

The what, how, & why of risk-based allergen management

The webinar will begin shortly.
Thank you for your attendance!



The what, how, & why of risk-based allergen management

Deb Smith – Vikan

- Global Hygiene Specialist

Dr. Joe Baumert – University of Nebraska

- Director, Food Allergy Research & Resource Program (FARRP).

Dr. Rachel Ward – Exponent

- Managing Scientist



Webinar housekeeping

- The presentations will last about 45 minutes.
- After the presentation, there will be an approximate 15-minute Q&A session. You are invited to submit your questions via the Q&A box provided.
- We will reach out after the webinar to answer any questions we do not address during the session.
- This webinar is recorded, and we will send you the recording a few days after today's event.

About our presenters



Dr Joe Baumert

Director, FARRP
University of Nebraska



Dr Rachel Ward

Managing Scientist
Exponent



About Vikan and Remco



Leading provider of advanced hygiene and cleaning products and solutions for key sectors, with a global presence in over 90 countries.



Vikan's dedicated presence in North America (US & Canada), supplying colour-coded cleaning and food handling tools for the food industry.

For more information, visit us at:

- <https://www.vikan.com/int/about-vikan/who-we-are>
- <https://remcoproducts.com/us/about-remco/who-we-are>



Allergen risk assessment: A brief history

- **1995:** FAO Technical Consultation on Food Allergies
 - Developed a science-based criteria to determine which foods/food products should be listed as a major allergen risk
 - Determined a class naming convention for allergenic foods/food products
- **1999:** Codex Committee on Food Labelling
 - Defined a list of foods and ingredients known to cause hypersensitivity to include in the General Standard for the Labelling of Packaged Foods
- **2020:** Codex Committee on Food Hygiene
 - Developed a Code of Practice on food allergen management for food business operators (farm to fork)
- **2020:** General Principles of Food Hygiene
 - Updated. Information on allergen control included



Allergen risk assessment: Time to review

- Increased prevalence of food allergies
- Globalisation of food supply
 - Consumer exposure to new and a greater variety of foods
- Changes in consumer consumption patterns
 - Increased consumption of pre-prepared and takeaway foods
- Different allergens in different countries
- Increase in food recalls due to unintended presence of allergens
- Better analytical methods
 - Detection
 - Quantification
- More scientific data on allergens available
 - prevalence
 - thresholds
 - control efficacy
- Increased, and often confusing, use of Precautionary Allergen Labelling (PAL)
 - Unregulated
 - Limits allergenic consumers' choices
 - Inconsistent PAL use confusing consumers and not proportionate to risk
 - Manufacturers adding an unnecessary allergen to a product and listing it on the ingredient list to avoid PAL or associated controls



Need for a risk-based approach to allergen management

- Codex Committee on Food Labelling requested
 - a re-assessment of the criteria use to determine allergens for addition and exclusion from the General Standard for the Labelling of Packaged Foods
- 2020: Committee convened



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

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

1. Validate & update the list of allergenic foods & ingredients in the General Standard for Labelling of Packaged Foods based on risk assessment
2. Establish threshold levels for the priority allergens
3. Evaluate the evidence in support of PAL
4. Determine foods & ingredients which can be exempted from mandatory declaration
5. Potential for establishing thresholds for some non-priority allergens



The what, how, and why of risk-based allergen management

Joe Baumert

Professor - Department of Food Science and Technology

Director - Food Allergy Research and Resource Program (FARRP)

Hazard

A Hazard is something that has the potential to harm you

vs.

Risk

Risk is the likelihood of a hazard causing harm

SHARK



A shark in the sea is a hazard



Swimming with a shark is a risk

LIGHTNING



Lightning is a hazard



Standing under a tree during a thunderstorm is a risk



Was the sign placed after a qualitative or quantitative assessment?

Qualitative

- Sharks may be in the water



Quantitative

- How often do sharks swim in the shallow water near the beach?
 - Seasonal changes in frequency?
- How long do they stay after appearing in the area?
- How many sharks appear at the same time?
- What's the probability of a shark in the water while the beach is open?
 - Night vs. day
- How often does a shark bite a nearby swimmer?
- How many people are at risk...
 - Today, this week, month, year?

