Precautionary Allergen Labelling and Allergen Thresholds

FSA 24/09/06 - Report by Rebecca Sudworth, Director of Policy

1. Summary

1.1 In our December 2023 Board paper, we provided an update on our work on precautionary allergen labelling (PAL). We said we would follow up with a Board paper on the use of allergen thresholds to inform the use of PAL.

1.2 Our focus in relation to PAL in recent years has been to improve the clarity and consistency of the use of PAL in the UK, within existing regulations. A summary of this work is in Annex A.

1.3 Alongside this, the UK has continued to participate in work in Codex (the international body that sets voluntary food safety standards) to improve the way PAL is applied globally. As part of this, Codex is considering whether to adopt recommended standard thresholds for PAL.

1.4 This paper sets out the current policy and evidence base on PAL and explores the benefits and risks of using threshold levels as part of standardisation of the use of PAL.

1.5 The Board is invited to:

a. **Discuss** the benefits and risks of considering thresholds based on reference doses as part of a standardised approach to PAL;

In relation to Codex:

b. **Agree** that the principles set out in paragraph 9 are consistent with UK policy objectives, and should be supported;

c. **Comment** on the draft Codex proposal to use ED05 as the basis for delivering the third of these principles.

2. Introduction to PAL

2.1 Unintended allergens (allergens which are not a listed ingredient) can be present in prepacked (footnote 1) food products due to cross contamination in the food chain and can pose a risk to people with food hypersensitivities.

2.2 The first line of defence is to reduce this risk as far as possible through good allergen management practices. Food businesses should carry out risk assessments for their products to inform food safety management systems.

2.3 If food safety management practices do not remove or adequately reduce the potential risk, then UK food businesses can **voluntarily** use PAL to alert consumers to the potential presence of the allergen(s).

3. When is PAL used, and what information does it convey to consumers?

3.1 Food businesses decide when PAL is necessary; there are no thresholds or standards set out in UK law about when PAL should be applied, or the wording to be used. This lack of consistency means consumers do not universally trust it. Our consumer research in the UK found that, whilst most consumers were aware of PAL, understanding of what it is meant to communicate is low and it does not help them to decide whether something is 'safe to eat'. As a consequence, some consumers disregard PAL information when deciding whether to consume a product.

3.2 Many consumers judged PAL as a statement intended to provide 'legal cover' for businesses in the event of accidental consumer harm and were unaware that it was not a mandatory requirement (footnote 2). It is important to note that PAL does **not** absolve businesses of their responsibilities under food safety law, including for effective allergen management. If these responsibilities are not met, then enforcement action may take place even if PAL has been used.

3.3 We have limited data on consumer perceptions of whether PAL restricts choice (one of the drivers of the Codex work). A joint FSA and FSANZ report (footnote 3) from October 2020 compared nine studies, two of which were UK-based. The UK-based studies found that participants perceived that PAL limited rather than enabled safe food choices, by imposing an overly restrictive diet. This was also the position of the studies of other countries within the report.

3.4 By its definition *Precautionary* Allergen Labelling is designed to support consumers in making their own assessment of the risk around consuming a product. The presence or absence of PAL is not intended to be an absolute indicator of risk or safety, rather a starting point for consumers to consider their personal risk. PAL does not mean that an allergen is definitely present in the product, **it is an indicator that there is a risk an allergen may be present**. Our overall aim should be to minimise the use of PAL as by implication its use demonstrates an inability on the part of the food business to fully manage the risks of cross contamination; however, we also want to ensure that consumers are aware if those risks of cross-contamination do exist.

4. Guidance and enforcement

4.1 In the UK the use of PAL is voluntary, with a guidance-based approach. This is currently the same in most countries (including the EU, US and Australia) that use it in some way. However, as noted above, if it is not applied and someone with a food hypersensitivity experiences an adverse reaction there could be a breach of food law, because the food may be unsafe. FSA guidance states that if, after a business conducts a risk assessment, an unavoidable risk of allergen cross-contamination has been identified (and cannot be sufficiently controlled through risk management) the product should have a PAL.

