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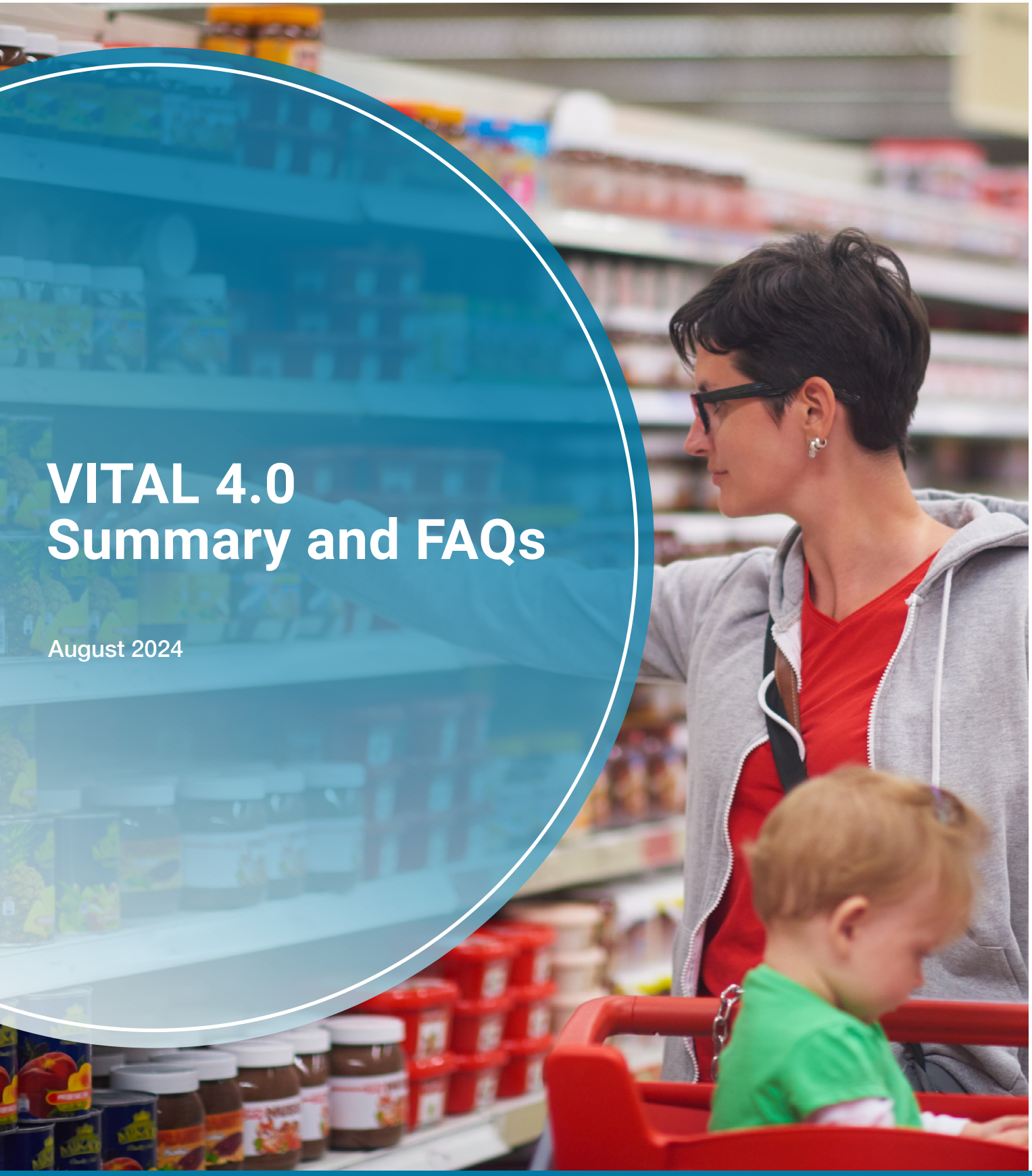
Allergen Bureau



