



Using allergen reference doses to help in decision making

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Who we are



More than

35 years of scientific excellence and **350** dedicated scientists



Scientific disciplines include:

Food science

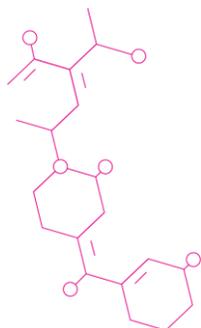
Nutrition

Chemistry

Biochemistry

Molecular biology

Physical sciences



Global reach of **>70** countries



ISO 17025 accredited



We offer a diverse range of product development, analytical testing and consultancy services supporting the full product life cycle



Your allergen partner for testing, training & consultancy



Finished product & ingredient testing

Accurate rapid results tailored to your needs helping you substantiate free-from claims, conduct effective cleaning validations and comply with labelling requirements.



Online training & E-learning

Created and delivered by our expert allergen consultants, our interactive allergen training courses are designed to support your business in all areas of allergen management.



Bespoke allergen management training

Tailored to your needs, allowing you to gain hands on experience on allergen topics including risk analysis in your manufacturing environment.



Site assessments & gap analysis consultancy

On-site allergen management guidance, including policies and procedures, risk analysis, supplier assessments, food safety risk assessments and compliance with regulations.



Allergen investigations & advice

Whether you are a manufacturer needing support with a customer or in the middle of a potential recall we provide a range of bespoke support services

Overview



- How do consumers currently manage allergen information?
- The legal position
- Reference doses
- Using reference doses to help in decisions
- The future for building consumer trust

How do consumers manage allergen information?



- Clinical diagnosis
 - Avoidance is the common preventative treatment
 - What advice is given about “may contain” (Precautionary allergen labelling – PAL)?
- Allergic consumers don’t know how sensitive they are at diagnosis
- Eating / preparing food
 - How much of that have you prepared from scratch?
 - How confident are you in knowing exactly what it contained or may have contained?



CHEDDAR CHEESE BISCUITS
Ingredients: Flour (**Wheat** Flour, Calcium, Iron, Niacin, Thiamin), Vegetable Oil (Palm), Dried Powdered Cheese (11%, of which Cheddar 50%) (**Milk**), Dried Autolysed Yeast, Raising Agents (Ammonium Bicarbonate, Sodium Bicarbonate), Glucose Syrup, Sugar, **Barley** and **Barley** Malt Extract, Natural Flavouring (Dried Yeast Extract, Potassium Chloride, Dried Cheese (**Milk**), Maltodextrin, Natural Flavourings, Dried Whey (**Milk**), Vegetable Oils (Coconut, Rapeseed), Dried Whey (**Milk**), Acid (Lactic Acid), Salt, Natural Flavourings.
For allergens, including cereals containing gluten, see ingredients in **bold**.
May also contain Sesame Seeds, Egg, Soya.

Ingredients: Water, Spinach (14%), Mature Cheddar Cheese (**Milk**), **Wheat** Flour (contains Calcium Carbonate, Iron, Niacin, Thiamin), Sautéed Onion (Onions, Rapeseed Oil), Feta Cheese (**Milk**) (10%), Free-Range Whole **Egg**, Red Peppers (4.5%), Vegetable Oils (Sustainable Palm Oil*, Rapeseed Oil), Wholemeal Spelt Flour (**Wheat**), Dried Skimmed **Milk**, Cannellini Beans, Butter (**Milk**), Cornflour, Double Cream (**Milk**), Butternut Squash Purée, Pine Nuts, Brown Linseeds, Golden Linseeds, Poppy Seeds, Salt, Nutmeg, Black Pepper, Paprika, Cayenne Pepper, **Mustard** Powder
For allergens, including cereals containing gluten, see ingredients in **bold**.
Also, not suitable for consumers with a **fish** allergy.
We've taken care to remove shell but some may remain.

Oat Biscuits
INGREDIENTS: **Oats** (51%), vegetable oil (palm, rapeseed, water, salt, natural flavouring), sugar, raising agent: ammonium bicarbonate.
For allergen information, including cereals containing gluten, see ingredients in **bold**.
Not suitable for nut & sesame allergy sufferers: may also contain egg, milk, mustard, peanut, soya and other gluten sources (wheat, spelt, rye, barley).