4.2 Although it is a voluntary food information, under food law it still must not mislead, be ambiguous or confusing. However, demonstrating non-compliance is very challenging for Local Authorities, and given the potential differences in risk management decisions businesses make following their risk assessment, there can be a reluctance to instruct food businesses to remove a misapplied PAL.

4.3 The onus is on the business to manage the risk. The Local Authority and sometimes the FSA tend to only become aware of cases where PAL should have been applied but has not if there is an incident, although the vast majority of incidents for prepacked food involve products

where an intentional ingredient has not been properly labelled rather than accidental cross contamination.

5. How do food businesses currently make decisions about PAL?

5.1 Discussions with larger food businesses confirm they carry out a risk assessment, in line with FSA guidance, as part of their allergy management system to inform if a PAL is required. This usually involves every stage of manufacture, from the procurement of raw materials to goods received, to controls in manufacture, packaging and distribution. Where a risk of contamination is identified, steps to remove or minimise risk are considered at each stage and applied as appropriate. A significant part of managing risk involves cleaning of production lines and testing the effectiveness of this cleaning process. This approach informs a company's labelling decision.

5.2 Information on how many and what types of businesses are applying PAL on their products and what, if any, thresholds they are working to, is very limited. Evidence from qualitative interviews shows considerable variation in risk assessment approach. For example, small and medium-sized businesses may rely solely on information provided by ingredient suppliers; some larger businesses apply PAL when there is a risk that an allergen may be present above a set threshold.

5.3 Some multinational food manufacturers that produce a large proportion of the world's prepacked foods, along with a proportion of UK food businesses, are members of VITAL (Voluntary Incidental Trace Allergen Labelling). VITAL recommends global best practice thresholds for allergens (footnote 4), and provides guidance about how to conduct a risk assessment to establish whether there is a risk that allergen contamination may exceed the threshold. More information about VITAL is in Annex B

5.4 The different approaches mean there is a spectrum of labelling accuracy. At one end there are products that are correctly labelled with PAL, at the other there are products which should not have PAL (such as 'may contain nuts' on packets of peanuts) which undermine the effectiveness of the PAL tool. In the middle is a 'no man's land' where there may be products which should have PAL but do not, or products that have PAL where risk is negligible. Individual business risk managers are making decisions about how to balance the responsibility to communicate risk to consumers, protecting public health, with the desire to avoid over-use of PAL , restricting choice.

6. Use of thresholds to inform the use of PAL

6.1 All decisions about whether to use PAL are informed by a judgement about risk and the ability to mitigate it. As with other aspects of food safety, it is rarely possible to reduce the risk of contamination to zero. In practice, this means that food businesses are already making a decision about what level of risk means that PAL is required.

6.2 Thresholds can help food businesses understand what levels of unintentional allergens in their prepacked products should trigger the use of PAL. This can help to standardise the approach. A food business calculates the amount of allergen contamination that may be present in a product and compares this with a 'reference dose'. If there is a risk that contamination will exceed the reference dose, PAL should be applied.

6.3 Reference doses are based on evidence about the likelihood of an objective reaction to specific allergens. An objective reaction covers the whole spectrum from mild to severe. The amount of allergen that causes a reaction with objective symptoms is known as an 'Eliciting Dose' (ED):

a. ED05 is the dose of allergenic protein at which 5% of the allergic population are predicted to have a reaction with objective symptoms. (More information about the hierarchy of risks of reaction at ED05 using peanut as an example is in Annex C);

b. ED01 is the dose where 1% of the allergic population are predicted to have a reaction with objective symptoms.

6.4 The introduction of thresholds based on reference doses has the potential to benefit consumers by ensuring that PAL describes the potential risk accurately and consistently across all products where it is used. It means that for products without PAL, if cross contamination does actually occur it would be no worse than the level set by the threshold. It does not mean contamination up to that threshold will always be present.

6.5 When assessing whether contamination may exceed a reference dose, risk managers consider the amount of food that consumers typically consume on a single eating occasion, to determine the action level (Annex D). For example, the risk of contamination in one biscuit may fall below the reference dose, but a risk manager should take into account that consumers are likely to eat more than one biscuit in a serving.

