

Overview on international developments in allergen management

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Acknowledgements



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Topics of this presentation

Update on recent developments with a focus on:

- › the request from Codex for an Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens
- › differing precautionary allergen labelling (PAL) strategies starting to appear across countries & their (unintended) consequences

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Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens



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Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens

- › Part 1: Review and validation of Codex priority allergen list through risk assessment
- › Part 2: Review and establish threshold levels in foods of the priority allergens
- › Part 3: Review and establish precautionary labelling in foods of the priority allergens

[More info on Part 1](#) (summary and conclusions), virtual meeting, 30 November – 11 December 2020, 28 January 2021, 8 February 2021
[More info on Part 2](#) (summary and conclusions), virtual meeting, 15 March – 2 April 2021
[More info on Part 3](#) (ongoing)



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Summary report of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens.

Part 1: Review and validation of Codex priority allergen list through risk assessment

- › Criteria: prevalence, severity and potency of immune-mediated hypersensitivity of each food
- › Global priority allergen list:
 - › Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains),
 - › crustacea,
 - › eggs,
 - › fish,
 - › milk,
 - › peanuts,
 - › sesame,
 - › ~~soybeans~~,
 - › specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).
- › Regional: Other foods may be considered for inclusion on priority allergen lists in individual countries

Virtual meeting, 30 November – 11 December 2020, 28 January 2021, 8 February 2021, [More info on Part 1](#) (summary and conclusions)



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Part 1: Review and validation of Codex priority allergen list through risk assessment

> Criteria:

> Global priority allergens:

> Cereals

> and products of these;

> crustaceans

> and products of these;

> eggs and egg products;

> fish and fish products;

> milk and milk products;

> peanuts and products of these;

> sesame and products of these;

> soybeans and products of these;

> specific tree nuts and products of these;

> Regional: Other foods may be considered for inclusion on priority allergen lists in individual countries

Recommendations are still being discussed within the Codex Committee on Food Labelling (CCFL).

Further discussion is dependent on the full-report being available.

Virtual meeting, 30 November – 11 December 2020, 28 January 2021, 8 February 2021, [More info on Part 1](#) (summary and conclusions)



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Part 1: Review and validation of Codex priority allergen list through risk assessment

ORIGINAL

- > Subgroups of the Expert Committee were established to review the literature on the prevalence, severity and potency of immune-mediated hypersensitivity of each food currently on the...
- > Original GSLPF list:
 - > cereals containing gluten and products of these;
 - > crustacea and products of these;
 - > eggs and egg products;
 - > fish and fish products;
 - > peanuts, ~~soybeans~~ and products of these;
 - > milk and milk products;
 - > tree nuts and nut products;
- > as well as other foods found on priority allergen lists established in individual countries or regions...
 - > (e.g. mollusks, mustard, celery, sesame, buckwheat, lupin, and others)

NEW RECOMMENDATIONS

- > Based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens:
 - > Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains),
 - > crustacea,
 - > eggs,
 - > fish,
 - > milk,
 - > peanuts,
 - > sesame,
 - > specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).
- > Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, such as buckwheat, celery, lupin, mustard, oats, soybean and tree nuts (Brazil nut, macadamia, pine nuts), should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries.

Virtual meeting, 30 November – 11 December 2020, 28 January 2021, 8 February 2021, [More info on Part 1](#) (summary and conclusions)



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Summary report of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens.

Part 2: Review and establish threshold levels in foods of the priority allergens

- Safety objective “to minimise, to a point where further refinement does not meaningfully reduce health impact, the probability of any clinically relevant objective allergic response, as defined by dose distribution modelling of minimum eliciting doses (MEDs) and supported by data regarding severity of symptoms in the likely range of envisioned Reference Doses (RfD)”.

