‘May contain’ warnings and allergen thresholds

If you or a family member/friend has a food allergy, you’ve probably seen labels like “*may contain nuts*” or “*produced in a factory that handles milk*.” These are called precautionary allergen labels (PAL), and they’re meant to warn you about the risk of accidental allergen exposure. This factsheet will help you understand how food companies decide when to use these warnings, and what terms like “allergen threshold” mean.

What does the term ‘threshold’ mean?

When talking about food allergies, the word **threshold** broadly refers to the amount of an allergen (such as peanut, milk, or egg) that triggers an immune response in someone who is allergic to that food. This is important because it helps scientists, doctors, and food companies understand how much of an allergen might be risky for people with allergies.

What is a clinical threshold dose?

The clinical threshold dose is a more precise term. It means the lowest amount of an allergen that has actually been shown to cause symptoms in a person during a medical test, such as a supervised food challenge in a clinic. In other words, it’s the ‘tipping point’ – the lowest amount of an allergen that triggers a reaction in real life, as observed by doctors.

Clinical thresholds can be measured for individuals (how much of an allergen you personally can eat without a reaction). Scientists can then use the clinical threshold doses from many people to help determine population thresholds (for example, the amount of an allergen that would cause a reaction in 1% or 5% of people with that allergy).

Why are thresholds important?

Knowing clinical threshold doses can help food companies and regulators decide when a food is truly risky for people with allergies. This information can be used to help make food labelling more consistent, accurate and meaningful, so ‘may contain’ warnings are only used when there’s a real risk, and people don’t have to avoid foods unnecessarily.

However, everyone’s clinical threshold is different and can change from day to day. Things like illness, stress, exercise, or alcohol can make you more sensitive, so even a very small amount of an allergen could cause a reaction at certain times.

Document reference: ACFS36
Publication date: September 2025
Next review date: September 2028

Because people's sensitivity to allergens can vary from day to day, clinical thresholds have a degree of uncertainly. This is why some experts urge caution about the potential of using population thresholds to set legal labelling levels in the future.

What is precautionary allergen labelling (PAL)?

Precautionary allergen labelling is the information you see on food packaging that warns you that a product might contain an allergen, even though it's not an ingredient. This can happen when foods share a production line or are produced in the same areas as other products, potentially leading to one product contaminating another. This is called cross-contamination. Whilst factories do their best to avoid this, sometimes it is not possible to remove the risk completely.

It's often seen on pre-packaged products in supermarkets and food shops.

What phrases are used in precautionary labelling?

You might see a variety of phrases on food packaging that warn about possible allergens, such as:

- *'May contain nuts'*
- *'May contain traces of egg'*
- *'Made in a factory that handles peanuts'*
- *'Not suitable for milk allergy sufferers'*

There isn't a single, set phrase that companies must use - these warnings are voluntary, so wording can vary. However, by law, any precautionary labelling must not be confusing or misleading and should only be used if there is a **real** risk of cross-contamination, making it a risk to someone with that food allergy, and only after a risk assessment has been carried out.

Do some phrases mean more risk than others?

Sometimes people think one type of statement means there is more risk than another type of statement. For example, that '*May contain nuts'* means more risk than '*Made in a factory that handles nuts'*, but this is not true. In reality, all these phrases mean the same thing: there is a chance of cross-contamination (the food could have come into contact with the allergen), and there is a possible risk for people with that allergy.

How much allergen is present if there is a PAL on a product?

At the moment, there is no legal rule about how much allergen needs to be present before a precautionary label is used. This means the actual amount of allergen in different products with the same warning could vary a lot - even between similar foods.

Document reference: ACFS36
Publication date: September 2025
Next review date: September 2028

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Although PAL is voluntary, food businesses do try and warn consumers if there is a real risk of cross-contact. By law, they must make sure the food they sell is safe under **General Food Law**.

If you think a label is misleading or missing important allergen information, you can report it to the FSA or your local Trading Standards Office (keep the packaging and batch code). The FSA also has an online tool for allergy or intolerance reactions and guidance on reporting misleading labelling.

If investigation shows the business has sold unsafe food, provided misleading information, or breached food safety law, enforcement action can be taken. Penalties vary with the seriousness of the offence and can include fines and, in grave cases, imprisonment.

If a product does not have a "may contain" warning but you are still worried about cross-contact, contact the manufacturer directly and ask how they manage cross-contact and allergens. Most companies will explain their processes.

How could labelling thresholds help?

If these clinical thresholds were used for informing food labelling, it would mean:

- precautionary labels are likely only to be used when the amount of allergen in a food is above a level that could cause a reaction for most people with that allergy.
- if the allergen cross-contamination is very low (below the threshold), companies wouldn't need to use a warning label, making it clearer which foods are truly risky.
- the food industry could work to reduce cross-contamination to below those specific levels and not use precautionary labelling when the risk is below that level.