Priority/major food allergens

United States



Milk



Egg



Crustacea



Fish



Peanut



Soybean



Tree nuts



Wheat



Sesame
(Jan. 1, 2023)

- ## Canada
- Top 9
 - Cereals containing gluten
 - Molluscan shellfish
 - Mustard
 - (Sulfites)

European Union

- Top 9
- Cereals containing gluten
- Molluscan shellfish
- Mustard
- Celery
- Lupine
- (Sulfites)

Causative Agents

- Naturally occurring **proteins**
- Heat-resistant
- Resistant to proteolysis
- Resistant to extremes in pH
- Usually, major proteins of the food
- Foods can have 1 or many allergens

Australia/New Zealand

- Top 9
- Lupine
- Molluscan shellfish
- Bee pollen/ propolis
- Royal jelly
- (Sulfites)

Japan

- Crab, shrimp, prawn
- Egg
- Milk
- Peanut
- Walnut
- Wheat
- Buckwheat

See FARRP International Regulatory Chart: <https://farrp.unl.edu/IRChart>

How much is too much?

Allergic patients present with different levels of sensitivity



0.2mg
(0.05 mg)

0.4mg
(0.1 mg)

1.0mg
(0.25 mg)

5.0mg
(1.25 mg)

25mg
(6.25 mg)

100mg
(25 mg)

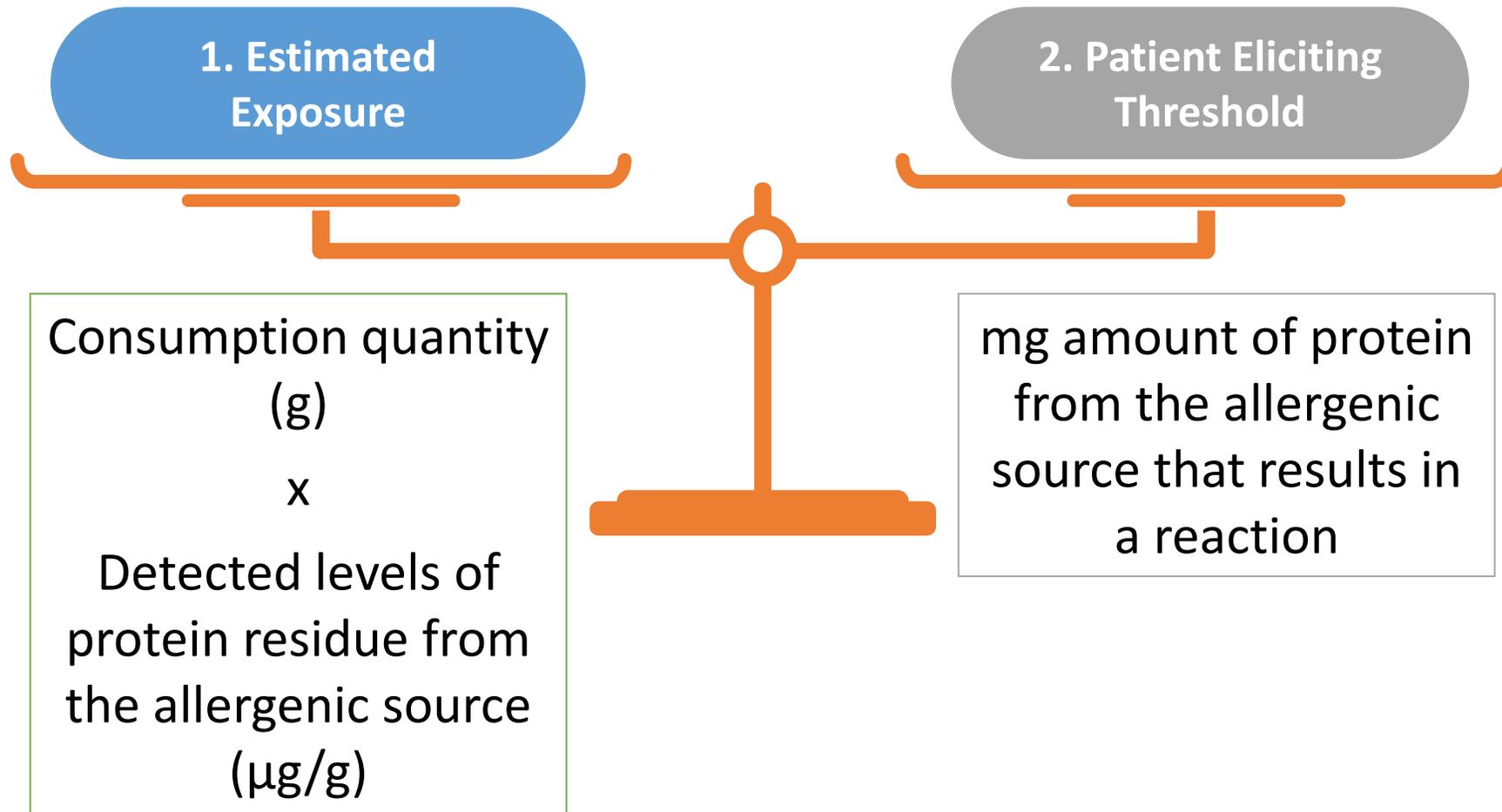
400mg
(100 mg peanut protein)

