

Allergen Thresholds

What does the term 'thresholds' refer to?

The threshold dose for a food allergen is the lowest amount that can trigger an allergic reaction if eaten.

For some years scientists around the world have been working to establish the threshold doses for several major allergenic foods. Once a threshold dose has been established for each of them, the food industry can work to reduce cross-contamination to below those levels.

Precautionary allergen labelling is currently used by food companies to warn people that a product may have been in contact with an allergen during the food production process, where it is not an intentional ingredient.

The aim of introducing allergen thresholds is to limit the use of precautionary allergen labelling (also known as PAL or 'may contain' warnings) so that it is only used where a food poses a real risk; while at the same time ensuring that people with food allergies are well-protected.

Scientists are confident they have enough information on threshold doses for fourteen allergenic foods (or groups of foods) to enable regulators such as the Food Standards Agency (FSA) and Food Standards Scotland (FSS) in the UK to offer strong guidance to food manufacturers on the actions they need to adopt to protect people with food allergies.

Those allergenic foods are peanut, milk, egg, some tree nuts (hazelnut, cashew, walnut), soy, wheat, mustard, lupin, sesame, shrimp/prawn, celery and fish.

Differing views have been offered by several different organisations including regulators, industry representatives, doctors and patient groups about the use of allergen thresholds for labelling purposes.

This article aims to help people with food allergies to understand the whole issue of thresholds.

What is the problem with precautionary allergen labelling?

Precautionary allergen labelling can be over-used and can therefore lack credibility. It has been seen on the labels of products that are likely to be very low risk; for example, 'nut traces' warnings have even been seen on the labels of bottled water.

Because precautionary allergen labelling lacks credibility, it is often ignored. In the case of some products, where the risk is real, this could be dangerous.

Where has an allergen threshold already been established and in use in the UK?

A threshold dose has been established for gluten (a protein found in some cereals such as wheat). Gluten must be avoided by people with coeliac disease, which is a condition that causes the immune system to damage the gut and limits nutrient absorption.

Under UK law, products labelled 'gluten-free' must contain no more than 20 parts per million of gluten (equivalent to between one and two tablespoonfuls in a tonne of food). The description 'gluten-free' is based on the principle that this level will be safe for people with coeliac disease.

Individuals with wheat allergy should be aware that the term 'gluten-free' may not be relevant to them because they may react to a product with less than 20 parts per million of gluten if a reasonable portion is eaten, or they may react to other wheat proteins. You may like to read our fact sheet on wheat allergy here:

<https://www.anaphylaxis.org.uk/fact-sheet/wheat-allergy/>

The case for establishing thresholds

There are various reasons to support the use of thresholds in allergen labelling in the UK:

- Food industry action based on agreed thresholds will lead to a reduction in the use of 'may contain' labels and make those that remain more meaningful.
- There will be greater consistency in allergen labelling throughout the food industry and as a result there will be less confusion among customers. This should lead to greater safety for those with allergies.

- Not introducing generally agreed thresholds may lead to even more precautionary labelling, further limiting the choices available to those with food allergies.
- Studies have offered reassuring evidence that reactions to small amounts of an allergenic food (of the order of thresholds proposed for the food industry) will be mild in the vast majority of cases.
- The fact that an allergic person's own threshold can vary from day to day has been taken into account by scientists working on thresholds.

In our experience, the most severe allergic reactions are normally caused, not by extremely small amounts of allergen, but by significant quantities of allergen, added intentionally as an ingredient to the food. In such cases, there is usually a major error made somewhere along the way, either by the person supplying the food or the person eating it.

The case against thresholds

Not everyone agrees with the idea that allergen thresholds should be used to limit the use of precautionary labelling.

Calls to our helpline suggest that the main argument against is based on the perception that extremely small amounts of a food allergen can kill. Although, this perception may be founded on scare stories and extreme cases, small amounts of an allergen can trigger symptoms in individuals who are highly allergic. Any symptom, however minor, can provoke anxiety, with the worry that it could progress to something more serious.

Furthermore, an allergic person's own threshold can vary from day to day. How much they react to at any given time may depend on factors such as their general state of health, how well their asthma is controlled, whether they have been exercising hard or drinking alcohol, and other factors such as sleep deprivation. Even if allergen thresholds are agreed, these limits could be misleading if a person can react to lower amounts at certain times.

It is understandable that you should question whether any food industry actions based on agreed thresholds will protect 100% of the allergic population all of the time, although this does not differ in principle and practice from protection against other hazards in food.