	RfD Recommendation (mg total protein from the allergenic source)
Walnut (and Pecan*)	1.0
Cashew (and Pistachio*)	1.0
Almond**	1.0
Peanut	2.0
Egg	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Shrimp	200
Milk	[decision pending based on further data analysis]
Sesame	[decision pending based on further data analysis]

* see considerations in full report
** provisional

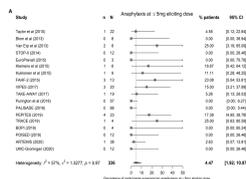
Virtual meeting, 15 March – 2 April 2021, [More info on Part 2](#) (summary and conclusions)



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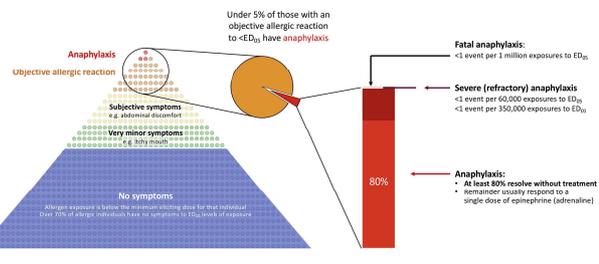
Supporting information for hazard characterization: Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens

- Using data from food challenges to inform management of food-allergic consumers: a systematic review with individual participant data meta-analysis



Patel et al., 2021. <https://doi.org/10.1016/j.jaci.2021.01.025>

- Peanut Can Be Used as a Reference Allergen for Hazard Characterization in Food Allergen Risk Management: A Rapid Evidence Assessment and Meta-Analysis



Turner et al., 2021. <https://doi.org/10.1016/j.jaip.2021.08.008>

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Summary report of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens.

Part 3: Review and establish precautionary labelling in foods of the priority allergens

› Ongoing

[More info on Part 3](#) (ongoing)



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Summary report of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens.

Part 3: Review and establish precautionary labelling in foods of the priority allergens

› FAO/WHO Expert Consultation Meeting: 18-29 October 2021

› Summary report, recommendations and conclusions being drafted

› **CCFL noted [item 134] that the proposed draft guidelines for the use of precautionary allergen labelling (PAL) [see Appendix III] were still at an early stage of development and that the WHO/FAO Expert consultation (EWG) on PAL was needed for the it's further development, and that written comments submitted to the Session should be taken into account by the EWG in the ongoing work on PAL**

[More info on Part 3](#) (ongoing)



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Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens

- › Recommendations are still being discussed within the Codex Committee on Food Labelling (CCFL)
- › Further discussion and potential adoption of recommendations is dependent on the full-report being available

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Differing precautionary allergen labelling (PAL) strategies starting to appear across countries & their (unintended) consequences

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Case study: Peanut in chili powder (0.625 ppm peanut protein)

- > 2.5 ppm peanut (0.625 ppm peanut protein) or 0.00025% peanut was detected in a batch of chili powder
 - > Highest possible usage (%) of chili powder was 0.88% in the final product
 - > **Worst case intake of 0.0011 mg peanut protein**
 - > Jar of chili powder ~40g
 - > **Consumption of 4 jars leads to predicted exposure of 0.1mg peanut protein**
- > Based on individual data points, the two most sensitive subjects in clinical literature available at that time were reported to react to 0.1 mg peanut protein or less
- > The VITAL® reference dose for peanut is 0.2 mg of peanut protein
 - > Exposures at this level predicted to cause a reaction in up to 1% of consumers with peanut allergy



* RASFF Notification details - 2015.1103

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Case study: Peanut in chili powder (0.0011 mg protein)

› Conclusion by risk-assessors

- › The risk of allergic reactions to peanut would be negligible for the overall population of consumers with peanut allergy

* RASFF Notification details - 2015.1103



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Case study: Peanut in chili powder (0.0011 mg protein)

› Conclusion by risk-assessors

- › The risk of allergic reactions to peanut would be negligible for the overall population of consumers with peanut allergy

› Conclusion by regulators (risk managers) in this particular country

- › RASFF Alert risk decision – serious
- › However, in other countries such as Canada¹...

› Conclusion by company

- › Product detained by operator

* RASFF Notification details - 2015.1103

¹ <https://inspection.canada.ca/food-safety-for-industry/food-chemistry-and-microbiology/food-safety-testing-bulletin-and-reports/gluten/eng/1595528213794/1595529245865>



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Reference Doses!



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Reference Doses!



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Why am I still talking about this spice example 6 years later?



