FSA Position on the Codex Precautionary Allergen Labelling Standard including Allergen Thresholds

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1. Summary

1.1 This paper sets out the latest on the Codex proposals for a global standard on Precautionary Allergen Labelling (PAL), including the use of thresholds. The Board is invited to comment on the proposals and discuss whether they are content to accept the Codex proposal to use an ED05 threshold as part of work to create an international standard for precautionary allergen labelling, taking into account the additional evidence, including further engagement with businesses and allergen charities conducted since the last Board discussion.

2. Introduction

2.1 In May 2019, the Codex Committee on Food Labelling (CCFL) 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 labelling. An Expert Consultation was convened by the Food and Agriculture Organisation and the World Health Organisation (WHO) to consider the international evidence base and provide scientific advice to CCFL.

2.2 The reports from the Expert Consultation were used as a basis for Codex proposals, discussed at the FSA Board Meeting in September 2024. The Board agreed with the majority of the principles around standardising controls, risk assessment and language, which together will go a long way to improving the consistency and clarity of PAL. However, the Board had reservations about whether they had seen sufficient evidence for the proposal to set a threshold for the application of PAL and the level of ED05 chosen, particularly in relation to the impact on UK consumers.

2.3 We have sought to address some of the evidence gaps through consideration of the most recent literature, and additional evidence gathering through stakeholder engagement with businesses and allergen charities (summarised below).

2.4 The UK needs to have a position on the PAL standard being proposed by Codex, including setting allergen thresholds at ED05, in time for CCFL in May 2026. This paper seeks a Board view on whether, given the evidence they have seen, they are content for us to support the Codex proposal. The Board is also invited to consider any additional mitigations to ensure that protections for UK consumers are not reduced by the adoption of the new principles.

3. The Case for Standardisation

3.1 PAL is a tool which can be used by businesses to communicate the risk that allergens are unintentionally present in a food. Businesses must take all possible steps to avoid cross-contamination in the production process, but it is not always possible to remove that risk entirely. Businesses may choose to warn consumers about this risk by using a PAL.

3.2 PAL only works if the public have confidence that its presence accurately reflects that there is a risk, and therefore those that need to follow it avoid the product when the label is present. It is a lack of confidence in the current approach that is driving work towards greater standardisation.

3.3 PAL is used by people to judge the risk to themselves or those they are buying food for. However, it is hard to make such a judgement if the basis on which PAL is applied varies from product to product (and internationally). The idea of standardisation is that PAL is applied in specific situations, clearly communicated, so individuals can judge what the presence of PAL means to them in terms of risk.

3.4 Setting a standard threshold will require drawing a line. The potential benefit of this is it creates a demarcation against which the meaning of PAL can be clearly explained, and people can be educated about what it means and how to use it in managing their risk. That line needs to be backed up by robust standards of risk management and behaviour by businesses to ensure the intended meaning is delivered. This is why the Codex approach (based on the principles set out in the previous Board paper) is designed as a package that includes risk management guidance for business and education for consumers alongside the threshold proposal.

3.5 The aim is to choose a threshold that ensures most people are better protected. However, set the threshold too high and there is the risk that some may experience severe reactions on non-PAL labelled goods, set it too low and PAL will be so prevalent people either ignore it, or it unnecessarily reduces choice. Both of these situations will potentially lead to low confidence in PAL, reducing its value rather than enhancing it. Codex have considered the available evidence and made a judgement that creating a standard based on ED05 thresholds provides an acceptable and practical balance of these risks.

An ED05 threshold

3.6 An eliciting dose (ED) is the total protein of the allergenic food at which a given percentage of the allergic population are predicted to have a reaction with objective symptoms (clinically observable symptoms such as a rash). It is written EDXX where XX is the percentage experiencing a reaction. ED05 means that 5% of people with the relevant allergy who are exposed to the allergen at this level will react. Similarly, a lower level such as ED01 would be predicted to lead to reactions in 1% of the sensitive population. For practical use in food production and labelling these measures are then converted into action levels that set the amount of allergen that may be in a portion of the product from unintended contamination without use of PAL. In reality, if good risk assessment and management practices are followed, levels will be reduced as far as possible and so the risk will often be mitigated.

