

A global regulatory update on food allergen labelling

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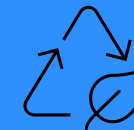
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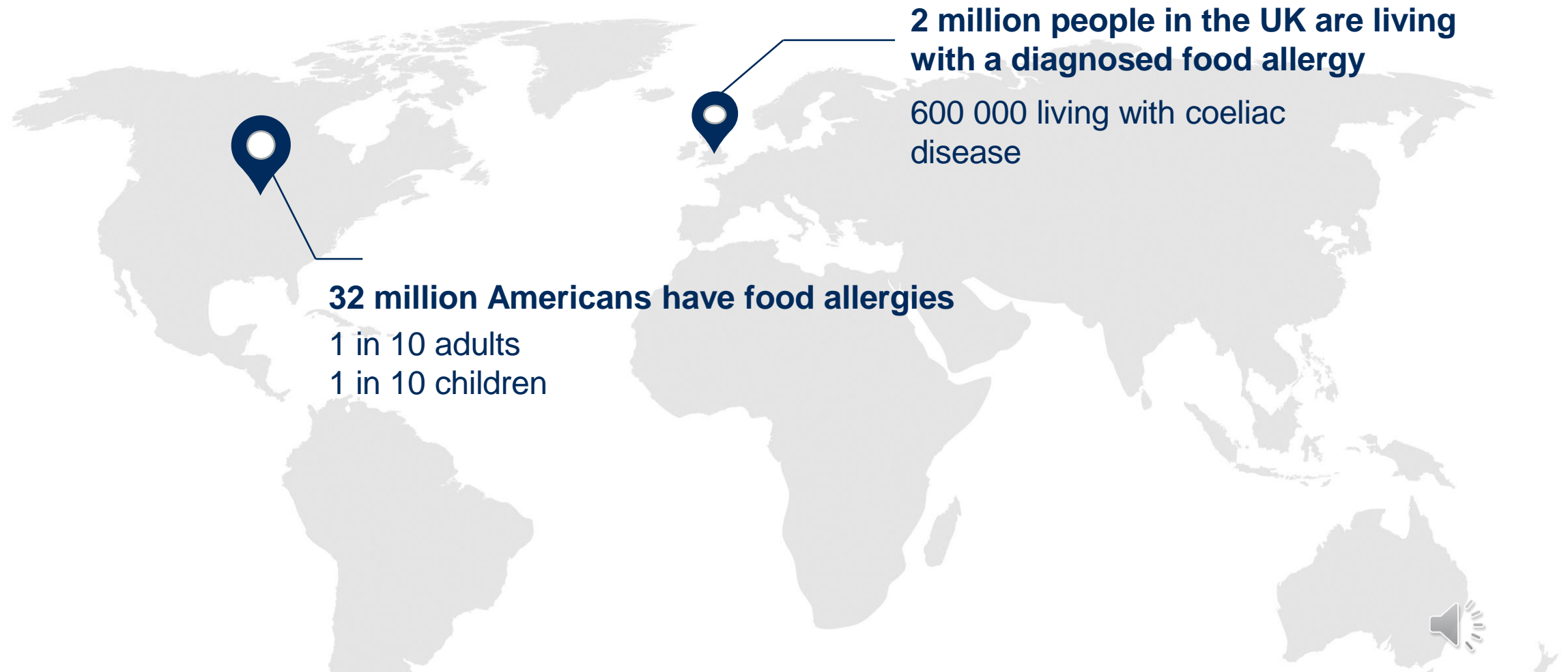


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Sustainability practice:
strategy, sustainable innovation,
product stewardship

Unique access to Group resource: e.g. additional language skills, toxicologists, food chemists

Prevalence of food allergies are rising around the world – greatest rise is in the US and other industrialised countries



The exact cause of the increase in allergen susceptibility remains unknown – some studies have attributed it to 4 main factors