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13 SEP 2021: RASFF NOTIFICATION 2021.5745

- › Traces of peanut in mild curry powder from India
- › 1 mg/kg - ppm (0.25 mg peanut protein/kg curry powder*)
- › RASFF Alert risk decision: **Serious**



Jar of curry powder ~40g

<https://webgate.ec.europa.eu/rasff-window/screen/notification/510633>
* Assumed protein conversion needed as value listed only as 1 mg/kg

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13 SEP 2021: RASFF NOTIFICATION 2021.5745

- › Traces of peanut in mild curry powder from India
- › 1 mg/kg - ppm (0.25 mg peanut protein/kg curry powder)
- › RASFF Alert risk decision: Serious

- › Consumption of 10 jars leads to predicted exposure of 0.1mg peanut protein



<https://webgate.ec.europa.eu/rasff-window/screen/notification/510633>

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13 SEP 2021: RASFF NOTIFICATION 2021.5745

- › Traces of peanut in mild curry powder from India
- › 1 mg/kg - ppm (0.25 mg peanut protein/kg curry powder)
- › RASFF Alert risk decision: Serious

- › Consumption of 20 jars leads to predicted exposure of 0.2mg peanut protein



<https://webgate.ec.europa.eu/rasff-window/screen/notification/510633>
<https://vital.allergenbureau.net/vital-science/>

VITAL[®]
an initiative of the Allergen Bureau

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13 SEP 2021: RASFF NOTIFICATION 2021.5745

- › Traces of peanut in mild curry powder from India
- › 1 mg/kg - ppm (0.25 mg peanut protein/kg curry powder)
- › RASFF Alert risk decision: Serious



- › Consumption of 110 jars leads to predicted exposure of 1.1mg peanut protein



<https://webgate.ec.europa.eu/rasff-window/screen/notification/510633>

ADVIES 24-2017 Betreft: Referentiedosissen voor de allergenen die zijn opgenomen in bijlage II van de Verordening (EU) nr. 1169 / 2011 van 25 oktober 2011

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13 SEP 2021: RASFF NOTIFICATION 2021.5745

- › Traces of peanut in mild curry powder from India
- › 1 mg/kg - ppm (0.25 mg peanut protein/kg curry powder)
- › RASFF Alert risk decision: Serious



- › Consumption of 200 jars leads to predicted exposure of 2.0mg peanut protein



<https://webgate.ec.europa.eu/rasff-window/screen/notification/510633>

Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 2: Review and establish threshold levels in foods of the priority allergens

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13 SEP 2021: RASFF NOTIFICATION 2021.5745

- › Traces of peanut in mild curry powder from India
- › 1 mg/kg - ppm (0.25 mg peanut protein/kg curry powder)
- › RASFF Alert risk decision: Serious

- › Measures taken: **Relabelling**



<https://webgate.ec.europa.eu/rasff-window/screen/notification/510633>

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How to interpret everything?

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Let's look at it another way

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Examples from current situation

- › Ambiguous PAL wording
- › Consumer not able to determine if presence or absence of PAL is due to a risk assessment
- › PAL is not a substitute for good allergen management
- › “Not suitable for” ≠ “Contains”
- › Contains statement with different allergens listed than ingredient list?
- › Same production lot, different labels?



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“Not suitable for” ≠ “Contains”

UK FSA

Precautionary allergen labelling

If there is a risk of a food product being affected by allergen cross-contamination, the label should include one of the following statements:

- may contain X
- not suitable for someone with X allergy

Precautionary allergen labelling should only be used after a thorough risk assessment. It should only be used if the risk of allergen cross-contamination is real and cannot be removed.

➤ <https://www.food.gov.uk/business-guidance/allergen-labelling-for-food-manufacturers>

Understanding how consumers with food allergies make decisions based on precautionary labelling