6.6 However, the setting of a threshold inevitably requires a judgment to be made by policymakers about the level at which an allergen can be present without the use of PAL. That judgment needs to be based on good evidence about the level of risk to consumers and informed by our risk appetite. First and foremost, we would need to ensure that any threshold provides sufficient protection for people with a food hypersensitivity, but there are also practical considerations like measurability (and associated costs for business), and other consumer interest considerations (e.g. proportionality, since greater use of PAL reduces food choice).

6.7 As previously stated, many larger businesses already use thresholds as part of their risk analysis, but further work is required to develop industry-wide thresholds, accounting for risk appetite and feasibility.

7. PAL thresholds: evidence base and further work needed

7.1 To be able to use reference doses effectively the allergen either needs to be measurable at the concentration required, or the threshold would have to be taken into account in the risk assessment by other means, such as an estimate based on investigations of particulate contamination. The current analytical methodologies and evidence vary significantly between allergens, and it is not currently possible to test for all 14 regulated allergens at ED05 levels and below. Annex E provides more information about current testing methodologies for priority allergens.

8. Codex proposals to introduce global standards for PAL

8.1 Codex is the international body that sets global food standards. Codex standards are voluntary; however, they are recognised by the WTO and used as reference texts for trade dispute purposes. As a result, many countries align their national rules with Codex texts, but countries can choose to set a higher standard. If they do so they may be required to justify the decision by another country if challenged.

8.2 In May 2019, the Codex Committee on Food Labelling agreed to review and clarify the provisions relevant to allergen labelling in the ‘General Standard for the Labelling of Prepackaged Foods’ and develop guidance on precautionary allergen or advisory labelling. An Expert Consultation of the Food and Agriculture Organisation and the World Health Organisation was formed to consider the international evidence base and provide scientific advice to Codex.

8.3 The Expert Consultation reviewed the evidence about allergen thresholds and concluded that, if thresholds are to be used, ED05 is a suitable level because it meets the criteria of 'exposure without appreciable public health risk'. The Expert Consultation found that the risk of severe anaphylaxis at ED05 is less than 1 event per 60,000 exposures in the allergenic population (for ED01 it is less than 1 event per 350,000 exposures). They found that the risk of fatal reaction at ED05 is less than 1 per million exposures in the allergenic population and is no greater than the risk at ED01 (Annex F). They also stated that there are no confirmed reports of fatal reactions at either ED05 or ED01.

8.4 It is important to note the limitations of the Expert Consultation review: it did not compare consumer risks under the current voluntary system of PAL labelling (where there are varying risk assessment approaches) with a standardised system employing ED01 or ED05 thresholds, so their report is not instructive on whether moving to standard thresholds will reduce or increase the risk of reaction.

8.5 The FSA commissioned the Committee on Toxicity (COT) to review the report and recommendations from the FAO/WHO Expert Consultation. COT did not have access to the full evidence base and were therefore unable to validate the conclusions (member countries maintain data confidentially). COT did not disagree with the use of thresholds, but expressed concerns about the accuracy of ED values based on the current global evidence base and did not agree, on the basis of available evidence, that ED05-based thresholds would not increase risk compared with ED01. Again, it is important to note that COT did not consider benefits and risks of ED05 or ED01 compared with the current system of PAL labelling. COT also recognised the need for consideration of wider factors as part of the overall risk management approach.

8.6 Based on the report and recommendations from the FAO/WHO Expert Consultation, the Codex Committee on Food Labelling has been developing draft guidance on the use of PAL. This includes principles for when PAL should be used and will include recommendations about whether to adopt a standard threshold. Indications are that the international consensus is likely to settle around a proposal to standardise PAL including a threshold based on ED05. We believe that the draft principles are helpful and broadly consistent with the UK approach. However, given the advice from COT, the UK has expressed strong concerns about adopting thresholds based on ED05, given the current evidence base.