Genetic factors



Environmental factors



Increase in allergy diagnosis



Increase in number of food allergies reported



WHO has defined the “Big 8” as the most common food allergens, responsible for the most allergenic reactions

1. Cereals containing gluten
2. Crustacea and products of these
3. Eggs and egg products
4. Fish and fish products
5. Peanuts, and products of these
6. Soybeans and products of these
7. Milk and milk products (lactulose included)
8. Tree nuts and nut products



Today's agenda

Allergen recognition

Common list, the case for tree nuts, unique allergens

Labelling

Mandatory labelling, exemptions, recent development, challenges, precautionary allergen labelling

Scientific awareness

Raw materials, food contact materials, and thresholds



Allergen recognition



Non-harmonisation on allergen recognition between countries around the world

	EU	US	Japan	Israel
Regulation	Regulation 1169/2011 Annex II	FALCPA / FASTER	Food Labelling Act	Public Health Regulations (food) (gluten labelling) 1996
Crustacean shellfish	X	X	X ¹	
Sesame	X	X		
Tree nuts	X	X	X ²	
Mustard	X			

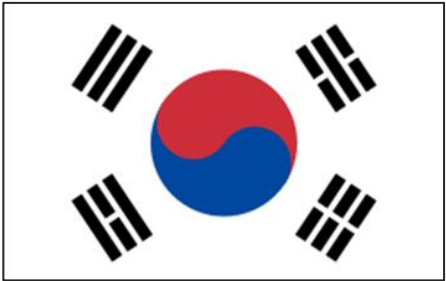
1. Crab; shrimp
2. Walnut and cashew



Increasing divergence leads to increasing complexity for labelling



- Not included in the definition of common allergens, however when bee pollen or food containing bee pollen as an ingredient is in the food product, a warning statement that the product contains bee pollen which can cause severe allergic reactions is applied. Same principle applies for royal jelly



- Recognises buckwheat, chicken, pork, tomatoes, beef, and peaches as allergens in addition to the common allergens



- Recognises mango as an allergen



Latex is a recognised allergen in Brazil

- Latex is also recognised as an allergen. It should be declared using the same format as the other food allergens



The case for tree nuts

United States

The list of tree nuts includes 21 ingredients which are:

Almond, beech nut, black walnut, Brazil nut, butternut, California walnut, cashew, chestnut, chinquapin, **coconut**, cola nut, hazelnut, ginkgo nut, heartnut, hickory nut, macadamia nut, palm nut, pecan, pili nut, pine nut, pistachio, shea nut, walnut

Recognise coconut as an allergen

GCC

The list of tree nuts includes 18 ingredients which are:

Almond, beech nut, Brazil nuts, butternut, cashew nuts, chestnut, chinquapin, **coconuts**, hazelnut, ginkonut, hickory nut, lichee nut, macadamia nut, pine nut, shea nut, hewal nut

Australia / New Zealand

The list of tree nuts includes 9 ingredients which are:

Almond, Brazil nut, cashew, hazelnut, macadamia, pecan pine nut, pistachio, walnut

Don't recognise coconut as an allergen

Brazil

Term “tree nuts“ not included in regulation – the 10 tree nuts recognised as a food allergen are individually listed- which are:

Almond, hazelnuts, cashew nuts, Brazil nuts, macadamia, walnuts, pecans, pistachio, pinoli, chestnuts



The case for tree nuts

South Korea

Walnut and pine nut

Turkey

Almond, walnut, cashew, pecan, Brazil nut, pistachio, macadamia nut and Queensland nut and products thereof

Mexico

It generally includes almonds and walnuts but applies generally to all nuts produced by trees, including hazelnuts, pecans, Brazil nut, cashew, chestnut, macadamia nut

Argentina






Almond, hazelnut, chestnut, cashew nut, Brazil nut, walnut, pecan, pistachio



Allergen labelling



Comparison of the general regulatory framework for allergen labelling among countries