Ballmer-Weber and Hourihane; image used with permission

How much is too much?

Milligram
amounts!
(ppm concentrations)

Comparing exposure doses versus patient eliciting doses (thresholds) to determine the risk of a reaction



Population threshold distributions for 14 priority food allergens

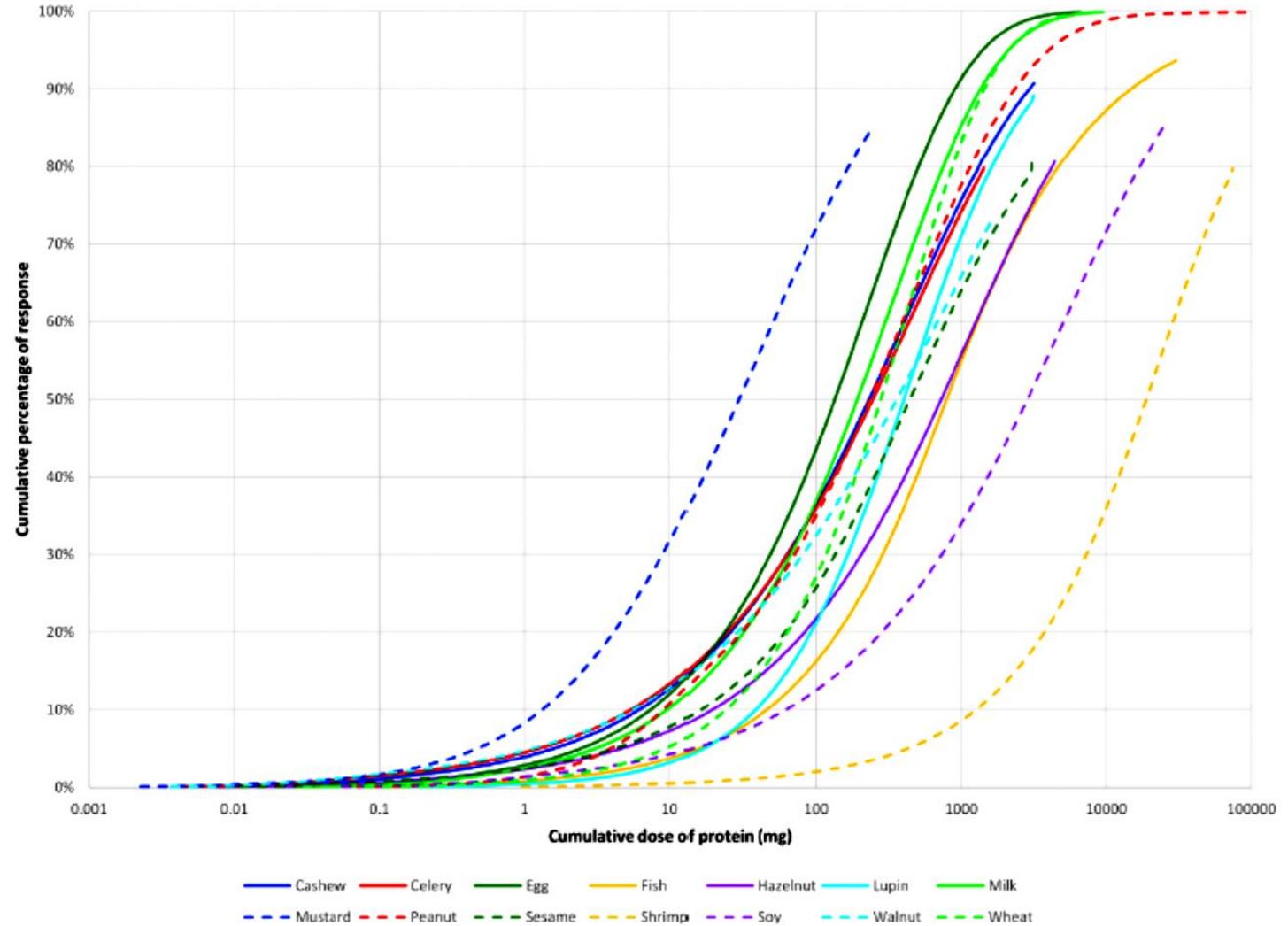