This could help make food labels more accurate and less confusing, so people with allergies can make safer choices without avoiding foods unnecessarily.

Different groups-including food companies, doctors, patient organisations, and regulators-are discussing whether and how to use allergen thresholds for labelling, as there are pros and cons to consider.

Document reference: ACFS36
Publication date: September 2025
Next review date: September 2028

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Are allergen thresholds already in use in the UK?

Some food businesses in the UK already use their own systems to assess the risk of cross-contamination with allergens. They may decide to add a precautionary allergen label (like "may contain nuts") if the amount of an allergen could be above a certain level.

However, there is currently **no single, official set of allergen threshold levels required by law** for when a PAL must be used. This means that different companies may use different standards, leading to inconsistent labelling. As a result, people with allergies may find it hard to know how much risk a precautionary label really represents, and whether it can be trusted.

Are there any regulated limits for any ingredients already in use in the UK?

Whilst all 'may contain' warnings are voluntary and have no legal thresholds set, the law does set clear limits for certain ingredients when making 'free-from' claims or declaring intentional use of an ingredient:

Gluten-free claim limit

- There is a set legal limit for gluten in foods labelled **"gluten-free."**
- Gluten is a protein found in some grains like wheat, barley, and rye. People with coeliac disease (an autoimmune condition, **not an allergy**) must avoid gluten because it causes their immune system to damage their gut.
- By UK law, foods labelled "gluten-free" must contain **no more than 20 parts per million (ppm) of gluten**-that's about one to two tablespoons in a tonne of food.
- This level is considered safe for people with coeliac disease.
- **Important:** the "**gluten-free**" limit of 20ppm relates specifically to **gluten** and does not cover **all proteins found in cereals**. People with **wheat allergy**—or allergies to **other cereals** like barley or rye—may react to different proteins in these grains, even in very small amounts. This means that "gluten-free" foods may still be unsafe for those with cereal-related allergies.

Read more about wheat allergy.

Sulphites declaration requirement

- In the UK, sulphur dioxide and sulphites must be listed on food labels if they are used intentionally in pre-packed foods and are present at more than **10 parts per million**.
- This is a declaration limit – any deliberate addition above 10ppm triggers a mandatory ingredient declaration of 'sulphites'.
- It means that people with sulphite sensitivity can identify and avoid foods containing problematic levels.

Document reference: ACFS36
Publication date: September 2025
Next review date: September 2028

- Research shows that most people with sulphite sensitivity do not react to amounts below this level.

Read more about Sulphites.

What about other allergens?

For the "top 14" UK allergens **no legal limits** currently exist for either "free-from" claims or PAL usage. This means:

- **PAL (e.g., "may contain…")** remains **voluntary** and based on each company's own risk assessment. There is no single official cutoff by law to use a PAL on a product.
- **Consumer guidance** varies, and shoppers cannot assume that all "may contain" labels reflect the same level of risk.
- **Legal limits** (20 ppm for gluten-free; 10 ppm for sulphite declaration) apply only to specific **"gluten-free"** or **sulphite declaration** rules, not for PAL guidance.

What are the pros and cons of using allergen thresholds?

Advantages of allergen thresholds

- **Clearer and more consistent labels:** if all food companies use the same rules for when to add a warning label, it will make food labels less confusing and easier to understand.
- **More trustworthy information:** people with food allergies and their families could trust labels more, knowing that warnings are only used when there's a real risk.
- **Fewer unnecessary 'May contain' warnings:** using thresholds could reduce the number of precautionary labels ("may contain") on foods, so these warnings would only appear when truly needed. This helps people with allergies have more food choices.
- **Better protection:** without clear rules, companies might put "may contain" on lots of foods just to be seen as safe, even when the risk is tiny. This can make life harder for people with allergies. Thresholds could help prevent overuse of these warnings.
- **Safer food choices:** foods without a warning label might still contain a very tiny amount of allergen, but studies show that these tiny traces almost never cause serious reactions. Scientists have also taken into account that a person's sensitivity can change from day to day.

Disadvantages of allergen thresholds

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Publication date: September 2025
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- **Not zero risk:** even with thresholds, there's no way to guarantee that food is 100% safe for everyone with allergies. A very small number of people are so sensitive that they could react to even the tiniest traces, below the set threshold.
- **Individual differences:** everyone's allergy is different. How much of an allergen it takes to cause a reaction can change depending on things like your general health, asthma control, stress, tiredness, exercise, or alcohol. This means a food that's usually safe might sometimes cause symptoms.
- **No warning for very small amounts:** if a food contains an allergen below the threshold, there may be no warning label. For people who are extremely sensitive, this could still be a worry, even though reactions to such tiny amounts are usually mild and rarely require hospital treatment.
- **Anxiety and perception:** some people worry that even the smallest amount of an allergen could be life-threatening. While this is extremely rare, the fear can still cause anxiety.