	USA	Australia/ New Zealand	European Union	China	Japan
Is allergen labelling mandatory?					
Format	<p>Ingredients: water, carrots, onions, red lentils (4.5%) potatoes, cauliflower, leeks, peas, cornflour, wheat flour, salt, cream (milk), yeast, concentrated tomato paste, garlic, whey (milk), sugar, celery seed</p> <p>Contains: milk, and wheat</p>	<p>Ingredients: water, carrots, onions, red lentils (4.5%) potatoes, cauliflower, leeks, peas, cornflour, wheat, flour, salt, cream (milk), yeast, concentrated tomato paste, garlic, whey (milk), sugar, celery seed</p> <p>Contains Milk, Wheat and Gluten</p>	<p>Ingredients: water, carrots, onions, red lentils (4.5%) potatoes, cauliflower, leeks, peas, cornflour, wheat flour, salt, cream, yeast extract, concentrated tomato paste, garlic, whey (milk), sugar, celery seed,</p>	<p>Ingredients: water, carrots, onions, red lentils (4.5%) potatoes, cauliflower, leeks, peas, cornflour, wheat flour, salt, cream, yeast extract, concentrated tomato paste, garlic, whey, sugar, celery seed</p>	<p>Ingredients: water, carrots, onions, red lentils (4.5%) potatoes, cauliflower, leeks, peas, cornflour, wheat flour, salt, cream, yeast extract concentrated tomato paste, garlic, whey (milk contained), sugar, celery seed*</p>






Draft regulation making allergen labelling mandatory in China

- Currently, allergen labelling requirements are non-mandatory requirements in China
- Chinese authority has issued a consultation on a draft new version of GB 7718, which will replace the current version (i.e., GB 7718-2011) after the new standard is finalized. The new draft standard mandates allergen labelling
- Regarding allergen labelling format, the draft standard states that allergens used as ingredients should be highlighted (through bold, underline, etc.) in the list of ingredients or declared in an allergen statement in proximity to the ingredients
- No estimated time of when it will be published



Comparison of the general regulatory framework for allergen labelling among countries in Latin America

	Mexico	Brazil	Paraguay	Argentina
Is allergen labelling mandatory?				
Format	<p>CONTIENE.... (followed by the allergen) (Contain...); or</p> <p>CONTIENE DERIVADO DE... (following by the allergen) (Contains derivate of...)</p>	<p>ALÉRGICOS: CONTÉM ... (followed by the common names of allergens)</p> <p>(Allergic: contains...); or</p> <p>ALÉRGICOS: CONTÉM DERIVADOS DE... (followed by the common names of allergens)</p> <p>(Allergic: contains derivatives of...); or</p> <p>ALÉRGICOS: CONTÉM (followed by the common names of allergens) E DERIVADOS</p> <p>(Allergic: contains...and derivatives).</p>	<p>CONTIENE.... (followed by the allergen (Contain...): or</p> <p>CONTIENE DERIVADO DE... (followed by the allergen) (Contains derivate of...)</p>	<p>CONTIENE.... (following by the allergen) (Contain); or</p> <p>CONTIENE DERIVADO DE... (followed by the allergen) (Contains derivate of)</p>



Exemptions are contributing further to the complexity

Country	Exemptions
USA	Because allergenic proteins are eliminated during refinement, highly refined oils are exempted from the allergen regulations while ice-structuring proteins (ISP) and their derivatives are exempted as a result from petitions to the FDA
Australia & New Zealand	These markets appear to have similar exemptions for fully refined oil. Wheat-based glucose syrups, distilled alcohol from wheat or whey, and soy derivatives that are tocopherols and phytosterols are also exempted
EU	
China	The draft standard will introduce refined vegetable oil, phospholipids, starches and dextrin's as foods exempted for allergen labelling