VITAL 4.0 Summary and FAQs

August 2024

Informing the food industry

allergenbureau.net

Allergen Bureau

Disclaimer

Material included in this publication is made available on the understanding that the Allergen Bureau is not providing professional advice, that the VITAL Program is intended as a risk management tool that may assist in a total approach to allergen risk management, and that using the VITAL Program does not guarantee that a consumer will not suffer an allergic response. If you intend to use information provided in this publication, you must exercise your own skill, care and judgement, evaluate the accuracy, completeness and relevance of any information or recommendation for your purposes, and obtain your own professional advice. Allergen Bureau provides no warranty and does not guarantee the accuracy or completeness of the material contained in this publication, or in any recommendation obtained from it, including compliance with food labelling laws and regulations or the management of the risk of product liability and personal injury. The Allergen Bureau disclaims all liability to any person in respect of any loss or liability suffered in connection with the reliance, whether wholly or partly, on any information contained in this publication.

Acknowledgment

The Allergen Bureau would like to extend gratitude to the members of the VSEP (VITAL Scientific Expert Panel) for their unwavering guidance and support over the past 20 years. To other reviewers in both the clinical and consumer advocacy area, thank you for your invaluable contributions and expert advice.

These are challenging topics to distil succinctly, and your continued dedication to fostering scientific collaboration and knowledge exchange has been instrumental in the development of FAQ's. We are truly appreciative of the time, effort, and insight you have generously provided throughout this process.

Thank you for your steadfast commitment to advancing our shared goals of a trusted food supply chain supporting consumers with food allergy to make informed choice.

Statement of Support

The Allergen Bureau has worked alongside Allergy & Anaphylaxis Australia (A&AA) to provide a foundation for clear and consistent allergen labelling for individuals with food allergy. We thank Maria Said AM and the team at A&AA for their continued support.

"A&AA support the use of ED_{05}-based RfDs rather than the more stringent ED_{01}, as the increased threshold will provide more choice to consumers with minimal impact on the risk to public health.

We accept that thresholds are based on levels agreed by the Expert Committee but suggest that they do need review at points in time when more data may become available.

There is a general lack of understanding that the intention of PAL is to communicate risk of cross-contact/ contamination in the production of packaged foods. Ignoring all PAL statements can increase the risk of allergic reactions, including anaphylaxis."

The full statement can be found here.

Allergy & Anaphylaxis Australia®
Your trusted charity for allergy support

Section 1

Information on Reference Doses

The Expert Panel and Purpose of This Document

Since 2011 a team of scientists, clinicians and risk management professionals have worked together as the VITAL Scientific Expert Panel (VSEP) to make recommendations for Reference Doses in the VITAL® Program. The current members of the VSEP are:

- Dr Steve Taylor (Chair of Panel) – Food Allergy Research & Resource Program (FARRP) (USA)
- Dr Joseph Baumert – Food Allergy Research & Resource Program (FARRP) (USA)
- Dr Geert Houben – Principal Scientist Food Allergy and Immunotoxicology (TNO) & Professor (Utrecht University and University Medical Centre Utrecht) (NL)
- Dr Rene Crevel (RENE CREVEL Consulting Ltd) (UK) (formerly of Allergy & Immunology, Unilever)
- Dr Simon Brooke-Taylor (Food Safety & Risk Analysis Consultant, Allergen Bureau) (AUS)
- Prof Dianne Campbell (Academic Paediatric Immunologist Sydney University, Children's Hospital Westmead, DBV-Technologies) (AUS).

Members of the VSEP together with other experts (including past VSEP member Dr Ben Remington (FDA, formerly independent consultant & TNO)), were part of the FAO/WHO Expert Consultation on Risk Assessment of Food Allergens, asked to review and establish allergen threshold levels[a]. The FAO/WHO Expert Committee met six times and delivered a series of reports providing advice to Codex in the areas of:

i. Validating and updating the list of foods and ingredients in section 4.2.1.4 of the General Standards for the Labeling of Packaged Foods (GSLPF) based on risk assessment,

ii. Establishing threshold levels in foods of the priority allergens and some regional (non-priority allergens (meeting two and meeting six),

iii. Evaluating the evidence in support of precautionary allergen labelling and,

iv. Developing a process for consideration of future exemptions.