The answer is that there is likely to be a very small minority of people who are so susceptible to an allergen that they could react to an amount below any thresholds that might be set. However, the scientists doing the work believe that any such reaction – should it occur – is likely to be mild and not require hospital treatment.

What has the scientific work involved?

The international scientific group leading the way has drawn on the experiences of Australia's VITAL labelling system (Voluntary Incidental Trace Allergen Labelling). A lot of the scientific work is based on food challenges – where allergenic foods are fed to patients in a controlled hospital setting to test how much allergen they react to. Proposed values for thresholds now rely on several thousand individual challenges, to which more are added on a regular basis.

In 2016, an international debate was held on the issue with representatives from the food industry, food safety authorities, the scientific community and patient organisations. They reached the following conclusions:

- The use of precautionary allergen labelling should be subject to defined conditions, which food producers would need to adhere to if they wished to use it. This means that in the food production chain there would be documented risk assessment and appropriate allergen management procedures to address cross-contamination.
- Communication is crucial. The wording of precautionary allergen labelling must be clear and consistent. And consumers need to know that a product has undergone a risk assessment if it does not have a precautionary allergen statement.
- Guidance for the food industry on good risk assessment practice is required.

Where are we now?

In 2019, updated threshold doses were recommended for the 14 allergenic foods listed on page 1 of this article. The recommendations are referred to as VITAL 3.0 and supersede the VITAL 2.0 threshold dose recommendations previously released in 2011.

A summary of the recommendations can be found here: <https://allergenbureau.net/vital-scientific-expert-panel-2019-summary-recommendations-the-new-allergen-reference-doses-for-vital-program-version-3-0/>

The thresholds currently proposed would need to be reviewed by the FSA and FSS before they could be adopted into official UK guidance. This would need to be in line with the law on the provision of food information to consumers. Many organisations are working together to ensure that the matter gets high priority with the FSA including allergen thresholds work in their overarching Food Hypersensitivity Strategy in 2020/2021.

What does the future hold?

If the established thresholds become part of official UK guidance to the food industry, it is likely there will need to be a transition period allowing food companies time to change their labels. During that transition period we would advise you to be proactive and contact manufacturers and retailers if you have questions about individual products.

Once food companies begin responding to any new official guidance by changing their labelling, it will be vital that the full implications of what the guidance means are communicated to those with food allergies. You will want answers to questions such as: If there is no 'may contain' label on a product, does this reliably mean I can eat it? There will be difficulties in understanding relating to allergenic foods for which there are no established threshold levels. Such communication comes under the remit of the FSA and FSS. Anaphylaxis UK will also play its part in keeping people with allergies informed.

An important question to ask will be: What system will be in place to notify the public of those products whose threshold-based labelling have still caused a reaction? This will be a matter for the FSA and FSS to manage. The FSA currently has a system whereby you can register to receive alerts, and these also appear on the FSA website. Anaphylaxis UK posts these allergy alerts on their website and social media platforms and will continue to share important updates with the allergic community.

Key advice

All cases of food allergy should be medically reviewed. If you suspect you may have a food allergy, you should see your GP, who may refer you to an allergy clinic. The degree of risk in your own case, and the need for any individual avoidance measures, can then be discussed.

Feedback

Please help us to improve our information resources by sending us your feedback at: -

<https://www.anaphylaxis.org.uk/information-resources-feedback/>

Sources

All the information we produce is evidence-based or follows expert opinion and is checked by our clinical and research reviewers. If you wish to know the sources we used in producing any of our information products, please contact info@anaphylaxis.org.uk and we will gladly supply details.

Reviewers

This article has been peer reviewed by Dr Andrew Clark, Consultant in Paediatric Allergy, Addenbrookes NHS Foundation Trust and Sue Clarke, Nurse Advisor to Anaphylaxis UK.

Disclosures

We are not aware of any conflicts of interest in relation to their review of this article.

Disclaimer

The information provided in this article is given in good faith. Every effort is taken to ensure accuracy. All patients are different, and specific cases need specific advice. There is no substitute for good medical advice provided by a medical professional.

About Anaphylaxis UK

Anaphylaxis UK is the only UK-wide charity solely focused on supporting people at risk of serious, life-threatening allergic reactions. We provide information and support to people living with allergies through our free national helpline and local support groups. We also campaign and fundraise to achieve our ultimate aim, to create a safer environment for all people at risk of serious allergies. Visit our website www.anaphylaxis.org.uk and follow us to keep up-to-date with our latest news. We're on Facebook @anaphylaxixUK, LinkedIn, Instagram @anaphylaxisUK, Twitter @AnaphylaxisUK and YouTube.