The US has a petition process for allergen exemptions



Free-from claims

- “Free-from” claims – where a label states that a product is free-from an allergen, this is based on specific and rigorous controls, ensuring that the final product is completely free of the particular allergen. In most countries this is the case
- “Gluten-free” claims – there is an exemption to gluten-free claims in most countries such as UK and South Africa, where a gluten-free product can contain a maximum of 20mg/kg of gluten



Case study: allergen labelling in Australia and US

- Requires allergen declaration in the **ingredient list emphasised in bold** as well as a contain **statement**



- Requires to have the allergens in the ingredient list and/or contains statement; however, the allergens in the ingredient list is not emphasised in bold, and the contains statement is only permitted in recognized allergens



Recent and future developments

United States

- Sesame became the ninth significant food allergen in January 2023 as a result of the Food Allergy Safety, Treatment, Education, and Research (FASTER) statute, a federal statute passed in 2021

Japan

- Walnut now a mandatory allergen. Food business operators shall comply by 01 April 2025
- Consideration of adding macadamia nuts and removing matsutake mushrooms from the voluntarily list for allergen labelling

CODEX

- Draft revision to the general standard for the labelling of pre-packaged foods – provisions relevant to allergen labelling will be forwarded for adoption at Step 5. The draft applies to all pre-packaged food

Brazil

- The review of labelling requirements of allergens is being discussed; however, it is part of a project in the regulatory agenda. No specific timeline established yet (no update expected for 2023)



Recent and future developments

China

- The Chinese authority has issued a consultation on a draft new version of GB 7718, which will replace the current version (i.e. GB 7718-2011) after the new standard is finalised. The new draft standard mandates allergen labelling, includes exemptions and labelling formatting

Israel

- A draft for allergens regulations was published for public comments on November 2022. The list of allergens in the proposed draft is quite close to the European Union Regulation; however, It does not include celery, mustard and lupin. The draft also species 10 different tree nut

Russia

- Draft Amendments N4 to the Technical Regulation of Customs Union 022/2011 Labelling of Food Products – contains an updated list of allergens. An example of the amendment is that the current listing of the allergen as ‘nuts and products of their processing’ will be replaced with a definition for nuts. The draft amendments may be adopted very soon (originally planned for the fourth quarter of 2022)




What is happening with precautionary allergen labelling? – CODEX

CODEX is developing new guidelines for PAL, as well as discussing the decision framework for the use of PAL. The proposed draft guidance on will:

- Include the definition for precautionary allergen labelling
- Establish how to use PAL
- Establish the action level for allergens

FOOD AND INGREDIENT	REFERENCE DOSE (RFD) (MG TOTAL PROTEIN FROM THE ALLERGEN)
Walnut, pecan, cashew, pistachio, and almond	1.0
Peanut, egg, milk, sesame, wheat	2.0
Hazelnut	3.0
Fish	5.0
Crustacea	200



What is happening with precautionary allergen labelling? – UK

In September 2023, the FSA published a food allergen labelling and information requirements technical guidance, advising in relation to PAL that food business should:

- Only apply PAL if there is an unavoidable risk of allergen cross-contamination
- Specify which of the 14 major allergens the PAL refers to
- Use PAL statements in combination with a ‘vegan’ label where a risk of cross-contamination with an allergen has been identified

It also establishes why businesses should not use a PAL alongside a “free from” as well as best practice for the use of No Gluten Containing Ingredient (NGCI) statements for food businesses in the non-prepacked food sector.



Are “may contain” statement permitted ?