The second FAO/WHO Expert Committee Meeting[1], resulted in the panel endorsing Allergen Threshold Modelling, the science used by the Allergen Bureau since 2019. Furthermore, the Expert Panel recommended ED_{05} based Reference Doses (RfD)[1]. The decision to use ED_{05} rather than ED_{01} was made because the review from the experts' determined that on balance an ED_{01} did not meaningfully reduce the health risks to food-allergic individuals but may impact food choices for individuals with food allergies.

As an evidence-based organisation, the Allergen Bureau has always ensured that the VITAL Program is underpinned by the best available scientific evidence. The VITAL program will therefore adopt ED_{05} RfD recommended by the FAO/WHO Expert Committee. This document explains the new set of Reference Doses, referred to as "VITAL 4.0" that will supersede the VITAL 3.0 Reference Dose recommendations as our default setting for the VITAL program.

a) For a full list of expert panel participants, please refer to the meeting reports www.who.int/publications/i/item/9789240042391

Methods

Allergen threshold levels are derived using probabilistic hazard assessment. This involves collection of data from escalating low dose oral challenges and modelling the dose-distributions using various parametric statistical models.

The previous Reference Dose recommendations (VITAL 3.0) were based on a Stacked Model Averaging program[3]. The program incorporates 5 different statistical models (Weibull, Log Logistic, Log Normal, Log Double Exponential, General Preto) and produces a single average distribution.

These models allow prediction of the proportion of the population (EDp, where p% is the percentage of individuals allergic to protein from a specific food) who will experience initial objective allergic reactions upon oral exposure to a dose of total protein from that food. The dose is referred to as the Eliciting Dose (ED). Importantly, these models do not identify a dose below which no individuals will react. ED_{05} represents the dose at which 5% of the allergic population will react with objective symptoms.

The Stacked Model Averaging program produces a single curve for each allergen from which Eliciting Doses may be derived. The source data set is drawn from that reported in the publications of Remington et al., (2020)[6] and Houben et al., (2020)[7], the current data set that underpins VITAL 3.0. These were considered by the FAO/ WHO Expert Committee as the most comprehensive and best-described source available, both in terms of content and curation, with supportive peer-reviewed publications. The data set was expanded slightly by the FAO/WHO Expert Committee, to consider additional new publications on sesame seed and cow's milk that improved the robustness of RfD estimates for those allergenic foods.[1]

The FAO/WHO Expert Committee after considerable review recommended the adoption of ED_{05}-based Reference Doses (RfD) as the basis for Precautionary Allergen Labelling (PAL) decisions. In 2019, the VSEP did consider and publish ED_{05} values. However the Allergen Bureau adopted ED_{01} values in VITAL 3.0 to prioritise the risk to consumers taking into account the lack of published data at the time evaluating the relative severity of the allergens at ED_{01} vs ED_{05}. The likelihood of global acceptance of VITAL and the degree of change from VITAL 2.0 to VITAL 3.0 Reference Doses were also factors in this decision.

VITAL 4.0 will adopt the ED_{05} based Reference Doses and Risk Management Values recommended in the FAO/WHO Expert Panel Report 2 and 5. Recommendations by the FAO/WHO Expert Committee after an extensive review concluded that a Reference Dose below ED_{05} did not meaningfully reduce the risk to food-allergic individuals and could decrease the availability of food for consumers with food allergies.

In addition, the VSEP has also provided a Risk Management Value for molluscs.

Results

Sufficient data was available to set thresholds for the priority allergens of

- Wheat, (Triticum aestivum and other Triticum species),
- Fish,
- Crustacea,
- Sesame Seed,
- Hazelnut (Corylus Avellana), Cashew nuts (Anacardium Occidentale), Walnut (Juglans Regia), Almond (Prunus Dulcis),
- Eggs (Hen's egg),
- Cow's Milk (Bos Taurus),
- Peanut (Arachis Hypogea).

