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ORIGINAL ARTICLE

Anaphylaxis to packaged foods in Australasia

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Aims: To examine reports of anaphylaxis in Australasia from consumption of packaged food products with or without precautionary allergen labelling (PAL), where the known allergen triggers were not a listed ingredient.

Methods: A questionnaire was sent to all members of the Australasian Society of Clinical Immunology and Allergy (n = 548). Participants were asked to complete a survey reporting whether they have had seen any patients over the last 3 months reporting anaphylaxis following ingestion of a packaged food where the suspected food allergen was not a listed ingredient.

Results: Of the n = 548 members approached, n = 198 responded (response rate 36.1%).There were 14 reports of anaphylaxis to packaged foods (where the suspected allergen was not a listed ingredient), which met the case definition from a total of 198 respondents over the 9-month period. Of those reactions, 50.0% (confidence interval 95% 21–78) were reported from foods that did not have a PAL statement, and 50.0% (confidence interval 95% 21–78) were due to peanuts.

Conclusion: Anaphylaxis to undeclared allergens was not rare and did not appear to depend on whether the product was labelled with precautionary advice. There is currently no reliable labelling system that can inform food-allergic consumers of safer food choices. Improvements in the regulation of food labelling with PAL are required.

Key words: anaphylaxis; food allergy; precautionary allergen labelling; voluntary incidental trace allergen labelling.

What is already known on this topic

1 Anaphylaxis to packaged foods, where the suspected trigger food is not a listed ingredient, is unknown.
2 Precautionary allergen labelling (PAL) labelling is currently voluntary (with some but not all packaged foods labelled with a variety of advisory warnings).
3 There is no effective way to currently determine whether or not an unlabelled product (foods without PAL) is safe for consumption by the food-allergic community.

What this paper adds

1 Anaphylaxis to packaged foods where the suspected trigger food is not a listed ingredient is not a rare occurrence, with peanuts being the most common suspected contaminating allergen in Australasia.
2 Current PAL practices do not assist consumers in selecting foods that are safe for consumption.

IgE-mediated food allergy in Australia is common, and Australia has the highest reported prevalence rates in the world. Hospital admissions for food-related anaphylaxis have increased in Australia and the USA.[1–3]With no established cure to date, the food-allergic community must rely on abstinence from the offending food. In order to achieve this, the food-allergic consumer relies on food labels. Anaphylaxis is a potentially life-threatening systemic allergic reaction that has a rapid onset that can also be fatal.[4] Motosue *et al.,* 2016, showed that from the period of 2005 to 2014, the rate of food-related anaphylaxis increased by 124% in emergency departments within the USA.[2] Similarly, Mullins *et al.* (2015) examined hospital admissions for anaphylaxis in Australia between 2005–2006 and 2011–2012 and compared their findings to previous published prevalence data. Their result showed that food-related anaphylaxis has increased in all age groups examined by 1.5 times over 7 years.[3]

Precautionary allergen labelling (PAL) is the practice of including statements on food products about the possible presence of allergens (such as 'may contain traces of XXX'). There is no standardised, uniform wording or regulation for PAL, although its use by the food industry is widespread. We have previously reported that 65% of packaged goods within a supermarket setting contain a PAL statement.[5] The abundance and ambiguous nature of these statements makes it very difficult for the food-allergic consumer to avoid these foods. We have shown that

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consumers and health professionals are confused by PAL and, as a consequence, may disregard PAL statements altogether.[6,7] The magnitude of the problem and how frequently anaphylaxis results from consumption of food products that do not list known trigger allergens as ingredients is unknown. The presence of undisclosed allergens in food is ubiquitous. Major allergens have been found in packaged food products with or without precautionary labelling.[8,9] Therefore, we aimed to investigate reports of new cases of anaphylaxis from packaged food products where the reaction was due to presumed allergen contamination (not to a listed ingredient) by surveying health professionals (HP) who most frequently care for patients with anaphylaxis in Australasia.