8.7 As previously stated, the proposed Codex standard is voluntary. The decision will rest with each Codex member to decide whether and/or how they wish to adopt the proposed Codex standard (including thresholds based on ED05) or go beyond it. However, it is worth noting that if the Codex proposed revisions currently under consideration are adopted in due course (and many countries do support it) that the use of a threshold using ED05-based reference doses will be used more widely and is likely to become the de facto norm.

9. Draft Codex Principles

a. PAL only to be used where the unintended presence of a food allergen cannot be prevented and controlled;

b. The decision to use PAL should be based on the findings of a risk assessment;

c. PAL should only be used if unintended allergen presence cannot be mitigated to a level at or below the action level based on the reference dose (n.b. Codex proposal is for a threshold set at ED05);

d. PAL should be accompanied by education/information to ensure understanding and appropriate use by consumers, health care providers and food business operators.

9.1 These principles (except for c) are broadly in line with the current UK policy.

10. Analysis and recommendations

10.1 The proposed revisions to the Codex General Standard set out a pathway to global consistency and harmonisation for the use of PAL. The intent is for an approach where PAL provides more meaningful messages for consumers, is trusted (so that people with food hypersensitivity avoid products that are labelled and not suitable for them) and is applied in a consistent way (based on a comprehensive allergen cross-contact risk assessment).

10.2 The Codex approach is to achieve this standardisation using a threshold with reference doses based on ED05. The approach recognises it will not reduce the risk for all and may increase it for those with the most severe food hypersensitivities who erroneously believe that they will not suffer adverse events at this level. The Joint FAO/WHO Expert Consultation has recommended this based on scientific estimates that, at this level, the risk of a fatal reaction in the allergic population is less than one in 1 million exposures.

10.3 Potential benefits of a threshold approach:

- **Consistency and certainty** - Providing food businesses with a standard to work to should result in PAL being applied in a more consistent manner. The use of thresholds is used across other areas of food safety (e.g. permitted levels of contaminants). It also sets a level playing field for industry and provides a more objective basis for the decision on whether or not to label products. It could also help Local Authorities with non-compliance, although there would be costs involved.

- **Understanding, trust and confidence** - At present the increased use of PAL is attributed by many consumers to food businesses covering legal liability. A consistent approach based on thresholds that is understood by consumers should help create more trust in the labelling system. The FSA's 'May Contain' Consultation in 2021 (footnote 5) found that 85% of members of the public supported setting allergen thresholds for prepacked foods to guide the application of PAL.

- **Improved safety** - With trust in a new standard, consumers should be more likely to heed the warning, rather than ignore it, or take a "trial and react" approach, resulting in fewer adverse reactions.

- **Information in Supply Chains -** A threshold-based standard could potentially improve PAL information in supply chains, as a knock-on effect, minimising labelling errors.

10.4 Potential risks of a threshold approach:

- **Testing** - The FSA Review of Allergen Analytical Testing Methodologies (footnote 6) in 2022 found that robust tests are not available for all 14 UK priority allergens; it reported that analysis can cost approximately £55 to £141 per sample and sometimes tests can be inconclusive resulting in food being held back or wasted, as well as these additional costs.

- **Technical capabilities** - SMEs in particular may not have the skills within their food businesses to carry out quantitative risk assessments, including employing sampling frameworks, utilising consumption amounts, and interpreting testing results in relation to

allergen thresholds.

- **Food cost** - The impact on food prices of a threshold-based standard would need to be considered, if food businesses pass on the increased cost of meeting the standard. (As an example, although not directly comparable, free-from products are 27% (footnote 7) more expensive than standard products).

10.5 Other considerations in relation to a threshold approach:

- **Food choice** – one of the drivers behind the Codex work is to reduce the use of PAL where it is not needed to avoid unnecessarily restricting food choice and having a dietary impact on those with a food hypersensitivity. As stated previously, we know that some consumers perceive this happening, but we do not currently have empirical evidence to prove or disprove this perception. However, a widely adopted threshold-based standard could possibly increase the use of PAL, if the standard is overall more stringent than the present widely varying approaches.