For full details on the number of data sets and other considerations please refer to the FAO and WHO 2022 Report Risk Assessment of Food Allergens: Part 2: Review and Establish Threshold Levels in Foods for the Priority Allergens, Chapter 6.

The FAO/WHO Expert Committee was also requested to meet again (Meeting 6) and review and set Reference Doses for the non-priority allergens, as noted in Report One. Sufficient data were available to set thresholds for:

- Celery and
- Soy.

Risk Management Values were recommended for

- Brazil nut
- Macadamia nut or Queensland nut,
- Pine nut,
- Lupin,
- Mustard,
- Buckwheat.

A RfD was not considered applicable for oats.

The "value for risk management" was proposed when it was not possible to provide an RfD for a specific food following the guidelines described in Part 2 of the FAO/WHO Expert Consultation".[3] For example, the data were too limited quantitatively or potentially too limited in quality, or both. The FAO/WHO Expert Committee also noted as a guiding principle for the discussions that risk management is best served if the RfD are defined for any given allergen, where the data permit, even if all adequacy criteria are not fully met.[3]

Using this principle, the VSEP met to discuss how this approach may be utilised to set a Risk Management Value for Mollusc, a regional allergen of significance in Australia, New Zealand, the EU and other regions. As such VITAL 4.0 includes a VSEP recommended risk management value for Mollusc. This value is based on the ED_{05} for crustacea, due to the similarities in the identities of the allergic proteins, with an added 10-fold uncertainty factor.

Table 1 - Recommended Reference Doses (mg protein)

Allergen	VITAL 3.0 Ref Dose (mg protein)*	VITAL 4.0 Ref Dose (mg protein)#	Change
Priority Allergens (RfD)			
Almond	0.1	1.0	↑
Cashew (and Pistachio)	0.05	1.0	↑
Egg	0.2	2.0	↑
Fish	1.3	5.0	↑
Hazelnut	0.1	3.0	↑
Milk	0.2	2.0	↑
Peanut	0.2	2.0	↑
Sesame	0.1	2.0	↑
Shrimp	25	200	↑
Walnut (and Pecan)	0.03	1.0	↑
Wheat	0.7	5.0	↑
Non-Priority Allergens (RfD)			
Soy	0.5	10	↑
Celery	0.05	1.0	↑
Non-Priority Allergens (Risk Management Value)			
Lupin	2.6	10	↑
Mustard	0.05	1.0	↑
Brazil nuts, Macadamia nuts, Pine nuts	0.1	1.0	↑
Buckwheat	-	10	+
VSEP Risk Management Value			
Mollusc	-	20	+
European Legislated Values (Netherlands)[10]			
Lupine (Netherlands Legislated Allergens-NVWA 2024)	2.6	15	↑
Mosterd (Netherlands Legislated Allergens-NVWA 2024)	0.05	0.4	↑

*Based on ED_{01}. #Rounded from ED_{05} + New Reference Dose or Risk Management Value

ED05 BASED REFERENCE DOSES AND THE VITAL® PROGRAM

Frequently Asked Questions

Why is the VITAL Program adopting the ED_{05}-based Reference Doses?

The Allergen Bureau has always accepted the scientifically substantiated recommendations of the VITAL® Scientific Expert Panel (VSEP), a group of expert allergen and food safety scientists. Members of the VSEP together with other experts were part of the FAO/WHO Expert Consultation on Risk Assessment of Food Allergens to review and establish allergen threshold levels.

These allergen threshold levels are derived using probabilistic hazard assessment which involves collection of data from escalating low dose oral challenges and modelling the dose-distributions using various parametric statistical models. These models allow prediction of the proportion of the population of individuals allergic to protein from a specific food who will experience initial objective allergic reactions upon oral exposure to a dose of total protein from that food. Put simply, an Eliciting Dose (EDp) ED_{01} and ED_{05} will estimate the amount of allergen which will elicit an objective allergic reaction in 1% and 5% of individuals allergic to that allergen, respectively.

