

VITAL 4.0 and Transition to ED₀₅

Presented by: Kirsten Grinter
Allergen Bureau
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Agenda

- About Us
- Re-Cap The VITAL Program
- VITAL 4.0
 - What has changed and why?
 - Impact to business
 - Impact to consumer
- Next Steps

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Our Membership

- Membership based organisation established to provide food industry with rapid responses to questions about allergen risk management in food ingredients and manufactured foods
- Established in 2005, pre-competitive, 'not-for-profit', Allergen Bureau directors provide voluntary, unpaid services

Become a member

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Multi Region Member



Single Region L Members



Vision & Mission

Vision: A trusted food supply for allergen sensitive consumers around the world

Mission: Lead the global food industry in best practice allergen management, sharing information that builds trust and transparency that supports allergen sensitive consumers to make informed choices

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The VITAL[®] Program

Quick recap

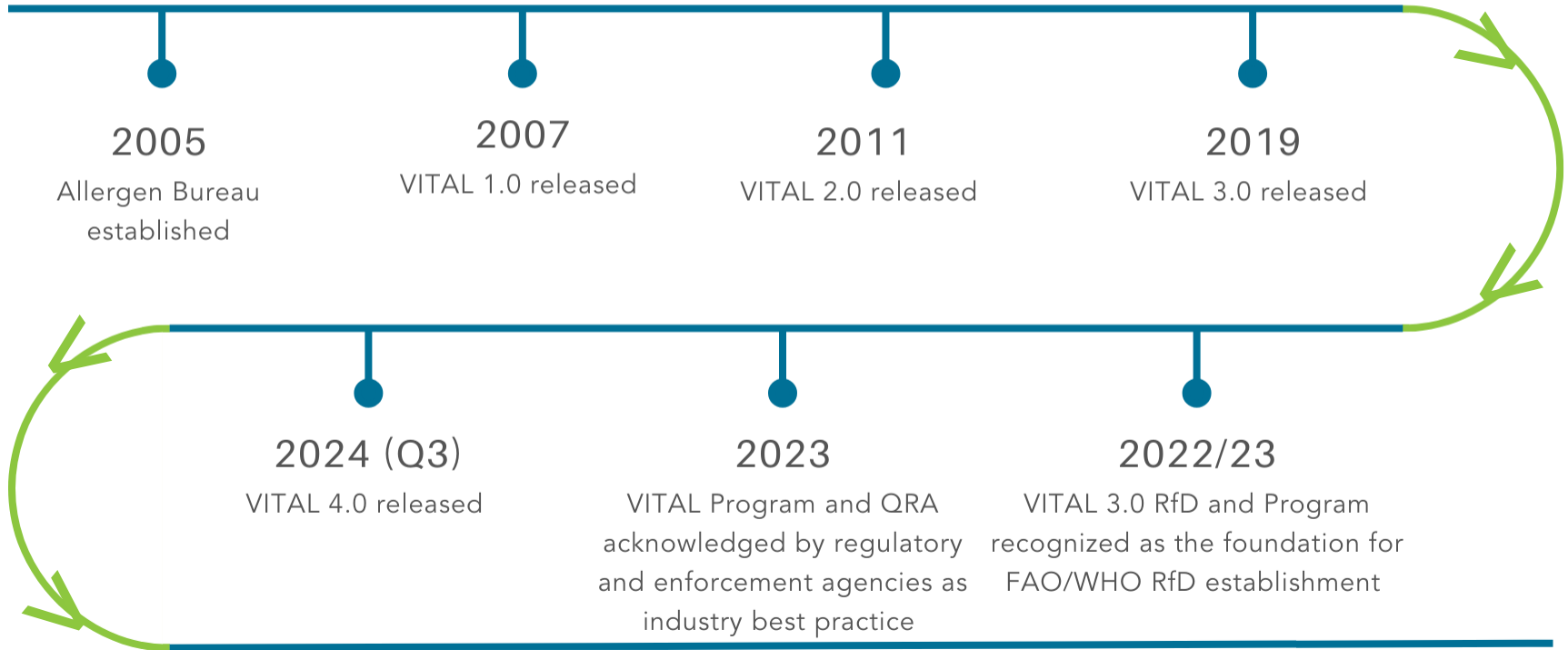
VITAL Program Overall Objective

To ensure manufactured food is **safe** to consume
for the vast majority of consumers with food allergy
by providing **consistent food labels** that declare the presence of
allergens, due to documented, unavoidable and sporadic cross contact thus
enabling consumers with food allergy and their carers to avoid purchasing
foods that may present a personal risk