➤ DunnGalvin et al., 2019. <https://doi.org/10.1111/cea.13479>

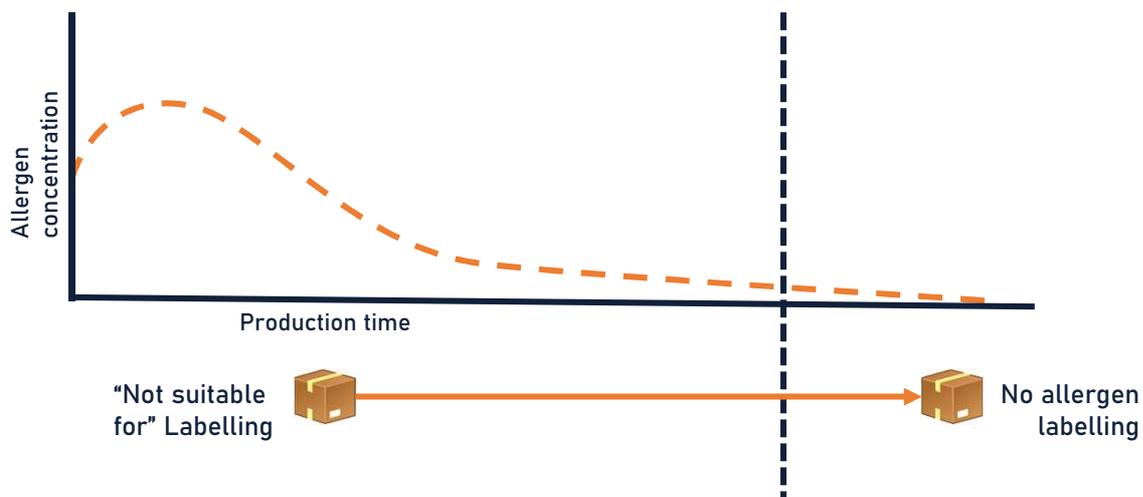
Results: Preference for labelling phrases and symbols

➤ The survey included preferences for three statement formats that identify foods that may contain an allergen due to cross-contamination. 'This product is not suitable for consumers with xy allergy' was selected as first choice by 46% overall. 'May contain xy (allergen)' was selected as the first choice by 44%, and 'Accidental presence of xy (allergen)' was least popular at 7%, with 3% choosing 'other' option. A significant association was found between country and phrase type ($\chi^2 = 28.3, P = .001$). 'This product is not suitable for' was ranked first by a higher proportion of respondents from the UK and Ireland (56%) and Germany (48%). 'May contain' was the first choice for Netherlands (44%) and Spain had the highest proportion of those who ranked 'Accidental presence' as first choice (11%).

➤ Seventy-three percent reported that it would improve their trust in a product if a QRA process had been used to make a decision about whether to include 'may contain'. Overall, 66% reported that a 'statement + symbol' on the label indicating a QRA, would help them to understand the risk assessment process that had been used by the food manufacturer.

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Same production lot, different labels? (Not helpful or feasible!!!!)



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After all of this...

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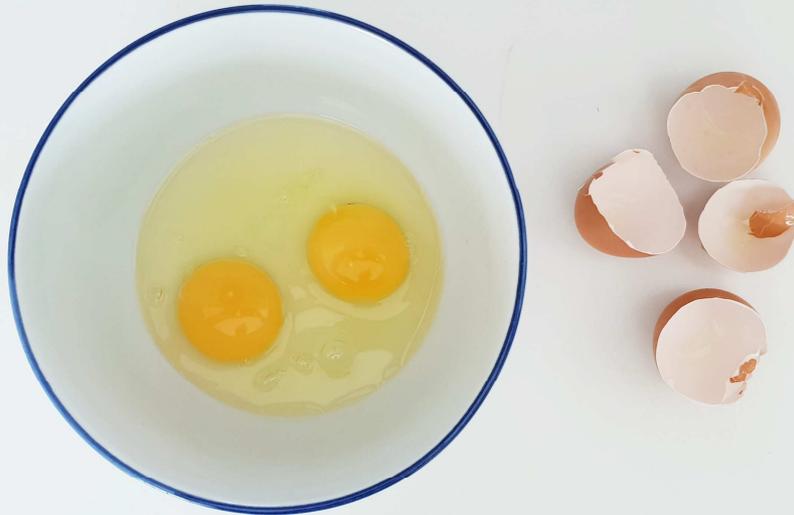


What does the future hold?

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The future...



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The future...