Fig. 1. ED curves from the model averaged population threshold dose distributions for 14 priority allergenic foods, based on discrete (upper graphs) and cumulative (lower graphs) dose datasets. Doses are expressed in mg total protein from the allergenic food.

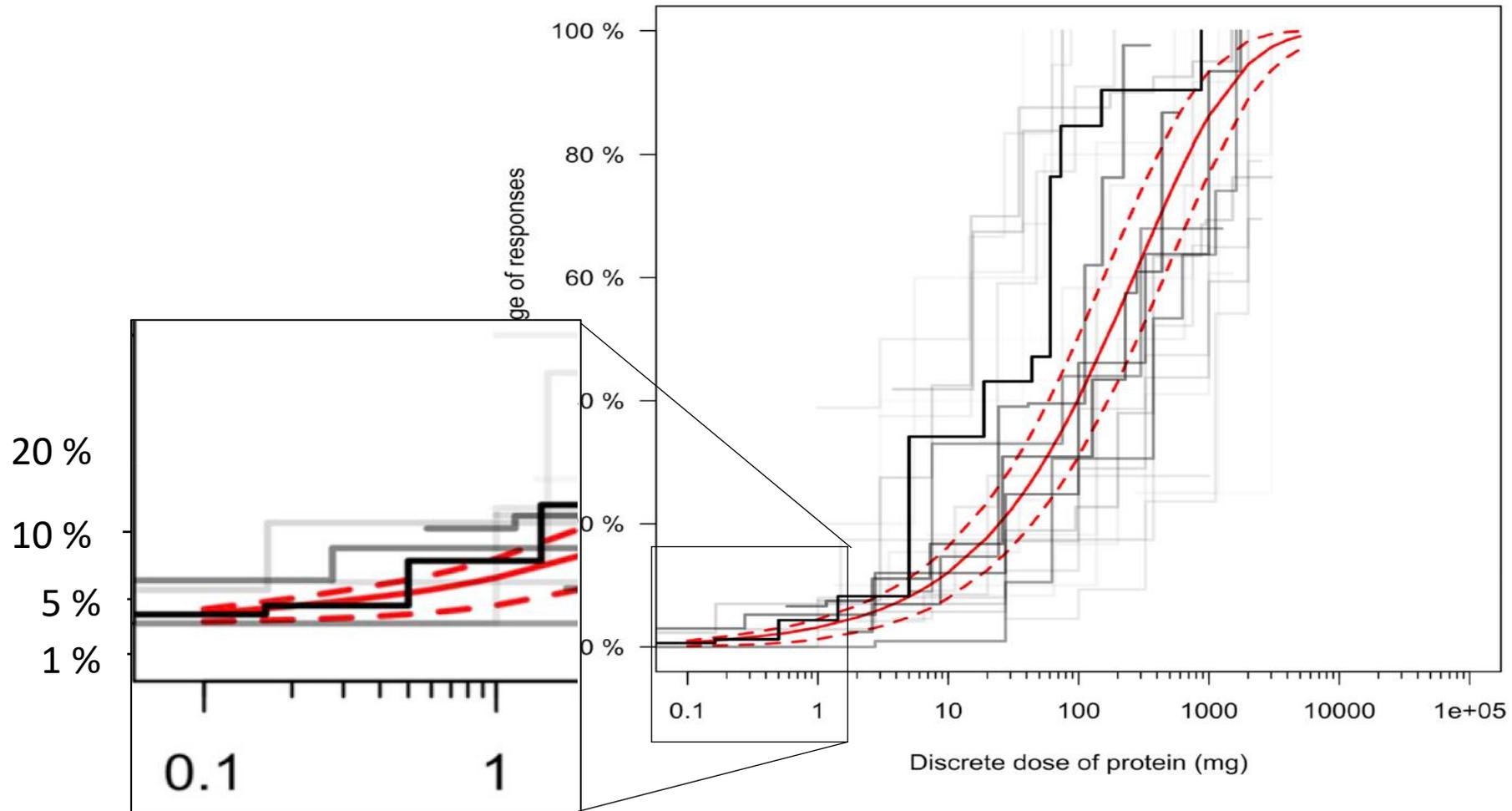
Fundamental allergen risk assessment for the allergic population