Methods

A questionnaire (Appendix S1, Supporting Information) was distributed to all members (548, 93% of members see patients) of the Australasian Society of Clinical Immunology and Allergy (ASCIA) over a 9-month period (from February to October 2016). ASCIA is the peak professional body of Immunology and Allergy in Australia and New Zealand. ASCIA sends out a monthly e-newsletter to its members. Each month, over the 9-month study period, the newsletter contained instructions on how to access and complete the survey. Participants were asked to indicate whether or not they had seen a patient reporting anaphylaxis following ingestion of a packaged food where the suspected food allergen was not a listed ingredient within the last 3 months and to complete the questionnaire where a report was made. We used responses from Q3, Q12–13 and Q15 in the HP survey to determine whether the report of anaphylaxis was eligible for inclusion (online resource). Steps were taken to avoid duplicated reports by HPs for the same event by checking the reported cases' date of birth, date of reaction and trigger food to ensure that it was not previously reported. At the end of the study period, all members were re-surveyed with a simple 'Yes' or 'No' question to indicate whether they had seen a patient over the past 9 months who they suspected had anaphylaxis to packaged food where the likely allergen was not a listed ingredient.

Definitions

Reports of anaphylaxis or allergic reactions to packaged foods where the suspected culprit allergen was a listed ingredient were excluded.

For case inclusion, anaphylaxis was defined as one or more of the following reported symptoms: difficult/noisy breathing, swelling of tongue, swelling/tightness in throat, difficulty talking and/or hoarse voice, chest tightness and shortness of breath, wheeze or persistent cough, persistent dizziness and/or collapse or being pale and floppy as part of a generalised allergic reaction (in young children only). HP were defined as any member of ASCIA, which included allergy/immunology specialist, trainee allergy and immunology specialist, other medical practitioners, nurses and dietitians.

Statistical analysis

Questionnaire responses were analysed quantitatively, and percentages and 95% confidence intervals were calculated in Stata, release 12 (StataCorp, College Station, TX, USA). Ethics approval was granted by the Royal Children's Hospital, Melbourne, Australia (HREC: 36051A).

Results

In total, 198 responses were received over the study period (87 from the initial questionnaire and 111 when re-surveyed), which represented 36.1% of the ASCIA membership (Fig. 1). Responses included HPs who responded either yes or no to seeing patients who had experienced anaphylaxis to packaged food. There were 14 reports of anaphylaxis, 7.1% (95% confidence interval 3.9–11.5), from health-care providers where sufficient information was provided to meet the study inclusion criteria (six allergy nurse practitioners; five paediatric allergists, two adult allergists and one general physician). A further 12 HPs reported possible cases, but there was insufficient information to confirm anaphylaxis, and these cases were excluded.

The age of patients reported ranged from 3 to 63 years (median 12). Eight were female, and six were male. Allergy to peanut was the most common known pre-existing food allergy among patients (n = 10, 71%) followed by milk (6, 42%) and egg and tree nuts (5, respectively; 35%), and six (43%) had multiple food allergies (Table 1). The suspected food trigger/s for the reported episode of anaphylaxis were peanut (6), tree nuts (4), cows milk (4), egg (1) and unknown (1) (two people reported two trigger foods.)

All individuals were reported to have symptoms of anaphylaxis on exposure to the packaged food in question (as per the case definition). Wheeze and/or persistent cough (n = 10) and swelling/tightness in throat (n = 10) were the most common symptoms reported. Six patients reported vocal hoarseness, five reported shortness of breath/difficulty breathing, and three reported tongue swelling. Other associated symptoms included urticaria (seven), abdominal pain (seven) and angioedema (five, Fig. 2). Nine (64%) reported reactions occurring within 5 min, three (21%) within 30 min and one (7%) within 1 h. Seven (50%) of the individuals reported that 2–5 bites of the offending packaged food was consumed before the onset of the allergic reaction; four (28%) consumed most of the serving; and in two cases, no details were available on timing of reaction. Eleven patients self-administered or were treated with epinephrine. Six (46%) patients were treated with a combination of epinephrine, antihistamines and steroids, five (38%) were treated with epinephrine only, and two (15%) received only antihistamines (one responder did not report on the type of treatment that the patients had received).

Of the 14 HPs who reported anaphylaxis, 12 also indicated whether a PAL statement was present on the packaged food. Of these, six patients reported to the HP that no PAL statement was present on the packaged food; four reported that the PAL statement specified the suspected trigger food; two reported that the PAL statement did not specify the trigger food; and in two cases, no PAL information was reported (Fig. 3).