- **Trade -** Depending on whether the use of a threshold is adopted and how many countries chose to introduce the Codex proposals, it could lead to divergence between UK and others in the international community. This would be of concern to industry, who want harmonised standards to facilitate trade of their products.

10.6 As previously highlighted, some of the bigger businesses and chains already use VITAL, which utilises thresholds., Evidence from the 'May Contain' consultation has shown there is majority support amongst stakeholders for the principle of standardised allergen thresholds, but there are also concerns about practical feasibility, because, given the current testing landscape, only a threshold of ED05 for some of the 14 allergens would be achievable. However, we have also learned that many businesses, particularly larger retailers, insist on tighter thresholds, used in a more qualitative manner to support their risk assessment and drive standards within their supply chains, and consequently decisions on PAL.

10.7 We have tested the idea of a standardised approach to thresholds with allergen charities and food industry and most recently with our expert working group. Allergen charities welcomed definitive threshold levels, so that people with food hypersensitivities can make more informed choices but had concerns about how a threshold would be communicated and what it would mean to an individual. We have not yet had more detailed conversations about levels for an allergen threshold standard. Consumers want to trust the information that is presented to be able to make decisions, but we have not yet done any specific consumer research about their understanding and views of thresholds.

10.8 We are seeking a Board view on the approach to PAL in the context of the development of this international guidance, given the discussion set out above and the current evidence available.

10.9 **Does the Board agree** with our assessment that the proposed principles a, b and d set out in para 9 are broadly aligned with our current domestic approach to allergen management and the use of PAL, and should continue to be supported?

10.10 **Does the Board support** the aim of principle c that there should be a more standardised approach (i.e. the use of thresholds) to when PAL should be used if the presence of an allergen cannot be mitigated? If so:

- Given the evidence of relative risk and accuracy of data currently available does the Board support the inclusion of ED05-based thresholds in the Codex guidance?

10.11 The international guidance is still being developed and under discussion at a technical level. As outlined above it will be considered by the full committee, Codex Committee on Food Labelling, to agree a recommendation for the Codex Alimentarius Commission (CAC) in November 2024, with Ministers responsible for setting the UK position. This does not necessarily mean it will be adopted in November, it may be referred back to the Working Group. The timing of this step will be dependent on how quickly consensus is reached in the full committee. **Are the Board content** for the Chair to communicate the Board's position to Ministers at the appropriate time?

Annex A – Food Hypersensitivity Policy work on PAL

The updated Food Allergen Labelling and Information Requirements Technical Guidance was published on 4 September 2023 following a Consultation from March to May 2023. The Consultation had over 80 responses from consumers, local authorities, businesses and trade associations. Key changes were around clearer best practice on the application of Precautionary Allergen Labels (PAL) to prepacked foods:

- PAL statements should make specific reference to one or more of the 14 allergens regulated by UK food law that could be unintentionally present in the food, e.g., may contain peanuts, not may contain nuts;

- PAL statements should name the specific food(s) within an allergen group, for example cereals, to enable people with allergies to have the greatest range of food choice and avoid ambiguity and confusion;

- PAL statements should not be used in conjunction with a free-from label for the same allergen

- How and why vegan claims can be used in combination with a PAL.

The Technical Guidance was published on the same day as new, complementary Food and Drink Federation (FDF) guidance (with a foreword from Susan) on how food businesses should apply PAL and communicate a change in allergen profile of a food product.

The updated Technical Guidance complemented a consumer advice campaign in March 2024 on vegan claims. The FHS Policy team worked with FSA Comms to advise that people with allergies should not use vegan labelling to manage allergies as it is not food safety labelling, and that they check labels at all times. It highlights that there is a risk that food of animal origin could be unintentionally present in foods labelled as vegan due to cross contamination. The key messages for this campaign were:

- a vegan label is not a food safety label;

- people with food hypersensitivities should not use a vegan label to manage their allergies;

- and people with food hypersensitivities should continue to thoroughly check labels and speak up about their allergies.