A function of the exposure dose (mg of protein from the allergenic source) compared to the reference dose (mg of protein from the allergenic source)

Exposure Dose < Reference Dose* = no predicted risk of an allergic reaction in a defined proportion of the allergic population

Exposure Dose ≥ Reference Dose* = a predicted risk of an allergic reaction in a defined proportion of the allergic population

Food allergen thresholds/reference doses



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 5: Review and establish threshold levels in foods of the non-priority allergens
- Part 3: Review and establish precautionary labelling in foods of the priority allergens
- Part 4: Review and establish exemptions for the food allergens

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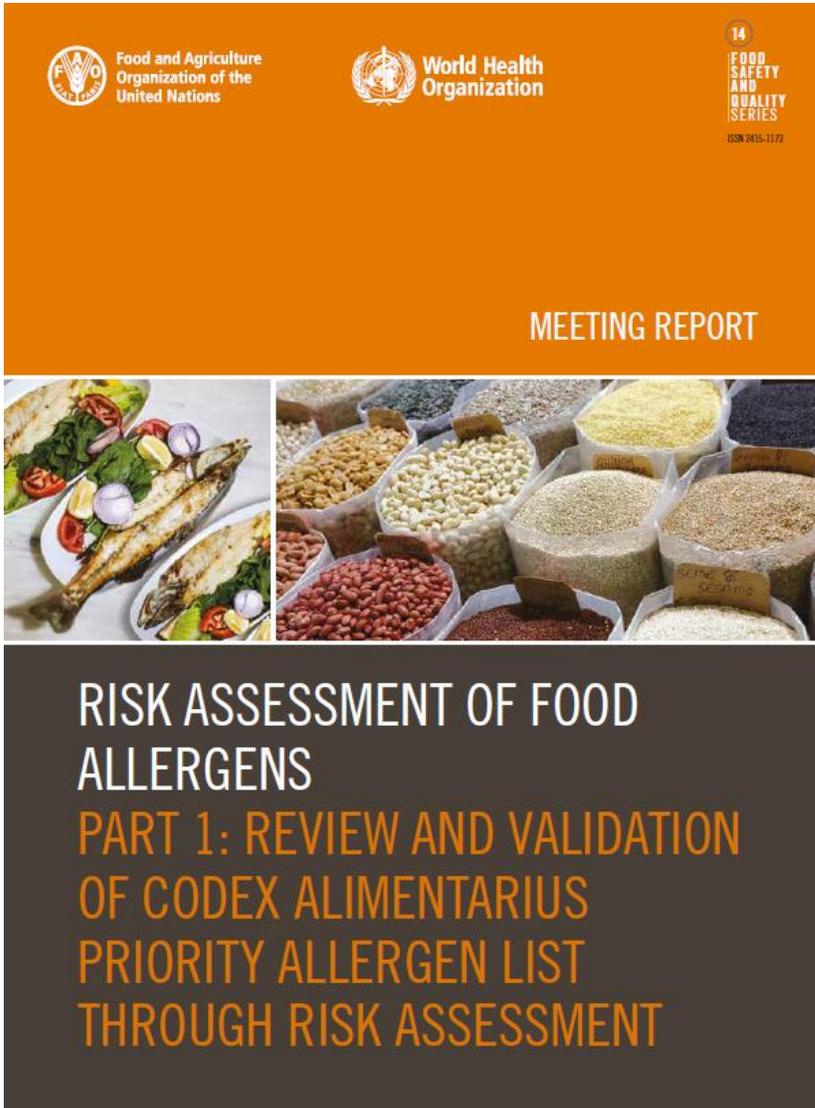
RISK ASSESSMENT OF FOOD
ALLERGENSPART 1: REVIEW AND VALIDATION
OF CODEX ALIMENTARIUS
PRIORITY ALLERGEN LIST
THROUGH RISK ASSESSMENT

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RISK ASSESSMENT OF FOOD
ALLERGENSPART 2: REVIEW AND ESTABLISH
THRESHOLD LEVELS IN FOODS
FOR THE PRIORITY ALLERGENS