The outcome of this review published in 2022[1], recommended using ED_{05}-based Reference Doses (RfD) as the basis for Precautionary Allergen Labelling (PAL) decisions. The decision to use ED_{05} rather than ED_{01} was made because the review from the experts' determined that on balance an ED_{01} did not meaningfully reduce the health risks to food-allergic individuals but may impact food choices for individuals with food allergies.

As an evidence-based organisation the Allergen Bureau has always ensured that the VITAL Program is underpinned by the best available scientific evidence and therefore has decided to update the VITAL program.

What does this change mean for food businesses?

Every food business should have an established allergen management program, enhanced by the application of the VITAL Program[4]. The VITAL program philosophy for food businesses to avoid, reduce and eliminate allergens has not changed.

Nor has the requirement for businesses to strive to manage cross-contact risks to the lowest possible level, preferably at or below, the VITAL Action Level transition point (Action Level 1). Our advice for when this is not possible remains unchanged, to manage the risk to at or below the outcome of the VITAL risk assessment.

Although the RfD may be increasing, the food industry can be assured that the clinical data and the assessment provided in the FAO/ WHO Expert Committee reports[1,5] support the safety of the ED_{05}-based reference doses.

With the move to adopt ED_{05} in VITAL, the risk profile for businesses or products is unlikely to change. The adoption of ED_{05} may result in PAL no longer being required on some products, ultimately providing more food choices to consumers with food allergy.

What does this change mean for consumers?

The aim of the VITAL program, which is to enable a risk-based methodology to avoid the indiscriminate use of PAL, remains unchanged. VITAL risk assessments, underpinned by ED_{05}-based RfD may result in fewer PAL statements by manufacturers. PAL statements derived under the VITAL Program remain meaningful, and consumers with food allergy should have the confidence in the allergen information provided as part of the PAL and pay regard to such statements.

In instances where the VITAL outcome indicates that a PAL is not required, consumers with food allergy may be confident that consuming these products is extremely unlikely to cause life-threatening reactions. A small proportion of individuals (up to 5%) may experience an objective allergic reaction, and of these individuals the vast majority (>95%) will experience mild or moderate allergic symptoms only.

Globally as we move to accept tolerable risk rather than zero risk, consumers can take greater confidence in products that have undergone a VITAL Risk Assessment, where no PAL statement is required.

Equally, they will know that they must avoid products that do carry a PAL statement as a result of the VITAL Risk Assessment outcome. Consumers need to understand that there could be times when mild to moderate reactions occur, even with products that do not carry a PAL statement, and which are produced in facilities implementing industry best practice allergen management. The risks of more severe reactions are not considered to be significantly greater for ED_{05} vs ED_{01}.

Why would the FAO/WHO Expert Committee recommend a Reference Dose that appears 5 times higher than the currently used ED_{01} value? Won't a higher percentage of the population react at this dose?

The FAO/WHO Expert Committee assessed the benefits and the risks of ED_{01} vs ED_{05}. They considered on balance that given the uncertainty around the clinical data at ED_{01} for priority allergens, and the estimated very low risk of severe allergic reactions at ED_{05} based upon much larger and more robust data sets, that the change did not meaningfully impact public health. They also considered that ED_{01} did not meaningfully minimise the probability of an objective allergic reaction over ED_{05}.

VITAL risk assessments, underpinned by ED_{05}-based RfD may result in fewer PAL statements by manufacturers providing consumers with food allergy more food choices.

Because ED_{01} and ED_{05} are based upon probabilistic modeling, ED_{05}-based reference doses **are not** 5 times higher than ED_{01} values. They vary based upon the priority allergen in question. However, it is true that at ED_{01}, up to 1% of individuals allergic to a specific allergen would be expected to react with objective symptoms, whereas at ED_{05}, up to 5% of individuals allergic to a specific allergen would be expected to react with objective symptoms.