Consumer risk



Higher Risk



Lower Risk

Inadequate Training

- Incorrect information
- Cross Packing / Wrong Meal
- Incorrect Recipe
- Gross Contamination
- Residual Cross contamination

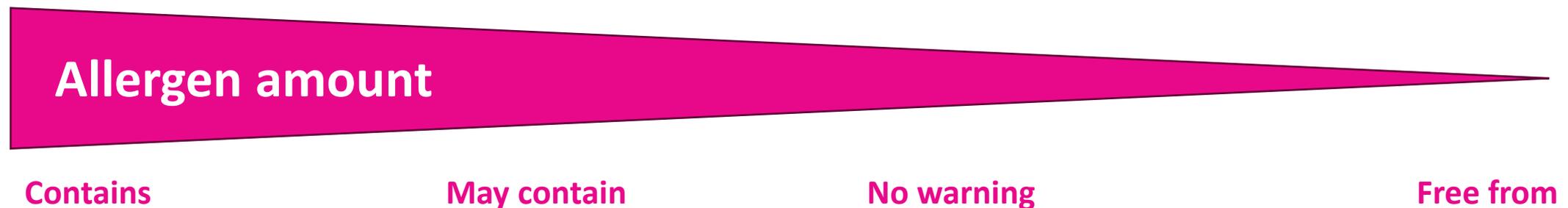


This risk could be where PAL is appropriate

The legal position



- Current position – assimilated Regulation (EU) No. 1169/2011
 - Allergic individuals must be **informed** about which allergens are present as ingredients – list of 14
 - Allergic individuals should be **warned** about allergens that **may be present** unintentionally
 - Decision on whether precautionary allergen labelling (PAL) is required should be based on outcome of risk assessment and risk management steps
 - Any voluntary information (including PAL) must not be misleading, ambiguous, confusing and be based on relevant scientific data
- There are no legally defined thresholds that determine the point at which precautionary allergen labelling should be applied



What are reference doses?



- Reference doses are amounts of protein at which people with food allergies can be predicted to start to have a reaction
- They have been calculated from global clinical feeding studies for each of the allergens
- The levels are in mg of **protein** – it is the protein that people react to
 - Based on a single eating occasion (portion size)
- Reference doses can be used to set action levels
 - The concentration of allergen in food that could trigger a PAL

$$\text{Reference Dose (mg protein)} \div \text{Portion Size (in kg)} = \text{Action Level (mg/kg)}$$

What are reference doses?



- Different reference doses are being used:
 - VITAL reference doses (3.0 and 4.0)
 - FAO/WHO reference doses
- One key difference is the eliciting dose levels – ED₀₁ and ED₀₅
 - ED₀₁ = Eliciting dose when 1% allergic population will start to react
 - ED₀₅ = Eliciting dose for 5% allergic population will start to react

Eliciting Dose	ED ₀₁	ED ₀₅
% of allergic community that has no reaction	99%	95%
Those that experience mild symptoms	0.8%	4%
Those that experience objective symptoms	0.2%	1%
Those that may have severe reactions	<0.01%	<0.05%

Comparison of reference doses



Allergen	Reference Dose (mg protein)		
	VITAL 3.0 (ED ₀₁)	VITAL 4.0 (ED ₀₅)	FAO/WHO (ED ₀₅)
Almond	0.1	1	1
Cashew	0.05	1	1
Celery	0.05	1	1
Mustard	0.05	1	1
Pecan	0.03	1	1
Pistachio	0.05	1	1
Walnut	0.03	1	1
Egg	0.2	2	2
Milk	0.2	2	2
Peanut	0.2	2	2
Sesame	0.1	2	2
Hazelnut	0.1	3	3
Fish	1.3	5	5
Wheat	0.7	5	5
Lupin	2.6	10	10
Soy	0.5	10	10
Mollusc	Insufficient Data	20	-
Shrimp	25	200	200

Precautionary allergen labelling (PAL) - Today



- Precautionary allergen labelling (PAL) or “may contain” should be a warning for allergic consumers to avoid that food
- **Today is not a zero-risk environment**
 - PAL not applied consistently; supply chain, manufacturers, food service
- Result is that consumers don’t understand, don’t trust and don’t heed warnings

“There is evidence that [allergic consumers] assume that the difference in wording on PAL statements reflects variations in the likely presence of an allergen within a product.”

“Current practices (e.g. the use of vague and/or overly technical terms) contribute to consumer confusion and uncertainty about which foods are safe for consumption.”

“Consumers viewed PAL as unhelpful and confusing, and that it ultimately restricts rather than enables safe food choices.”

Reference: Food Standards Australia New Zealand (FSANZ) and Food Standards Agency (FSA). 2020. Consumers and allergen labelling: A literature review of consumer response to allergen declarations and precautionary allergen labelling.