Discussion

Over a 9-month period, 14 patients were reported to have experienced convincing anaphylaxis (by history) to packaged food as

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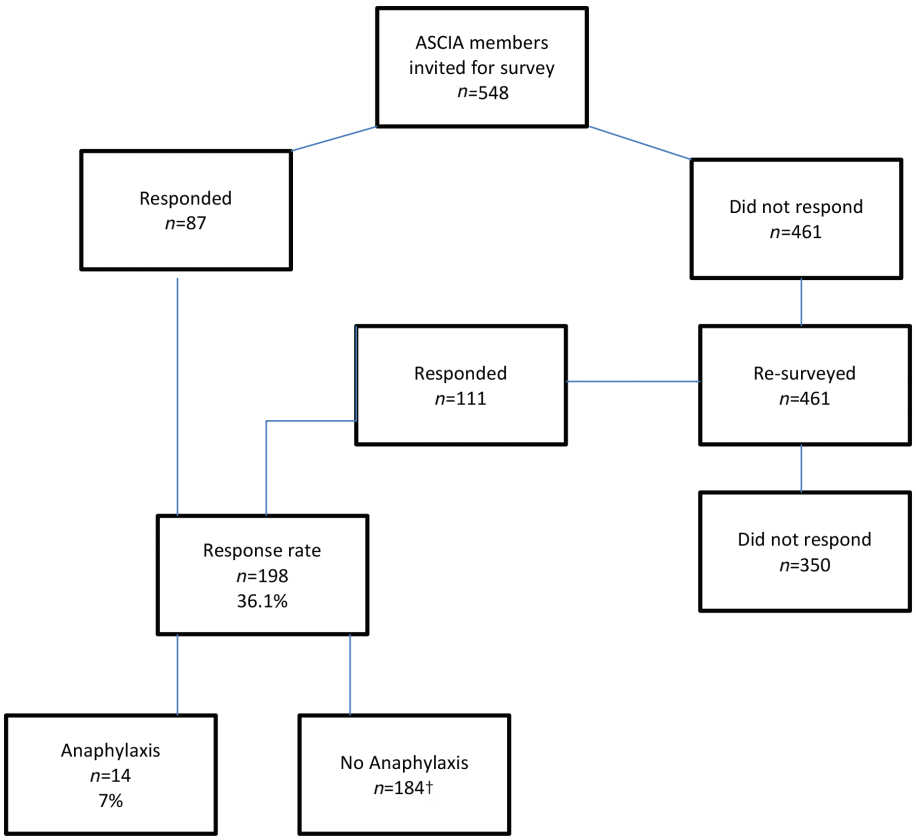


Fig. 1 Flow chart of responders. †Includes 12 reports of possible but unconfirmed anaphylaxis.

a result of likely allergen contamination, of which half were to products that did not have PAL. Of the HPs who responded to the survey, 7% reported a case that met our inclusion criteria, which suggests that anaphylaxis to undeclared allergen in Australasia is not rare. A further 12 cases were reported, with insufficient detail to confirm or refute that anaphylaxis had occurred.

Table 1 Known IgE-mediated food allergies and other allergic diseases reported in the sample (n = 14)†

	n	%
IgE food allergy	13	93
Peanut	10	71
Milk	6	42
Egg	5	35
Cashew	5	35
Other tree nuts	5	35
Walnut	1	7
Sesame	1	7
Multiple	6	43
Other allergens‡	0	0
Food allergy (non-IgE mediated)	0	0
Eczema	9	64
Asthma	7	50
Allergic rhinitis	6	43
Insect allergy	0	0
None§	1	7

†Answers are not mutually exclusive. ‡Other allergens: Soy, wheat, fish, prawn and other seafood. §One patent had no history of allergic disease.

A strength of the study is that we relied on doctor confirmation of the history of anaphylaxis and not self-reported reactions, which can overestimate incidence. We were interested in anaphylaxis rather than other milder allergic reactions as we considered that these to be potentially life-threatening events, likely to be recalled and reported to HP. Milder allergic reactions would have been significantly harder to substantiate by history alone and less likely to be recalled and reported. However, it is likely that we only captured a small proportion of such events across the community as many patients may not report even severe allergic events at all or may report to their local family practitioner or emergency department, rather than to a HP active in the management of patients with allergic disease. We used the ASCIA definition of anaphylaxis, which is well accepted in Australia but is narrower than some other internationally recognised definitions, such as those of the WAO or AAAAI – which include systemic symptoms in any two systems – rather than requiring at least one symptom to include the respiratory tract or cardiovascular system. Similar surveys outside Australia could therefore result in a higher frequency of reports of anaphylaxis to packaged foods based on variations in definition. Only 36% of the ASCIA membership responded to the survey, and although many members are not in active allergy practice (immunologists, pathologists), it is likely that the number of cases identified underrepresents the total burden of disease. Furthermore, we were unable to substantiate the reports by laboratory analysis of the packaged food in question.