What is the risk of anaphylaxis at ED_{05}?

Based upon available clinical food challenge data, it has been estimated that at an ED_{05}, <5% of the allergic reactions which occur at this allergen dose would meet criteria for anaphylaxis for the majority of priority allergens including peanut, cow's milk, cashew, walnut, hazelnut, sesame, egg and wheat. For example, for peanuts this risk at ED_{05} is estimated to be less than 25 episodes of anaphylaxis per 10,000 exposures compared with 5 episodes per 10,000 exposures at ED_{01}.

It is useful to consider the severity of anaphylaxis in this context. Fatal food anaphylaxis is very rare (estimated as <1 per million in the allergic population). Reassuringly, clinical data available to date has not reported fatal anaphylaxis at or below an ED_{05} threshold for any priority food allergen. However, the FAO/WHO Expert Committee acknowledged that the dataset available and examined to date does not preclude the possibility of such a severe reaction. Overall, the risk of severe anaphylaxis is estimated to be very, very low, while the risk of fatal anaphylaxis is negligible at ED_{05} doses[1].

Anaphylaxis severity data at ED_{01} and ED_{05} has been largely reported for peanut and cow's milk allergens, where the spectrum of severity of anaphylaxis reported across controlled food challenges from multiple studies/cohorts was mild to moderate, with no severe anaphylaxis (Grade 4 or 5 WAO criteria). The FAO/WHO Expert Committee assumed that this severity data is generally applicable to other priority food allergens.

For these reasons, the Expert Committee concluded that applying a RfD lower than those chosen (based on ED_{05}) would not significantly reduce the health impact on consumers. Similarly, values greater than ED_{01} up to the endorsed ED_{05} based figures, do not significantly increase the risk to consumers, based on the available clinical evidence.

Will mild and transient reactions in individuals with food allergy occur to products assessed as not requiring a PAL under ED_{05} levels?

The ED_{05} -based reference doses were chosen by the FAO/WHO Expert Committee as values that can be used by the food industry globally to assess the risk from unintentional allergen presence, to ensure that consumers can enjoy the broadest range of products possible with the lowest possible risk of severe outcomes.

VITAL risk-based assessments are not underpinned by a 'no risk' philosophy. The ED_{05} -based Reference Doses estimate the amount of allergen which will trigger an objective allergic reaction in 5% of individuals who are allergic to that food. The databases used to set the RfD are based on objective responses (those that can be observed and/or measured by a third party), occurring during controlled clinical oral challenges of individuals with food allergy. It is important to note that the clinical data used does not rely upon subjective manifestations and symptoms that cannot be observed or measured in an individual by a third party.

Objective symptoms can range in severity from mild through to severe (anaphylaxis). The risk-benefit considerations of no risk over a risk-based assessment take into consideration the overall likelihood of occurrence of an allergic reaction which would be harmful to health. This is a somewhat subjective concept; however, it is generally considered to relate to the minimisation of severe allergic reactions (anaphylaxis). In either case, mild or transient reactions can occur with food products at ED_{01} or ED_{05} which have been assessed as not requiring a PAL.

Based upon the clinical data sets examined, the vast majority (>95%) of allergic reactions which occur at ED_{05} (and ED_{01}), are mild and moderate allergic reactions, which do not meet criteria for anaphylaxis and have not required treatment with adrenaline.

Do ED_{05}-based Reference Doses overlook augmentation or co-factors? If so, does this imply a likelihood of more people reacting or experiencing more severe reactions than suggested by clinical data?

The FAO/WHO Expert Committee did consider co-factors, as noted in Part 2 meeting report[1]. Cofactors, such as exercise, sleep deprivation, illness, medication and alcohol may play a role in reducing the amount of allergen required to trigger an allergic reaction in some individuals. However, the clinical relevance of these cofactors in the change from ED_{01} to EED_{05} is unclear and probably negligible.