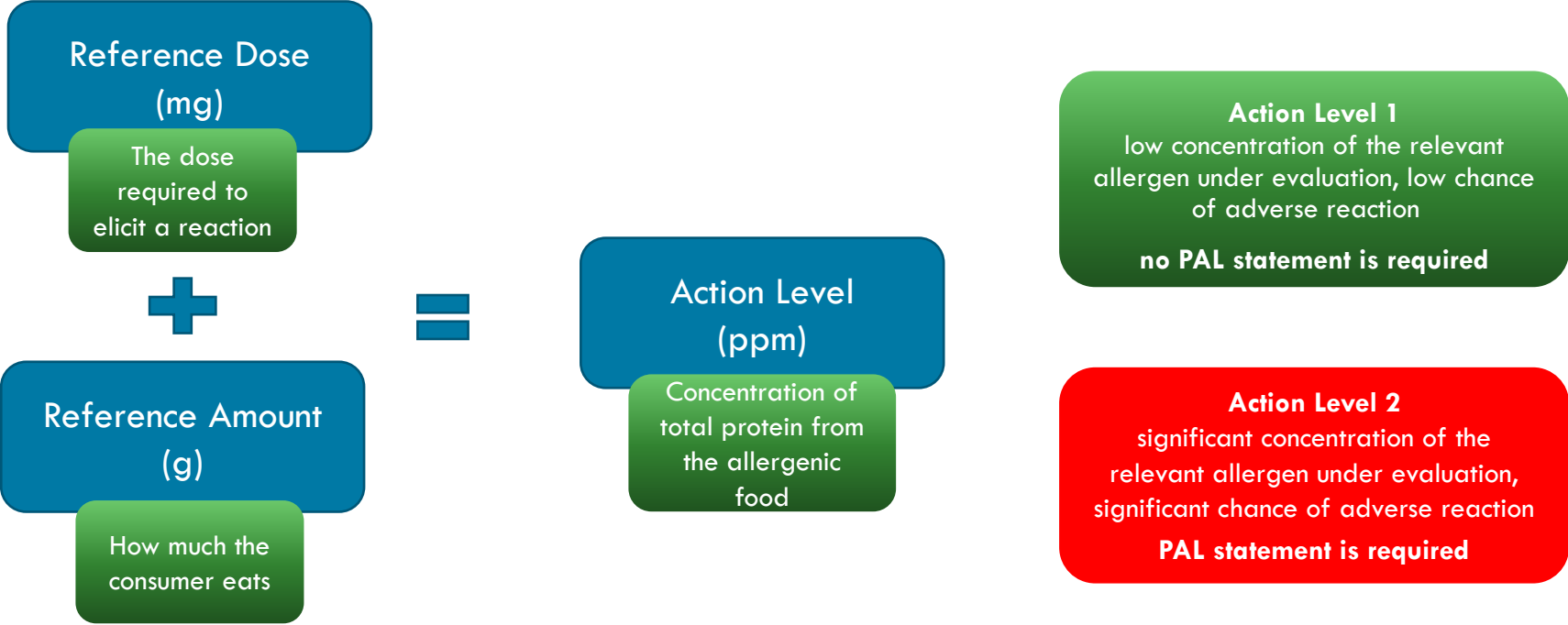
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VITAL – 17 years of best practice and evidence-based science



Re-cap - VITAL Risk Assessment





The VITAL[®] Program can be used to assist food producers in presenting allergen advice accurately and consistently for allergic consumers using a **single simple standardised precautionary allergen statement (PAL)**



The VITAL precautionary statement is:
May be present: allergen x, allergen y.

VITAL[®] 4.0

- **Based on FAO/WHO Expert Panel ED₀₅ Reference Doses**
- Includes Legislated European Values (The Netherlands & Belgium)
- Additional - Canadian Jurisdiction
- ED₀₁ Action Level Grid (VITAL 3.0)
- Additional - Risk Value for Mollusc
- Default setting for jurisdiction
- Pop up reminder for particulates
- Updated T&C's

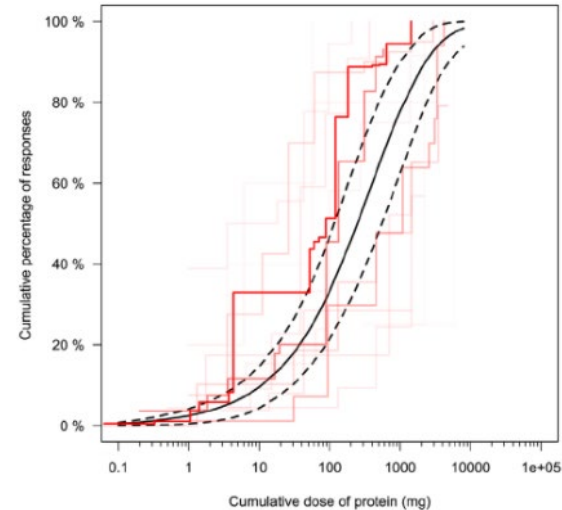


Allergen Risk Assessment underpinned by globally recognised, evidence based, scientific data