PAL Research:

Research	Objective	Published
Qualitative research with 30 people with FHS on PAL and NGCI	To understand experiences, interpretations and views of precautionary allergen labelling and information to improve how it is applied.	06/06/2022
Qualitative research with 60 FBOs and online interviews on application of PAL	To understand current interpretation, experiences, and usage of PAL by small and medium sized enterprises (SMEs) and to check whether they are being used effectively and consistently.	06/06/2022
Interviews with 42 FBOs on risk analysis and PAL	To understand the extent to which allergen risk analysis is conducted by micro, small, and medium-sized (SME) food businesses, and whether this informs PAL. The report focused on whether the risk assessment and identification of critical points of allergen cross-contact were undertaken.	06/06/2022

Research	Objective	Published
PAL ‘may contain’ consultation involving a series of workshops and online survey with FBOs, LA s, healthcare professionals, allergy charities, consumers, and other interested parties	To obtain information and views relating to the provision of precautionary allergen labelling and precautionary allergen information, to inform potential approaches for PAL for prepacked foods and precautionary allergen information on non-prepacked foods.	06/12/2021-14/03/2022
International review of the literature and guidance on cleaning to remove food allergens	To find information from literature on cleaning to remove food allergens, to inform approaches to FSA cleaning guidance. We are developing a guide for SMEs on validating and verifying their allergen cleaning.	05/06/2023
Review of allergen analytical testing methodologies: measurement parameters and sensitivity of methods	To identify strengths and limitations of current allergen testing capabilities, to progress towards a suitable, harmonised, testing protocol.	04/09/2023

Annex B - Allergen Bureau VITAL 4.0

Source: Authors and Allergen Bureau

The Allergen Bureau’s VITAL® (Voluntary Incidental Trace Allergen Labelling) Program is a standardised allergen risk assessment process for food industry which includes best practice allergen thresholds for precautionary allergen labelling.

Some of the large multinational food manufacturers that produce most of the world’s prepacked foods are members of the VITAL Program, including a proportion of UK national food businesses.

In August 2024, the Allergen Bureau published VITAL 4.0, within which new ED05-based reference doses were published, based on the Joint FAO/WHO Expert Consultation’s

recommendations. Up to August 2024, the VITAL standard was set at ED01, but has since changed to ED05.

The decision to use ED05 rather than ED01 was made because the review from the experts' determined that on balance an ED01 did not meaningfully reduce the health risks to food-allergic individuals but may impact food choices for individuals with food allergies. The Allergen Bureau considers the Joint FAO/WHO Expert Consultation results to be the best available scientific evidence and therefore made the decision to update their VITAL program.

More information from the Allergen Bureau on VITAL 4.0 can be found here: VITAL 4.0 Summary and FAQs.

Annex C – Risk hierarchy (using peanuts as an example)

A threshold based on ED05 means that products that have a risk of an allergen being present below a level at which 5% of the allergenic population are predicted to have an objective reaction would not have a PAL. It does not mean the allergen is present. An objective allergic reaction is one with externally observable symptoms e.g. a rash, hives etc.

Figure 1: Hierarchy of risks faced by people susceptible to IgE-mediated food allergy in relation to reactions to peanut in peanut-allergic individuals. Estimates refer to occurrence of allergic symptoms at ED05 levels of exposure in food-allergic individuals.

Source: Turner, P.J., Patel, N., Ballmer-Weber, B.K., Baumert, J.L., Blom, W.M., Brooke- Taylor, S., Brough, H. *et al.* 2022a. Peanut can be used as a reference allergen for hazard characterization in food allergen risk management: a rapid evidence assessment and meta-analysis. *The Journal of Allergy and Clinical Immunology: In Practice*, 10(1): 59–70. https://doi.org/10.1016/j.jaip.2021.08.008

Annex D - Glossary and acronyms

Action level: the concentration of allergenic protein present in the food product (in milligrams per kilogram) that could potentially trigger an allergic reaction. Food businesses calculate the action level using the reference dose for the specific food allergen and the reference amount (i.e. the amount of the food product eaten in a single typical eating occasion), i.e. Reference dose (mg) / reference amount (kg) = action level (mg/kg).