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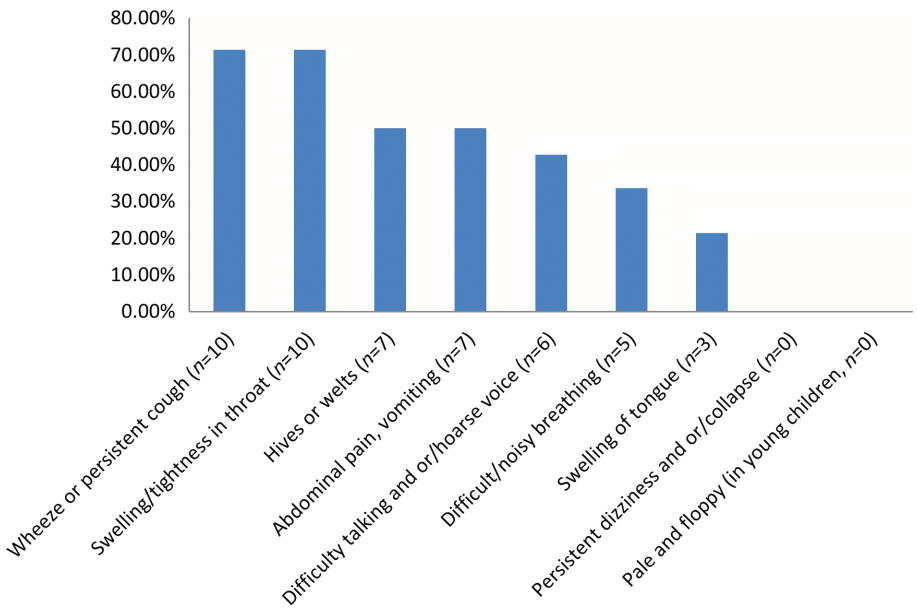


Fig. 2 Symptoms that took place during the episode of anaphylaxis reported by the patient to the health-care provider (n = 14). Every individual that has reported anaphylaxis to their health-care provider was validated to have had anaphylaxis as per definition. The groups are not mutually exclusive.

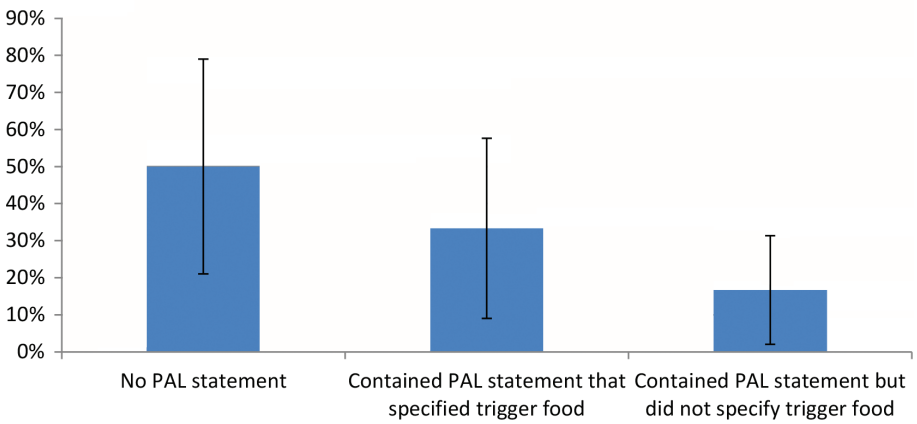


Fig. 3 The prevalence of precautionary allergen labelling (PAL) statements on package foods that triggered anaphylaxis; 12 health professionals answered the question about PAL on the packaged product that resulted in anaphylaxis. One answered 'don't know', and one did not answer the question. Error bars represent 95% confidence intervals.