VITAL Underpinned by Robust Scientific Data



- FAO/WHO Ad hoc Expert panel endorsed VSEP RfD Methodology
- “Stacked Model Averaging” which incorporated 5 different statistical models to produce a single “averaged” distribution
- Selected an **ED₀₅** Reference dose
- Increased data set for sesame and cow's milk
- Severity data used to support FAO/WHO work
- **ED₀₅** values simplified by rounding down



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ED₀₅ based values are not a new concept

- The VSEP recommended **ED₀₅** based values in 2019
- Stakeholders were not ready for the move
- **ED₀₅** based values have now been confirmed by the FAO /WHO panel & legislated in some markets
- We are likely to see **ED₀₅** in Codex soon/potentially
- VITAL 4.0 a QRA harmonised global approach



Why ED₀₅ was Chosen

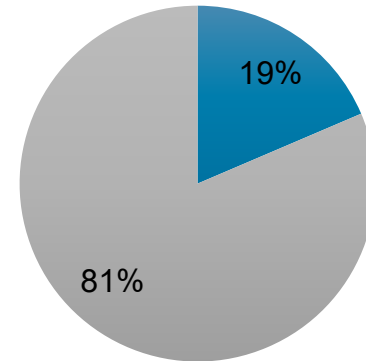
- The ED₀₅ data is based on upon a larger and more robust data set
- An ED₀₁ does not meaningfully reduce the health risks to food-allergic individuals but **does impact their food choices**
- Because ED₀₁ and ED₀₅ are based upon probabilistic modelling, RfD are not 5 times higher than ED₀₁
- ED₀₅ may positively impact food choices for individuals with food allergies



Does ED₀₅ make more Food Choices Available?

- Approximately **19% of products** currently labelled with a PAL may no longer need one
- PAL statements derived under the VITAL Program remain meaningful so consumers can have **confidence in the allergen information and pay regard to these statements**

Impact of ED05 on labelling outcome



■ PAL Reduction ■ No PAL Reduction

The New ED₀₅ Reference Doses

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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 ED₀₁. #Rounded from ED₀₅ + New Reference Dose or Risk Management Value

Your Questions Answered

- The change to **ED₀₅** is supported by the VITAL 4.0 summary document Q&A and is a foundation for **aligned stakeholder understanding and messaging**
- What is the Risk of Anaphylaxis at **ED₀₅**?
- Will reactions occur to products without a PAL?
- Does **ED₀₅** based RfD consider co-factors such as exercise, sleep deprivation, illness etc.?
- What about consumers with FDEIA (wheat and seafood)?
- What about the cumulative effects of consuming 1 or more products without a PAL statement at the same time?
- Can I still use **ED₀₁** or do I have to use **ED₀₅**?
- Can't we have zero risk allergen management?





Key Messages for Consumers with Food Allergy

- VITAL RA underpinned by **ED₀₅** based **RfD** may result in **fewer PAL statements**
- **PAL statements** derived by **VITAL** remain **meaningful** and consumers should have strong regard to these statements
- Where a VITAL outcome indicates **that no PAL is required**, consumers with food allergy should be confident in consuming the product



Key Messages for the Food Industry

- Every food business should have an **AMP** enhanced by the **VITAL program**
- The **VITAL philosophy** remains unchanged - to avoid, reduce and eliminate allergens and manage cross contact risks to the lowest level
- The **RfD is changing to ED₀₅**
- The clinical data supports the **safety of ED₀₅ RfD**
- The Business risk profile is **unlikely to change**
- This move to **ED₀₅** may result in **greater food choices for consumers**



Summary & Next Steps

- The VITAL Program is now underpinned by **ED₀₅** reference doses – using evidenced-based science
- This is great news for industry and consumers
- We should be proud of this work. It is a fabulous example of collaboration to ensure the best outcome for our consumers with food allergy and the food industry
- Key thing to remember – The value of VITAL lies in the rigour of the process. It is about the journey not just the destination
- Timings – August 13, VITAL Online goes live

THANK YOU

CONTACT US:



info@allergenbureau.net

allergenbureau.net

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