For example, Eliciting Dose (ED) values derived from reaction thresholds in the presence of some of these co-factors were no lower than those observed in the largest worldwide threshold dataset, as published by Remington et al. (2020)[6] and Houben et al. (2020)[7]. This suggests that the variability in ED induced by co-factors may not exceed the ED threshold range already encompassed in such a comprehensive database, upon which ED_{05} is based.

Therefore, the impact of cofactors doesn't seem to surpass the inherent variability seen in ED thresholds for most priority allergens.

Consumers with food-dependent exercise-induced anaphylaxis (FDEIA) (predominantly to wheat and seafood) may be an exception, with exercise causing a much greater change in reaction thresholds. However, for these consumers, the thresholds for reactions without exercise are typically reported to be 2–3 log greater than the ED_{05}, and thus are a different scenario. It is recommended that individuals affected by FDEIA should receive specific advice as the how to avoid the risk of cofactor-dependent reactions.

High quality data on the role of cofactors in influencing severity of allergic reactions is limited. This is an acknowledged knowledge gap.

What does this mean for consumers?

Whilst the Expert Committee did consider the effect of cofactors on an individual's threshold, published data did not suggest a large effect in the majority of consumers with food allergy. Some consumers are at higher risk of severe reactions, for example those with FDEIA, and are best managed by health care professionals providing tailored advice to them. Consumers are encouraged to discuss situations which could impact on their individual thresholds with their doctor or dietitian.

What does this mean for food businesses?

The magnitude of the influence of cofactors in modifying thresholds is not well established, however the clinical data set which underpins VITAL, has dose threshold ranges which encompass known effects of co-factors. The Food Industry can be assured that the clinical data, and the assessment provided in the FAO/ WHO Expert Committee reports[1,5] do support safety of the ED_{05}-based reference doses.

Has there been any consideration given to the cumulative effects that might exist for consumers who may consume one or more products without a PAL statement at the same time (i.e. during one meal)?

A study conducted in 2014[8], did consider such scenarios, and evaluated simulated studies to determine the health impacts of these. This study found that combined risk from the consumption of foods incidentally contaminated with the same allergen at levels below RfD-based action levels was low.

The VSEP also note that such scenarios should only be considered on a single meal basis because cumulative exposure from sequential consumption of allergen residues below reference doses over several meals during a day is unlikely to provoke IgE-mediated food allergies. Typically, reactions occur within minutes to less than one or a few hours after consumption of the allergenic food residue.

When the VITAL program is effectively implemented, even in the event where consumers may be exposed to the cumulative effect of levels that meet the Action Level 1 definition, data suggests that allergen levels would likely be below significant risk levels.

How much of a factor was testing capability when setting the Reference Doses recommended by the FAO/WHO Expert Committee?

The RfD recommended by the Expert Committee were NOT primarily based on analytical method capabilities. The Expert Committee established the Health Based Guidance Values (HBGV; the RfD) first. A logical sequence is to first set a HBGV and then derive analytical values. To understand the relationship with analysis, the presence of the RfD in each portion of food needs to be expressed as 'mg of total protein of the allergenic source per kg of food analysed'. Although the role of analysis in risk assessment is confirmatory only, the capability to assess RfD's was considered in the overall assessment of ED_{01} vs ED_{05}. The Expert Committee has challenged the analytical community to develop test methods capable of reliably supporting those RfD.

The VSEP notes that the Codex Committee on Methods of Analysis and Sampling (CCMAS) has indicated that it is commencing work on food allergen residue analysis and that the Association of Official Analytical Chemists International has published Food Allergen Kit Developer Validation Guidelines.

PAL determination should not solely rely on analytical data due to significant uncertainties associated with testing and sampling. These uncertainties need to be understood and considered when interpreting and applying analytical results.

Before testing, evidence should be collected along the supply chain such that the likely outcome of the risk assessment can be estimated. Ensuring the testing outcome is in line with the expected outcome is an important step in allergen risk assessment. VITAL assists the risk manager to contextualise the analytical result (understanding the degree of uncertainty), verifying that the result is in line with the expected level of risk. Instances of misalignment warrant further investigation of the initial evidence collected, sampling methodology, and testing suitability to enhance confidence in the risk assessment outcome.