Outcomes at ED05 or lower levels

3.7 By definition, more people with an allergy would expect to have a reaction at ED05 than ED01, if exposed to the allergen. However, the scientific evidence including from direct challenge experiments (people are given the allergen in a clinical setting) indicates that the additional reactions at ED05 are similar to those seen at ED01 and likely to be mild to moderate with no reports of severe or life-threatening reactions. There are no reports in the experimental literature of severe reactions from levels below ED08.

3.8 Using ED05 to determine the application of PAL should therefore not create a risk of severe reactions but it might be expected that consumption of some products without PAL could result in some additional people having mild or moderate reactions.

3.9 The occurrence of these reactions will almost certainly be more than would be seen at ED01 but still much less than the 5% of the time ED05 might be thought to imply. This is due to a combination of two factors:

- food manufacturers should be using risk management to ensure levels of contamination are as low as possible and this should continue whatever threshold is set for risk communication through PAL. ED05 would be used as the basis for a decision around when risk is communicated, it should not be used by businesses as a 'target' for risk management;

- as robust risk management means most products will contain no allergen contamination, or levels well below ED05, products with sufficient allergen to cause a reaction should be rare. The particular item with allergen present would need to be consumed by a sensitive person. This makes it much less likely to occur than the statistics based on direct challenge experiments might at first imply.

3.10 Where there is no chance of contamination reaching ED05 levels, setting a labelling threshold at ED05 would mean that there would be no PAL even if some contamination at lower levels could not be ruled out. This has the potential to reduce the use of PAL compared to now, although it is not possible to quantify by how much. The consequence of this would be a greater choice of foods without PAL labelling. A lower labelling threshold such as ED01 would mean a greater number of products with low levels of contamination would be expected to have PAL with the consequential impact on choice.

3.11 However, some stakeholders have suggested the introduction of a standard may prompt additional businesses to start using PAL. With standardised thresholds in place, it may also make it more likely PAL information is communicated through the supply chain, which may increase PAL for good public health reasons. Given these potential responses the overall effect on choice is uncertain.

3.12 More analytical tests are capable of detecting and quantifying the range of allergens at ED05 than ED01 so it should be easier to base the decision on PAL, and determine whether it is properly applied, on direct evidence. There are currently no effective measurement methods to determine contamination at ED01 for some of the priority allergens so this would be harder to implement as a threshold for determining when to communicate risk through PAL. This does not mean that where such sensitive tests do exist, they could not be used as part of the risk management verification process, with the aim of reducing potential contamination to the lowest possible level, this would just be separate from the decision to provide PAL.

4. Balancing the risks

4.1 We have discussed the challenges of setting a standard for PAL with a number of charity, business and scientific stakeholders. These were fairly small numbers so not necessarily representative of all those with an interest in PAL but gave an indication of views.

4.2 Allergen charities raised several problems with the current system that any standardised system needs to address, including: lack of clarity around the current system; a strong consumer misconception that it is more regulated than it currently is; a lack of trust; and suspicion over whether it is actually being used for the benefit of individuals rather than businesses. This

presents a complex picture of consumer attitudes. Charities suggested there will be some people, particularly those with the most severe or multiple allergies, who are unlikely to trust any PAL system even if a threshold were set at a very low level such as ED01. Those with the most severe allergies may use other risk mitigation strategies such as preparing their own food and avoiding prepacked products altogether or purchasing the often more expensive 'free from' products.