That reports of anaphylaxis included reactions to products both with and without PAL is of concern. Allergen contamination in packaged food is not rare, and our results are consistent with studies, which have examined products for allergen contamination. For example, in the USA, Ford *et al.*, 2010, examined the frequency and level of contamination of products with and without PAL for milk and egg contamination. The author's results showed residues of allergenic food in 5.3% of PAL products and 1.9% of products without PAL.[9] From 2009 to 2014, 43.4% of US food product recalls were related to undeclared allergens. The most frequently reported food types were cookies, muffins and cakes, with the major allergen being egg, milk, peanut and tree nuts. A large amount of these recalls were caused by the product not been placed in the correct package..[10] In the UK, a recent report investigated the risk of an allergic reaction within the milk-, wheat-, hazelnut- and peanut-allergic populations both with and without PAL. There were detectable levels of common allergens in products with PAL, including gluten in 6.1% of products, cows milk in 8.2%, hazelnut in 2.9% and peanut in 0.21%. In products without PAL, gluten was found in 3.3%, cows milk in 2.1% and hazelnut and peanut detected in none. Of those allergens that were measured in the study, all were greater than the VITAL 2.0 action levels (as below), and this would indicate that precautionary labelling should have been used.[11]

Australasia has led the way with the allergen bureau's VITAL 2.0 process (The Allergen Bureau Ltd, Hobart, Tas, Australia). Although this is one of the many risk assessment processes currently in use around the world, a major limitation of its usefulness to the consumer is that it is not possible to differentiate products that have been through this risk assessment process and remain unlabelled due to their low risk from unlabelled products that have not been through any risk assessment process. We have identified that serious allergic reactions to undeclared allergens present in packaged foods are not rare, and the presence of PAL

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did not appear to assist consumers in making safe food choices. Unfortunately, in the current unregulated PAL environment, it is not possible to determine which foods, either labelled or unlabelled with PAL, have undergone a rigorous risk assessment process. This leaves allergic individuals in an impossible situation of not being safe to eat food labelled with PAL but not being able to determine whether foods not labelled with PAL are safe either. Our results highlight this dilemma.

Conclusion

We believe there is currently a need for clear, consistent, standardised and reliable PAL to be introduced. Without improved and meaningful labelling, the current state of confusion around PAL and risks of serious allergic reactions to allergic consumers will continue.

Acknowledgements

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1. Incidents of anaphylaxis from packaged food products.

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1. Definition of anaphylaxis

The purpose of this survey is to try and gain a better understanding of how frequently anaphylaxis occurs following ingestion of food allergens in packaged products, where that food is not a listed ingredient.

For the purposes of this survey the definition of anaphylaxis includes any one of the following:
Difficult/noisy breathing
Swelling of tongue
Swelling/tightness in throat
Difficulty talking and/or hoarse voice
Chest tightness and shortness of breath
Wheeze or persistent cough
Persistent dizziness and/or collapse
Pale and floppy as part of a generalized allergic reaction (in young children)

2. Incidents of Anaphylaxis from packaged food products

CONSENT

* 1. I have received information regarding this research and had an opportunity to ask questions. I believe I understand the purpose, extent and possible risks of my involvement in this project and I voluntarily consent to take part.

- ◯ I do consent
- ◯ I do NOT consent

3.

2. Please identify which of the following best applies to you ?

- ◯ Medical practitioner
- ◯ Consultant adult allergist
- ◯ Consultant adult immunologist
- ◯ Trainee adult allergist
- ◯ Trainee adult immunologist
- ◯ Consultant paediatric allergist
- ◯ Consultant paediatric immunologist
- ◯ Trainee paediatric immunologist
- ◯ Trainee paediatric allergist
- ◯ Dietitian
- ◯ Nurse practitioner
- ◯ Other (please specify)

4. MEDICAL HISTORY

* 3. In the last 3 MONTHS have any of your patients reported experiencing anaphylaxis (as per definition above) following ingestion of a packaged food, where the likely trigger food was NOT listed as an ingredient?

If you have had more than 1 please complete the survey for each patient. If you have NOT HAD ANY you do not need to progress any further with the survey

- ◯ Yes
- ◯ No

5.