Whilst improved methods are being developed, in cases where a VITAL outcome is below the limit of a kit sensitivity, regard may need to be given to setting a temporary acceptance criterion (at the limit of quantitation), for business decision-making, potentially in combination with other measures.

How can we have confidence in the scientific recommendations if the data is not publicly available for independent review?

The risk assessment of Food allergens FAO/WHO report is publicly available. The majority of the individual studies which underpin the VITAL database are also published and publicly available. The FAO/WHO Expert Committee considered that the data reported in the publications of Remington et al. (2020)[6] and Houben et al. (2020)[7] was the most comprehensive and best-described source available, both in terms of content and curation, with supportive peer-reviewed publications. Additionally, the data set was expanded slightly, to consider additional new publications on sesame seed and cow's milk that improved the robustness of RfD estimates for those allergenic foods. The data selection and handling (Westerhout et al. 2019)[2] and dose-distribution analysis methodology (Wheeler et al. 2021)[9] were similarly well-described, again with supportive peer-reviewed publications. The Expert Committee carefully reviewed the clinical literature relating to dose-response relationships. However, these other publications often relied upon food-allergic patients enrolled in immunotherapy trials which, by design, excluded higher-dose reactors from their datasets.

Why are some of the Health Based Guidance Values (HBGV) described as Risk Management Values rather than RfD?

The FAO/WHO Expert Panel in meeting 5, was asked to recommend HBGV for the non-global-priority allergens identified at its first meeting. The Expert Committee noted that the available clinical data for some of the non-global priority allergens was not sufficient to support the establishment of RfD using the criteria developed at the second meeting. Nonetheless, the available data were sufficient to suggest similarities in potency to other allergens for which RfD had been established. The Expert Committee chose, therefore, to recommend Risk Management Values in these cases, which while not based on a complete risk assessment, could be used to inform PAL decisions[3].

Buckwheat and lupin appeared to align with soy in terms of allergenic potency and consequently Risk Management Values of 10mg were recommended, aligning with the RfD established for soy. Similarly, mustard appeared to have a potency in a similar range as the higher potency allergenic foods (cashew, walnut, almond) and a Risk Management Value consistent with the RfD for these (1mg) was recommended. No data were available for estimating the potency of Brazil nuts, macadamia and pine nuts and from a precautionary point of view, Risk Management Values consistent with the RfD for the most potent allergenic foods (1mg) were recommended.

Clinical data for molluscs were not available, but the VSEP considered that a Risk Management Value based upon the one established for crustacea (primarily shrimp) could establish a baseline due to existing known similarities in the identity of allergenic proteins in both types of shellfish. However, because clinical data is lacking, the VSEP encourage the use of a 10-fold uncertainty factor in the case of molluscs resulting in a RfD of 20 mg protein.

The Expert Committee noted that the recommended Risk Management Values are not based on comprehensive challenge data for the actual allergenic food and are therefore subject to change when more and adequate data becomes available.

Risk Managers must recognise the uncertainties in the evidence collected along the supply chain and consider this when interpreting results.

Can I still do an assessment using ED_{01}?

For the reasons outlined above the Allergen Bureau encourages businesses to adopt the ED_{05}-based Reference Doses. However, we do recognise that there may be rare occasions when it may be suitable or necessary to consider the labelling outcome if an ED_{01} value was used. To cater for this, the Allergen Bureau has added in the VITAL Online tool a new "legislation", VITAL 3.0 Reference Doses, based on the ED_{01} values as described in the 2019 VITAL 3.0 Summary.

This " jurisdiction" is only available in the Action Level Grid Report functionality of the tool and should be used for comparison purposes only.

Businesses are reminded that that Action Level Grid function is not intended to be used in isolation or in conjunction with analytical results alone to determine whether a labelling outcome is required.

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