4.3 For food businesses, allergen management practices vary depending on factors such as food production processes and risks of contamination in raw materials, and thresholds are already often a key part of this. The fundamental driver expressed by businesses for their chosen PAL approach was consumer safety. Manufacturers were additionally motivated by retailer requirements, whilst retailers were also concerned about consumer choice, brand protection and legislative requirements. Key challenges were around general resource requirements for risk assessment and subsequent allergen management (like dedicated lines); adequate test methods (such as managing cross reactivity of some tests) and these were amplified by lack of standardisation and understanding what good looks like. There is a consensus new standards, are needed, especially to support communication of risk through supply chains, but less consensus on what those standards should be.

4.4 Given that PAL exists to communicate the outcome of a risk management process all groups acknowledge that achieving zero risk is impossible, and applying PAL in all cases of non-zero risk would mean PAL would be on nearly all products and therefore be meaningless. Furthermore, with views that those with the greatest risk of severe outcomes would be unlikely to trust and rely on any precautionary labelling system and evidence that designing a system sensitive enough to meet their needs would be practically difficult given the limits of testing technology, it was considered impossible to create a perfect system that protects everyone. Unfortunately, there is therefore potentially a group of people with very high sensitivity to allergens for whom PAL in any form will not provide a sufficient safeguard.

4.5 Therefore, the communication of PAL standards needs to focus on three key elements:

- What PAL is, and what it is based on (including the risk assessment process used to manage contamination);
- What the level of non-zero risk is when there is no PAL, what people might expect from this
- Who it is and is not designed to help (although for those that do not currently rely on PAL but use alternative risk mitigation the risk does not change).

4.6 On this basis, there is general support for a standardised approach from both businesses and the allergen charities and a recognition that the Codex proposals with an ED05 threshold represent a reasonable balance of protection, clarity and practicality. It was also recognised that an element of experiential learning will be part of the journey for people with any new global standard and that understanding experiences will be important to the ongoing education and refinement of any system.

4.7 Based on the discussion set out above we do not consider that the Codex international approach will result in unintended negative consequences for UK consumers and may have benefits for some, so therefore we **recommend** the Board support it.

5. Maintaining strong protection for UK consumers

5.1 The Codex standards set an international benchmark for communication of PAL; however, it is important that this does not become perceived as a ‘target’ for risk management and that businesses continue to endeavour to minimise cross contamination as far as possible. If in future our monitoring (see below), or new evidence suggests the response to the international standardisation is not sufficiently protective we may wish to go further such as tighter standards for some allergens.

5.2 Codex standards are voluntary, countries are not obligated to adopt them, and businesses may independently choose to follow them to facilitate supply chains. However, they are recognised by the World Trade Organization (WTO) and used as reference texts for trade dispute purposes, so many countries choose to benchmark their national rules to Codex texts as doing so means they are deemed WTO compatible. Countries can choose a different (higher or lower) level of protection for their population so long as they have evidence to justify that decision if challenged by another country. Such challenges can occur where, for example, a trading partner feels that their exporters are being disadvantaged by domestic rules that are not aligned with global norms based on Codex texts. Some form of formalised ability to go further on thresholds would avoid the risk of such a challenge and the need for further justification.

5.3 The argument against going further is that without standardisation across all countries the benefits of common meaning and understanding of labelling may be lost both in terms of consumer experience and international trade, particularly the transmission of PAL information along supply chains. Adopting a standard for risk communication does not prevent more stringent risk management by individual business.

5.4 There are three options for how we approach the Codex discussions depending on the extent we might wish to mitigate the risks and retain the ability to go further on thresholds, for example using a different ED level, if desired:

a) Accept the Codex approach and rely on its voluntary nature.

b) Aim to negotiate flexibility in the text for countries to apply different thresholds if it meets the needs of their consumers and is supported by evidence (recognising that this is a negotiation so may not be achievable).

c) Put forward a reservation on the specific text with respect to thresholds

5.5 **Option 1** would see us support progression of the update of General standard for the Labelling of Pre-packed foods recommended for approval and adoption at the Codex Alimentarius Commission (CAC) in July 2026. A global standard would mean that imported goods should have PAL on a basis at least as precautionary as ED05. The UK could still choose to move to tighter thresholds on a regulatory basis and provided this was an evidenced based approach and decision, the risk of trade disputes outlined above could be mitigated.