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RISK ASSESSMENT OF FOOD
ALLERGENSPART 3: REVIEW AND ESTABLISH
PRECAUTIONARY LABELLING
IN FOODS OF THE PRIORITY
ALLERGENSPart 1 Report: <https://www.fao.org/documents/card/en/c/cb9070en>Part 2 Report: <https://www.fao.org/documents/card/en/c/cc2946en>Part 3 Report: <https://www.fao.org/documents/card/en/c/cc6081en>



Criteria for assessing priority allergen status

Prevalence

Potency

Severity

Criteria for addition to/exclusion from Codex list

Severity

GROUP C (I) Lower proportion of anaphylaxis, all regions	GROUP C (II) Higher proportion of anaphylaxis, 1 region	GROUP B Higher proportion of anaphylaxis, 1-2 regions	GROUP A Higher proportion of anaphylaxis, 3+ regions
Tree nuts ->Shea nut		Tree nuts ->Pine nuts* ->Macadamia*	PEANUT Tree nuts ->WALNUT, Pecan* ->CASHEW, PISTACHIO ->HAZELNUT ->ALMOND ->Brazil nut*
Coconut			Sesame*
	Mustard (France)		WHEAT*
	BUCKWHEAT CELERY		EGG COW'S MILK (+ other mammalian milk)* FISH CRUSTACEA
	Mollusca	Lupin*	
SOY*	Fruits ->Peach*		

Prevalence

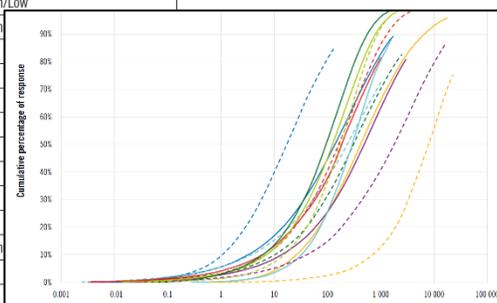
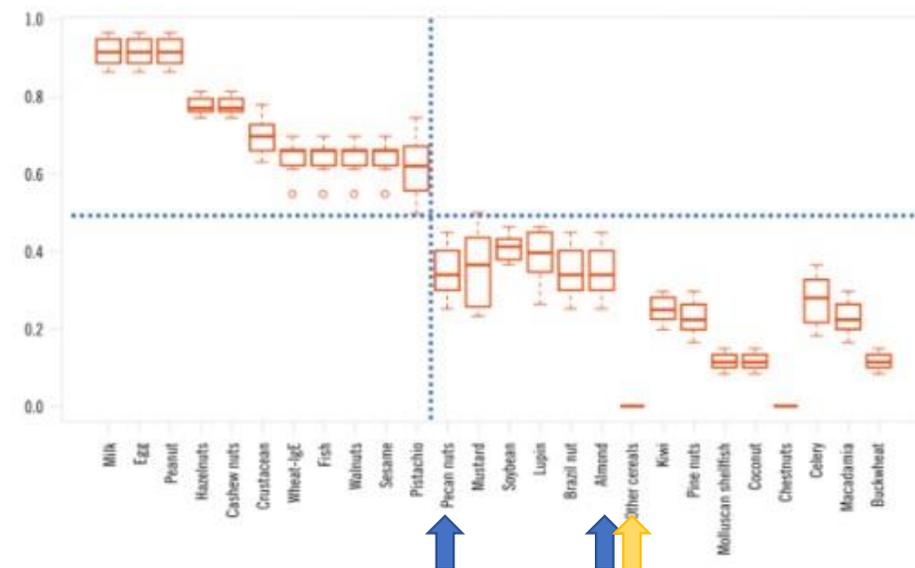
FOOD	PREVALENCE GROUP				
	0 INSUFFICIENT DATA TO DETERMINE LOW OR HIGH	1 VERY LOW	2 LOW	3 MIXED	4 HIGH
Animal food allergens					
Cow's milk					
Hen's egg					
Fish (as codfish)					
Crustacean shellfish					
Molluscan shellfish					
Plant-derived foods					
Wheat - Coeliac disease					
Wheat - IgE-mediated food allergy					
Barley - IgE-mediated food					
Rye - IgE-mediated food					
Oats - IgE-mediated food					
Fruits and vegetables					
Celery					
Kiwi					
Lupin					
Legumes					
Peanut					
Soybean					
Seeds					
Buckwheat					
Mustard					
Sesame					
Tree nuts					
Almond					
Coconut					
Brazil nut					
Cashew nut					
Hazelnut					
Macadamia nut					
Pecan (needs to be on the list because of homology with walnut)					
Pistachio					
Pine nut					
Walnut					

