable for people with (BLANK) Allergy"	824	29.3	(27.7-31)
"Packaged in a facility that also packages products containing Allergen"	33	1.2	(0.8-1.6)
"Manufactured on same equipment with products containing allergen"	166	5.9	(5.1-6.8)
Other	80	2.8	(2.3-3.5)
Percent of Respondents Choosing Top PAL Format (n=2810)			
PAL statement with VISUALS of the potential individual food allergens in the product (Allergen Icons)	543	19.3	(17.9-20.8)
Use of GENERAL symbol on all packaging to designate that there is some form PAL present	86	3.1	(2.5-3.8)
PAL statement followed with a short URL (Website Link) or machine-readable BARCODE that you scan with your smartphone that is regularly updated with allergen and manufacturing information	457	16.3	(14.9-17.7)
PAL statement followed with 1-800 PHONE NUMBER listed to call for more information	54	1.9	(1.5-2.5)
PAL statement BOLD and in CAPITAL letters with a larger standardized font	414	14.7	(13.5-16.1)
PAL statement that SPECIFIES THE ALLERGENS that may be at risk for cross contact, rather than a category of allergens. Example: "May contain hazelnut" vs. "May contain tree nuts"	903	32.1	(30.4-33.9)
I don't care where the PAL is, as long as it remains consistent	321	11.4	(10.3-12.7)
Other	32	1.1	(0.8-1.6)
Percent of Respondents Choosing Top PAL Placement (n=2810)			
On the front of the package and immediately following or close to the ingredient list	1111	39.5	(37.7-41.4)
Only immediately following or close to the ingredient list	930	33.1	(31.4-34.9)
I don't care as long as it is consistent on all products	757	26.9	(25.3-28.6)
Other	12	0.4	(0.2-0.8)

Table V. Adjusted associations with Key PAL Responses

[illegible]

\$100K or over	0.67	(0.53-0.86)	0.001	0.82	(0.62-1.09)	0.172	1.10	(0.86-1.40)	0.440	0.88	(0.67-1.17)	0.380	1.22	(0.96-1.55)	0.107
Unknown or prefer not to answer or other	0.78	(0.59-1.02)	0.067	0.68	(0.49-0.95)	0.024	0.87	(0.66-1.14)	0.314	0.75	(0.54-1.04)	0.090	1.10	(0.84-1.44)	0.490
Severe Reaction History (ED Visit or Epinephrine Use)															
Yes	1.93	(1.55-2.41)	<0.001	0.87	(0.69-1.11)	0.274	0.99	(0.81-1.21)	0.921	0.84	(0.66-1.06)	0.141	1.14	(0.93-1.39)	0.208
No	reference			reference			reference			reference			reference		
Labeling Knowledge															
Number of correct questions (0-4)	0.96	(0.90-1.03)	0.297	0.88	(0.81-0.96)	0.004	0.93	(0.87-1.00)	0.040	0.92	(0.85-1.00)	0.050	1.08	(1.01-1.16)	0.033
PAL Discussion with Healthcare Provider															
We did not discuss PAL labeling management	-	-	-	reference			reference			reference			reference		
I should avoid all PAL labels	-	-	-	0.29	(0.21-0.40)	<0.001	0.26	(0.21-0.31)	<0.001	0.24	(0.18-0.33)	<0.001	0.41	(0.32-0.51)	<0.001
I can eat products with PAL labels with the allergen(s)	-	-	-	3.72	(2.49-5.56)	<0.001	2.46	(1.53-3.95)	<0.001	3.21	(2.16-4.76)	<0.001	2.16	(1.24-3.76)	0.007
I can eat foods we have in the past and feel safe with but avoid new foods with PAL	-	-	-	1.60	(1.08-2.37)	0.020	2.37	(1.54-3.65)	<0.001	1.27	(0.86-1.88)	0.224	1.82	(1.12-2.97)	0.016
I don't remember, I don't know or other	-	-	-	1.32	(0.96-1.81)	0.092	1.24	(0.92-1.67)	0.152	1.06	(0.77-1.45)	0.717	1.11	(0.80-1.55)	0.538

Note: OR=odds ratios. Sample is limited to respondents who had a child with food allergy or their own food allergy that was diagnosed by a healthcare provider. Observations with missing race, education, or PAL responses are excluded.

I would feel more confident about purchasing foods with PAL if there was...