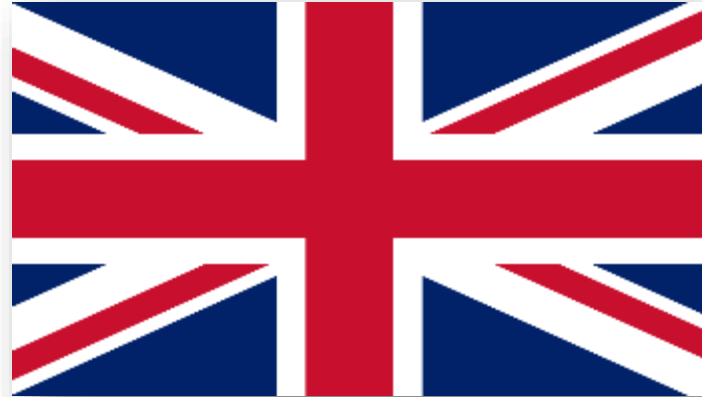
Market	PAL guidance
Argentina	Only permitted upon authorisation
Japan	The phrase “The plant manufacturing this product produces products containing XXX” (本品製造工場ではXXXを含む製品を生産しています) is recommended but ‘may contain’ or similar is prohibited
South Africa	Only if documented steps have been taken to assess and manage the risk, and the statement is not used to circumvent the implementation of Good Manufacturing Practice
EU	Should only be used after thorough risk assessment and as a risk-based indication that an allergen could be unintentionally, but unavoidably, present in a product
Taiwan	Statement for cross-contamination or cross-contact such as that a product is made in a factory where the production facilities or line also handle allergen ‘X’
UK	Should only be declared after thorough risk assessment when genuine risk of allergen cross-contact within the supply chain is identified that cannot be removed through careful risk management actions. It warns that excessive use of PAL can unnecessarily limit consumer choice and devalue the warning for consumers with a food allergy or intolerance



Challenges in bakeries and restaurants



FDA Food Code was updated in December 2022 to call for allergen labelling of unpackaged food sold at restaurants. The changes within the code are simply a representation of the FDA's advice on this topic, and it is up to each state to decide whether or not and how to incorporate this model.



Allergen information is mandatory for all establishments that sell food; however, the presentation and formatting may depend on the food sold.



Food businesses are not subject to allergen declaration. However, it is mandatory for food service businesses selling 'favourite foods of children' (i.e. bakery/confectionery, ice cream, hamburger/pizza) in accordance with provisions on allergen labelling of favourite foods of children.



Upcoming technological challenges



Emerging raw materials & formulations

**Global warming,
health and well being**

**Manufactures expanding their
portfolio with plant-based
ingredients**

**Plant-based products
containing isolated
proteins**

**Increase of
allergen
susceptibility**



Food contact materials

Switch from non-biodegradable straws to biodegradable ones i.e. switch to from plastic straws to corn or wheat straws



Straws made from corn

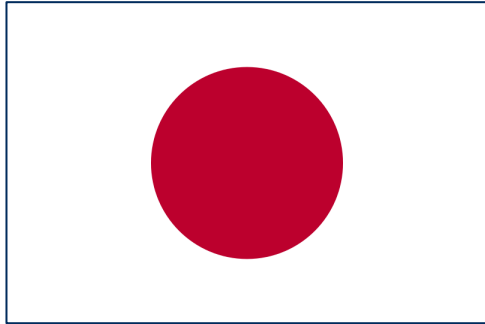
Contains a protein called “zein”, although uncommon allergen there may be still a chance due to allergenicity from other ingredients



Straws made from wheat

These items are gluten-free since they are manufactured from the stem – which does not naturally contain gluten, yet there is still a substantial potential of cross-contamination.

A major issue: detection techniques & lack of thresholds



According to a Q&A published by the **Ministry of Health, Labour, and Welfare**; it is considered that when the amount of the total protein of specified ingredients contained in the food is **less than a few $\mu\text{g}/\text{ml}$** concentration levels or a few $\mu\text{g}/\text{g}$ content levels, there is **no need to label the allergens**



A threshold is a value below which it is unlikely that a food allergic individual would experience an adverse effect



Key takeaway points



Key takeaway messages

1. Divergences exist not only in recognition of allergens but also formatting
2. It is important to keep up with evolving regulations, as there are forthcoming changes in allergen recognition
3. Emerging plant-based formulation may increase allergen susceptibility
4. Food contact material suppliers should be mindful on declaring the presence of allergens in their products



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