In summary

Allergen thresholds for 'may contain' labelling could make food labels clearer and more reliable, helping people with allergies make safer choices and enjoy a wider range of foods. However, they can't remove all risk, and a small number of people may still need to be extra careful. If you have concerns about your own allergy, talk to your allergy specialist for personal advice.

What has the research involved?

The **CODEX** Alimentarius committee, is an international committee that sets global food standards. They have been working on guidance related to precautionary allergen labelling and allergen thresholds. They have spent a long time researching how much of an allergen is enough to cause a reaction in people with food allergies.

Their work includes research from Australia's VITAL labelling system (Voluntary Incidental Trace Allergen Labelling), as well as the FAO (Food and Agriculture Organisation of the United Nations) and the WHO (World Health Organisation).

Their goal is to make food labelling safer, clearer, and more consistent worldwide.

How do they find the right threshold?

Researchers use "food challenge" studies, where volunteers with food allergies are given very small amounts of the allergen under medical supervision. This helps find the smallest amount that can cause a reaction. By combining results from thousands of people in many studies, scientists can work out "reference doses"-the amounts that are likely to cause reactions in only a very small percentage of allergic people.

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Data has been published for the following allergens - peanut, milk, egg, some tree nuts (hazelnut, cashew, pistachios, pecans, walnut, almond, macadamia, Brazil nut), soya, wheat, mustard, lupin, sesame, crustaceans, celery, fish, and molluscs.

You can find out more about the latest reference doses here:

- https://vital.allergenbureau.net/vital-science/
- https://vital.allergenbureau.net/vital-resources/

These reference doses are being proposed by these scientific groups to guide labelling, but they are **not** mandatory labelling limits in the UK at present.

How protective are these thresholds?

Previously, research was carried out to determine thresholds that would protect 99% of people with allergies (the ED01, or the amount that would cause a reaction in just 1% of allergic people). Recent expert reviews suggest that using the ED05 (the amount that might cause a reaction in 5% of allergic people) still protects the vast majority of people, while making food labelling less restrictive. Experts also considered the seriousness of reactions and the need for people with allergies to have safe food choices.

Can we always detect such small amounts?

Testing for allergens at these very low levels is technically challenging and can be cost/labour intensive. Laboratories and food companies are working to improve testing methods so thresholds can be used accurately in real-world food production.

What does the future hold?

Many organisations - including the Food Standards Agency (FSA) and Food Standards Scotland (FSS) - are working hard to understand allergen thresholds and whether they could be introduced. However, it is still too early to know exactly when, how, or if these thresholds will be introduced in the UK.

If new guidance is published and thresholds are introduced, the FSA and FSS would need to give clear instructions to food manufacturers on how to use them to make their labelling accurate and consistent to protect people with allergies.

It will also be important to explain these changes to people with food allergies, so everyone understands what the new labels mean and how to use them safely. For example:

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- **if there's no 'may contain' label, does that mean a food is definitely safe for me?**

- **what if I'm allergic to a food that doesn't have an agreed threshold yet?**

Anaphylaxis UK will help share this information and answer your questions if guidance changes.

Key messages

- The **clinical threshold dose** is the smallest amount of a food allergen that could cause an allergic reaction in someone with that allergy.
- Using labelling thresholds could help reduce unnecessary precautionary allergen labelling ("may contain" warnings) and make labels more meaningful.
- There are both benefits and challenges to using thresholds for food labelling.
- It is too soon to know exactly when or if allergen thresholds will be used for food labelling in the UK, but research and planning are ongoing.

Remember: If you have a food allergy, always read labels carefully and speak to your healthcare team if you have questions about new labelling or your own risk.

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 or you would like a version of this factsheet with the references included, please contact info@anaphylaxis.org.uk and we will gladly supply details.

Reviewers

The content of this Factsheet has been peer-reviewed by Barbara Hirst, Food Safety and Quality Consultant at Reading Scientific Services Ltd (RSSL).

Disclosures

Document reference: ACFS36
Publication date: September 2025
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We are not aware of any conflicts of interest in relation to the review of this factsheet.

Disclaimer

The information provided in this factsheet is given in good faith. Every effort has been 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 raise awareness 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 @anaphylaxisUK, LinkedIn, Instagram @anaphylaxisUK, Twitter @AnaphylaxisUK and you can find our podcast here.

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