Ad hoc Joint FAO/WHO Expert Committee: in response to the request from Codex for scientific advice, including current evidence of consumer understanding of allergens, FAO and WHO convened a series of expert meetings to provide scientific advice on this subject.

Codex: The Codex Alimentarius, or "Food Code" is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission.

Codex Alimentarius Commission: also known as CAC, is the central part of the Joint FAO/ WHO Food Standards Programme established by FAO and WHO in 1963 to protect consumer health and promote fair practices in food trade. Defra provides the UK lead for Codex and the official UK Codex Contact Point (CCP), but FSA takes the UK policy lead on Codex committees dealing with food safety.

CCFL: Codex Commission on Food Labelling, FSA takes the UK lead on allergen labelling

CCFH: Codex Commission on Food Hygiene

COT: Committee on Toxicity

Eliciting Dose/ED: the eliciting dose predicted to provoke reactions in a specified percentage of the allergic population

ED01: the eliciting dose predicted to provoke reactions in 1% of the allergic population

ED05: the eliciting dose predicted to provoke reactions in 5% of the allergic population

EWG: Electronic Working Group

FAO: Food and Agriculture Organisation of the United Nations

GSLPF: General Standard for the Labelling of Prepackaged Foods, the Codex General Standard, the CCFL have consulted and have proposed changes to the Standard

PAL: Precautionary Allergen Labelling

WHO: World Health Organisation of the United Nations

Annex E - Allergen testing methods

Source: Authors and Scientific, Sampling and Laboratory Policy Team (SSLP)

An FSA review of allergen testing capability for the 14 allergens was published on 12th September 2023. The research combined a literature review and stakeholder consultation. It highlighted gaps in testing capabilities such as cross-reactivity of ELISA test kits, lack of published data and transparency by kit manufacturers on performance and applicability of the test kits and variations in outputs of different kits when testing for the same allergen and when testing raw vs processed foods.

For some allergens, there are either no analytical methods (to quantify the amount of allergenic protein), or they have significant limitations. These include mustard, celery, fish other than cod, cereals other than wheat, and some tree nuts (e.g. Brazil and processed cashew). The FSA review of allergens testing methods concluded that the following allergens - milk, egg, peanut, tree nuts (almond, hazelnut, walnut, pecan, unprocessed cashew and pistachio), fish (cod only), and crustacea can be tested for at ED05 in certain food matrixes. (Sulphur dioxide sulphites have their own 10ppm threshold which they can be tested at). More work needs to be done to review testing methods for, specific tree nuts, mustard, celery, soya, sesame, molluscs and lupins. The review did not look at what can be tested at lower ED thresholds.

The report has been shared with the Codex Committee for Methods of Analysis and Sampling (CCMAS) EWG on food allergen methods of analysis to support Precautionary Allergen Labelling. The Codex EWG is chaired by the USA and co-chaired by the UK (FSA) and is looking

at methods used by international labs and validating them against the FAO/WHO Codex thresholds.

The FSA review of allergen testing capability provided a summary of testing methods for each allergen.

Annex F – Estimated rate of reactions based on reference doses based on ED01 and ED05

Source: FAO & WHO. 2023. Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens, Meeting report. Food Safety and Quality Series No. 16. Rome. https://doi.org/10.4060/cc6081en

1. Prepacked food is any food put into packaging before being placed on sale

2. FSA and Basis Social (2022) Precautionary Allergen Labelling: Insight from UK micro, small and medium sized food businesses and consumers

3. FSA & FSANZ (2020) Consumers and allergen labelling: A literature review of consumer response to allergen declarations and precautionary allergen labelling

4. Allergen Bureau (2024) VITAL 4.0 Summary and FAQs

5. FSA (2021) Precautionary Allergen Labelling (PAL) & Precautionary Allergen Information: the ‘may contain’ consultation, Report on findings and summary of stakeholder responses

6. FSA (2022) Review of allergen analytical testing methodologies: measurement parameters and sensitivity of methods

7. FSA (2022) Estimating the Financial Costs to Individuals with a Food Hypersensitivity