4. If YES how many ?

	How many
*	

6. Case 1

5. What was the likely food responsible for the episode of anaphylaxis you are reporting?

- [ ] Peanut
- [ ] Cashew
- [ ] Walnut
- [ ] Other tree nut
- [ ] Egg
- [ ] Milk
- [ ] Soy
- [ ] Wheat
- [ ] Fish
- [ ] Prawn
- [ ] Other seafood
- [ ] sesame

Other (please specify)

7. Case 1

6. Age of patient

7. Date of patient reaction

DD MM YYYY

* ____ / ____ / ____

8. What is the patient's gender

- ◯ Male
- ◯ Female

8. PAST MEDICAL HISTORY

9. What medical problems does your patient currently suffer from? Check all that apply.

- [ ] Food allergy (IgE mediated)
- [ ] Food allergy (non IgE mediated)
- [ ] Eczema (atopic dermatitis)
- [ ] Asthma
- [ ] Allergic rhinitis
- [ ] Insect allergy
- [ ] None

9. ALLERGIC STATUS

10. Please indicate the basis on which the patient was known to be allergic to the food implicated in the recent episode of anaphylaxis you are reporting?
(tick all that apply)

- [ ] Medically supervised challenge
- [ ] History of convincing objective IgE mediated reaction
- [ ] Positive Sick Prick Test (SPT)
- [ ] Positive ssIgE
- [ ] Avoiding on basis of SPT or ssIgE without any known prior ingestion
- [ ] Not known to be allergic prior to this episode

Other (please specify)

11. What are the known IgE- mediated food allergies of the patient?
(tick all that apply)

- [ ] Peanut
- [ ] Cashew
- [ ] Walnut
- [ ] Other tree nut
- [ ] Egg
- [ ] Milk
- [ ] Soy
- [ ] Wheat
- [ ] Fish
- [ ] Prawn
- [ ] Other seafood
- [ ] sesame

Other (please specify)

10. REACTION

12. How quickly did your patient’s symptoms develop after eating the food in question?

- [ ] Within 5 minutes
- [ ] Within 30 minutes
- [ ] 30 minutes till 1 hour
- [ ] 1-2 hrs
- [ ] 3-4 hrs
- [ ] >4 hrs

Other (please specify)

The following questions are trying to understand if you're patient developed anaphylaxis from consuming products with precautionary allergen labelling

13. What type of symptoms did the patient report?

- [ ] Difficult/noisy breathing
- [ ] Swelling of tongue
- [ ] Swelling/tightness in throat
- [ ] Difficulty talking and/or hoarse voice
- [ ] Wheeze or persistent cough
- [ ] Persistent dizziness and/or collapse
- [ ] Pale and floppy (in young children)
- [ ] Swelling of face, lips and/or eyes
- [ ] Hives or welts
- [ ] Abdominal pain, vomiting

Other (please specify)

14. What is the approximate amount of food consumed for the episode you are reporting?

- [ ] One bite or less
- [ ] 2-5 bites
- [ ] Most of the serving size
- [ ] Don’t know

Other (please specify)

15. How was the episode treated? (Tick all that apply)

- [ ] EpiPen Administration
- [ ] Ambulance gave adrenaline
- [ ] Emergency department gave adrenaline
- [ ] Antihistamine
- [ ] No treatment

Other (please specify)

16. What is the patient's WORST previous known reaction to the likely food allergen prior to the current report of anaphylaxis?

- [ ] No past hx
- [ ] Urticaria and angioedema only
- [ ] Vomiting
- [ ] Upper or lower respiratory symptoms consistent with anaphylaxis (stridor, tightness in the throat, chest tightness, wheeze, persistent cough, tongue swelling)
- [ ] Hypotension/collapse
- [ ] Pallid floppy episode

Other (please specify)

11. CAUSE OF ANAPHYLAXIS

Did the packaged food which caused the anaphylaxis have a precautionary allergen labelling statement such as "may contain traces of peanuts"?



17. Please choose only one

- ◯ Yes
- ◯ No
- ◯ Don't Know

* 18. Was the likely food allergen responsible for the episode of anaphylaxis specifically listed within the precautionary labelling statement?

- ☐ Yes
- ☐ No
- ☐ Not sure

19. Was there any type of testing performed on the food product?

- ◯ Yes
- ◯ No
- ◯ Not sure

If Yes what type of testing was performed and what was the outcome of the testing?

20. Can you please list if know the type of product or brand that cause the reaction?

12. YOUR DETAILS

21. This section is voluntary but It would be helpful if we could contact you if we require any further details

Name:	
Address 1:	
Address 2:	
City/Town:	
State/Province:	
ZIP/Postal Code:	
Country:	
Email Address:	
Phone Number:	

13. END OF SURVEY

Thank you for your help this is the end of the survey