Reference dose - Uses



- Assess whether an ingredient could be used
- Assess whether a PAL is required on product if an ingredient is supplied with unintentional allergen contamination
- Assess whether a PAL is required when carryover during manufacture cannot be avoided
- Assess whether unintentional contamination in product on the market should be recalled



When reference doses should not be used



- When PAL is not appropriate
- Intentionally added ingredients
- Re-work
- Limited testing information
- Hot-spot contamination



- Allergen protein levels present in the ingredient or finished product
 - Worst-case scenario levels – sampling is critical
 - Must be in mg allergen protein / kg food
 - Validated analytical testing
- Portion size of the product/s
 - Maximum amount likely to be consumed in one eating occasion
 - May be higher than that stated on pack
 - Use information from dietary surveys
- Information from supplier
 - Are the levels they are reporting in allergen protein?
 - How likely is it that these represent the worst-case scenario?

If levels are to be used in decision making for precautionary labelling, the data needs to be accurate

Testing choices



- Suitable ELISA test
 - Does the test report as or can be converted to protein levels?
 - Into total allergen protein
 - Gluten levels not equivalent to cereal protein levels
 - Has uncertainty been added?
 - Laboratory validation
 - Positive control testing
 - Spike recovery testing
- If no suitable ELISA test, need to re-assess
 - May need to use theoretical levels
- Results from surface swabs, rinse waters and other indirect measures from cleaning cannot be used
 - There is no direct relationship between residues from a surface or rinse water to what a consumer would be exposed to from eating a product

Common mistakes



- Reference doses are discreet dose amounts (mg allergen protein) – not concentrations (e.g. ppm or mg/kg)
 - Misconception that tests need to be able to detect down to the reference dose level
- Calculations based on testing results that are not reported in total allergen protein
- Used for assessing levels when an ingredient has been deliberately added
- Portion size not considered, or underestimated
- Used when contamination is not evenly distributed
- Used on results from environmental samples (e.g. swabs)



- Reference doses could be helpful in moving to a managed risk approach
- Could bring consistency in use of PAL
- Could increase consumer trust to avoid products with PAL
- Testing needs to be much more robust
 - Reference dose calculations are based on total allergen protein in food
 - Reporting of results must be compatible
 - Validation required under accreditation (e.g. UKAS) is not enough
- Reference doses can be helpful in decisions on whether a **real** risk is **significant**
 - Peanut in garlic and peanut in soya lecithin
 - Risk is real but not significant
 - Soya in wheat flour and other cereals in wheat flour, etc.
 - Risk is real but not consistent, so may / may not be significant

Latest position of FSA



- First consultation launched in December 2021 – in response to consumer surveys that had highlighted a need to review how precautionary allergen labelling (PAL) is applied
 - Allergic consumers find the warnings inconsistent and don't always trust them
- FSA Board Meeting 10th December 2025
 - Paper presented on whether to align with Codex's approach to PAL and allergen thresholds
 - Consultations with industry, charities supporting people with food hypersensitivities
 - Standardisation would strengthen supply chain confidence
 - Agreement that in the future UK could adopt an ED05 allergen threshold for risk communication
 - FSA Board unanimously supported Codex alignment
 - UK are now in lock-step with EU and global
 - Codex adoption expected in July 2026
 - No immediate domestic changes



CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS



Food and Agriculture
Organization of
the United Nations



World Health
Organization

E-mail: codex@fao.org - www.codexalimentarius.org

Key messages



- Use of reference doses could provide a basis for decisions about PAL
- Reference doses are an amount of allergen protein in a serving of food at which either 1% or 5% of the allergic population start to react – this is likely to be a mild reaction
- Where there is currently a lack of regulatory limits or instruction on how to apply PAL, reference doses can help provide a rationale
- Using reference doses is only appropriate when the use of PAL is appropriate – it should not be used to compensate for poor adherence to GMP or lack of management of allergens
- Reliable data is critical
 - Testing results must be in total allergen protein
 - Validation is key

Additional training options



RSSL offer a range of training in different aspects of allergen management

- Bespoke on-site workshops
- Awareness level training
- Allergen risk analysis
- Allergen cleaning validation
- More details visit www.rssl.com or email fsgtraining@rssl.com



 **From 28 Jan**  4 hrs

Best Practice in Allergen Cleaning Validation



 **From 19 Feb**  4 hrs

Using reference doses for precautionary allergen labelling



 **From 24 Mar**  4 hrs

Considerations for Allergen Sampling and Analysis



 **From 11 Jun**  3.5 hrs

An Introduction to Allergens and the Law

Thank you for your time and attention



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