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Slides for reading

Balancing Accepted Risks and Differences of opinion

- › ED01 (1% accepted risk, 99% expected level of protection) presented in VITAL 3.0, but others may wish for a different level of accepted risk...
- › VITAL Scientific Expert Panel (VSEP) predicted this possibility and also presented the ED05 mg protein amounts for each allergen¹
 - › ED05 (5% accepted risk, 95% expected level of protection)
- › Remington et al² presented both the ED01 (with 95% confidence intervals) and ED05 (with 95% confidence intervals) from discrete and cumulative dosing intervals for a full overview
- › Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens³ agreed that, for all priority allergens, the safety objective would be met by starting the definition of Reference Doses at the ED05



1. Allergen Bureau, 2019. http://allergenbureau.net/wp-content/uploads/2019/09/VSEP-2019-Summary-Recommendations_FINAL_Sept2019.pdf
2. Remington et al., 2020. <https://doi.org/10.1016/j.fct.2020.111259>
3. [More info on Part 2](#) (summary and conclusions)

EU Member States

- › The European Food Safety Authority (EFSA) has not derived Reference Doses for food allergens
- › A number of stakeholders and national agencies have begun to adopt the use of reference doses in their risk assessment practices or analytical guidances
- › Different levels of accepted risk and different reference doses or action levels have been recommended by the following Member States
 - › Germany¹ (analytical considerations to support action levels if using VITAL 3.0 Ref doses and set 100g consumption amount)
 - › Belgium² (proposed lower 95% confidence interval of ED05 for reference doses)
 - › Netherlands³ (proposed most sensitive ED01 result in literature for reference doses [although an updated review/reference dose is potentially underway])
 - › Czech Republic⁴ (established action levels for maximum "zero" values and maximum "trace amount" values based on analytical test kit capabilities)



1. Beurteilungswerte Allergene – BVL, 2020 (in German), prior version (in English) Waiblinger, Schulze, 2018 <https://doi.org/10.5740/jaacint.17-0383>
2. FAVV SciCom, 2017. http://www.afsca.be/wetenschappelijkcomite/adviezen/2017/_documents/Advies24-2017_SciCom2017-01_referentiedosisenallergenen.pdf
3. NVWA BuRO, 2016. <https://www.nvwa.nl/binaries/nvwa/documenten/consument/eten-drinken-roken/overige-voedselveiligheid/risicobeoordelingen/advies-on-preliminary-reference-doses-for-food-allergens/Advice+preliminary+reference+doses+roof+allergens+2016.pdf>
4. Czech State Agricultural and Food Inspection Authority, n.d. <https://www.szpi.gov.cz/soubor/oznacovani-aler genu-pdf.aspx>

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EU Member States (continued)

- › Different guidances regarding levels of accepted risk and different reference doses or action levels have been published by the following Member States
 - › Nordic countries¹ (guidance for risk assessment methods if using ED01 or ED10, but did not establish regulatory thresholds)
 - › Ireland² (support reference doses and report for the information required for risk assessment of undeclared food allergens)



1. Sjögren Bolin, 2015. <https://www.livsmedelsverket.se/globalassets/publikationsdatabas/rapporter/2015/rapport-17-riskvarderingsguide-allergener.pdf>
2. FSAI, 2019. <https://www.fsai.ie/WorkArea/DownloadAsset.aspx?id=17186>

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Countries of note Outside of the EU



- › United Kingdom¹ (provides guidance for risk assessment but has not established regulatory thresholds)

- › United States
 - › No official allergen thresholds for PAL or recall situations
 - › However, unofficial discussions have indicated that the concentration of allergenic protein and exposure amounts are being considered in the risk assessments which determine whether to deem a recall Class I or Class II
 - › State of New York Recalls have begun to use action levels for Undeclared Dairy and companies have been forced to recall products, even if the label bears a PAL

- › Australia
 - › VITAL is supported by all stakeholders and encouraged to use, but it is still voluntary²
 - › Multiple guidances exist from the Allergen Bureau
 - › An Australian House of Representatives Committee³ recently recommended that the Allergen Bureau in collaboration with Food Standards Australia New Zealand (FSANZ), work with the food industry to encourage the consistent use of the VITAL food allergen risk assessment program, including the introduction of a VITAL 'V' tick on packaging to inform consumers that a product has been through this process.

1. UK Food Standards Agency, 2020. <https://www.food.gov.uk/business-guidance/allergen-guidance-for-food-businesses>

2. Allen et al., 2014. <https://doi.org/10.1186/1939-4551-7-10>

3. Australia House of Representatives Standing Committee on Health Aged Care and Sport, 2020. https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Allergiesandanaphylaxis/Report