5.6 **Option 2** we could encourage the inclusion of flexibility to use FAO/WHO ED01-based reference doses if members had safety concerns about the use of ED05-based reference doses for people with food allergies within their jurisdiction. We would need to persuade other countries to support this.

5.7 **Option 3** would be to enter a formal reservation on thresholds. This could be done if Option 2 was pursued but unsuccessful or as the lead option. A reservation is a formal statement attached to the official note of the Codex Alimentarius Commission meeting which we could use to express our intention not to use the standard. This would be a Ministerial decision so we can only make a recommendation.

5.8 If the Board agrees with our recommendation to support the Codex position Option 1 would be our recommended approach. If the Board still has some concerns regarding the

uncertainties, we could pursue either or both of the other options.

6. Gluten and PAL

6.1 There is additionally a specific issue with the Codex proposals unique to gluten around the interaction between two labelling systems for people with coeliac disease: free-from and PAL . This is because people with coeliac disease use both PAL and free-from labels to inform purchasing decisions. PAL thresholds are based on amount of protein per portion size whereas the existing gluten threshold (for gluten free labelling) is based on a concentration irrespective of amount consumed.

6.2 This could lead to an issue in two ways:

1) smaller portions might not carry a PAL because the weight of protein is too low, but the gluten level would be above the gluten threshold or conversely

2) some products could carry a PAL for specific grains such as wheat, but the gluten content is below the gluten threshold which would unnecessarily restrict choice for those with coeliac disease (who already tend to have reduced options).

6.3 We have consistently reflected the concerns raised in our responses to Codex consultations and this is being discussed by the FAO/WHO expert consultation. Therefore, we do not propose any further intervention on this specific point as we expect the issue to resolved through the Codex process and in the meantime, we continue monitoring progress and raising concerns as necessary.

7. Monitoring and Evaluation

7.1 We propose that whichever way the Board decide to respond to the Codex proposals that we seek to establish a baseline on the way in which consumers and UK businesses use PAL.? This would provide evidence to support any future decisions about the use of PAL in the UK.? Consumer perceptions once the Codex proposals are adopted could be looked at through the annual Food and You2 survey, seeking to measure whether there were any changes to their experience of PAL. This would require minimal resource. To have meaningful baseline data on the use of PAL from a business perspective is more challenging given the range of products on which PAL is used. We would need to consider the scope and feasibility of this work, to help determine the resource requirements and practicality. We would welcome Board views on whether we should scope this work further.

7.2 In addition, the Food Law Code of Practice provides examples of circumstances where incidents should be notified to the FSA which includes a list of ‘serious localised hazards’ covering ‘undeclared allergens, a serious anaphylaxis reaction requiring medical intervention as a result of allergens in food, hospitalisation, or death as a result of allergens in food’. We will explore with Incidents colleagues whether there are any new ways to get further data on any incidents relating to PAL to try and monitor any changes in trends if the Codex proposals are adopted.

8. Conclusion

8.1 How to move forward on thresholds for PAL in the UK is a complex decision given the uncertainties, particularly around potential behaviour of both sensitive individuals and businesses. However, on balance we feel that the evidence available does support the reasonable international approach set out in the Codex proposals, with the benefits that a global standard would bring outweighing the potential risks and this would provide a firm basis for future

action. This view is supported by the allergen charities and businesses we have spoken to if accompanied by suitable communications.

8.2 We are therefore asking:

1. Does the Board **agree our recommendation** that we should support the Codex proposals for a global standard taking into account the evidence base (acknowledging the levels of uncertainty)?

2. If the Board still has some reservations, do they want us to go beyond the Option 1 approach in our discussions with Codex and if so, which other options should we consider?

And ask the Board to **note**:

3. We expect concerns about gluten to be resolved through the international process.

4. The proposals for potential future monitoring of the impact of PAL and to **indicate** if they feel it is of value to scope this work in more detail.