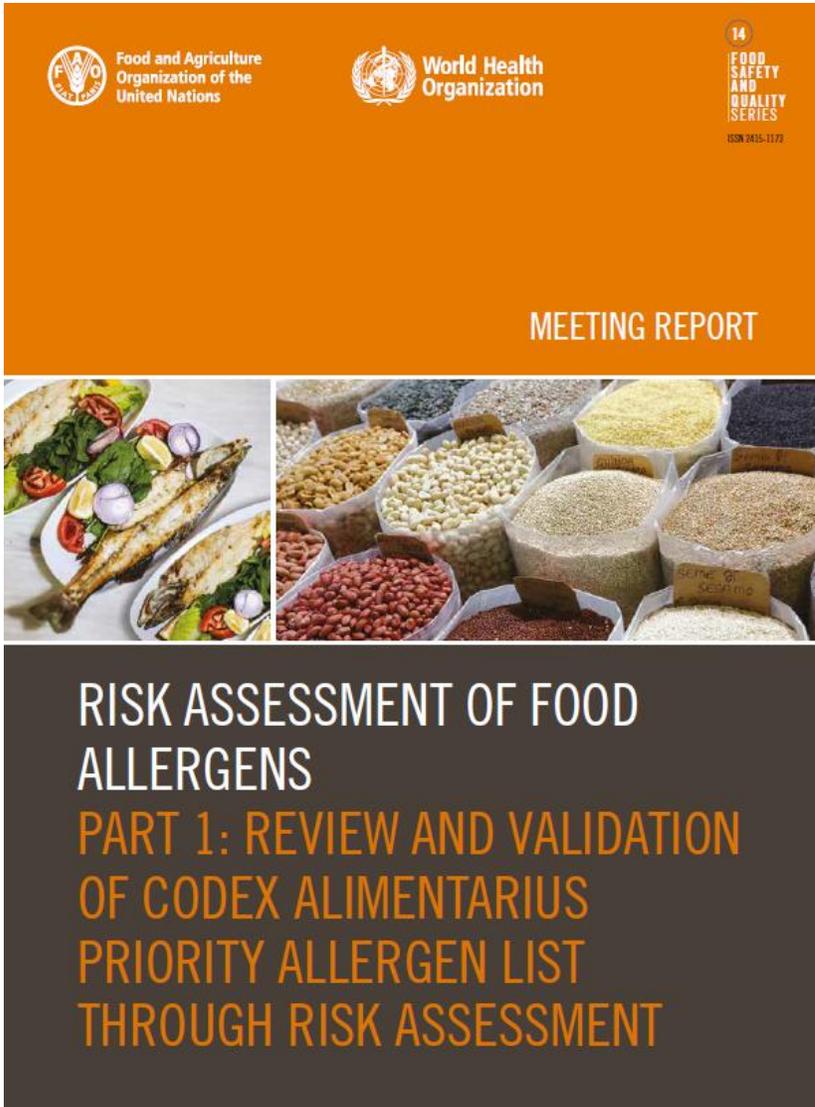
Potency

ALLERGEN	POTENCY
Milk	Medium
Egg	Medium
Peanut	Medium
Hazelnuts	Medium
Cashew nuts	Medium
Crustacean	Low (shrimp); N/A for others in group
Wheat - IgE	Medium
Fish	Medium
Walnuts	Medium
Sesame	Medium
Pistachio	N/A (cross with cashew)
Pecan nuts	N/A (cross with walnut)
Mustard	High
Soybean	Medium/Low
Lupin	Medium
Brazil nut	N/A
Almond	N/A
Other cereals	N/A
Kiwi	N/A
Pine nuts	N/A
Molluscan shellfish	N/A
Coconut	N/A
Chestnuts	N/A
Celery	Medium
Macadamia	N/A
Buckwheat	N/A



Data scoring and normalisation





Criteria for assessing priority allergen status

Prevalence

Potency

Severity

- Sesame was recommended as a priority allergen
- Others: Cereals containing gluten, crustacean, eggs, fish, milk, peanuts, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio, and walnut)
- Soy was recommended to be removed from the global list of priority allergens, but was mentioned in the list for regional consideration

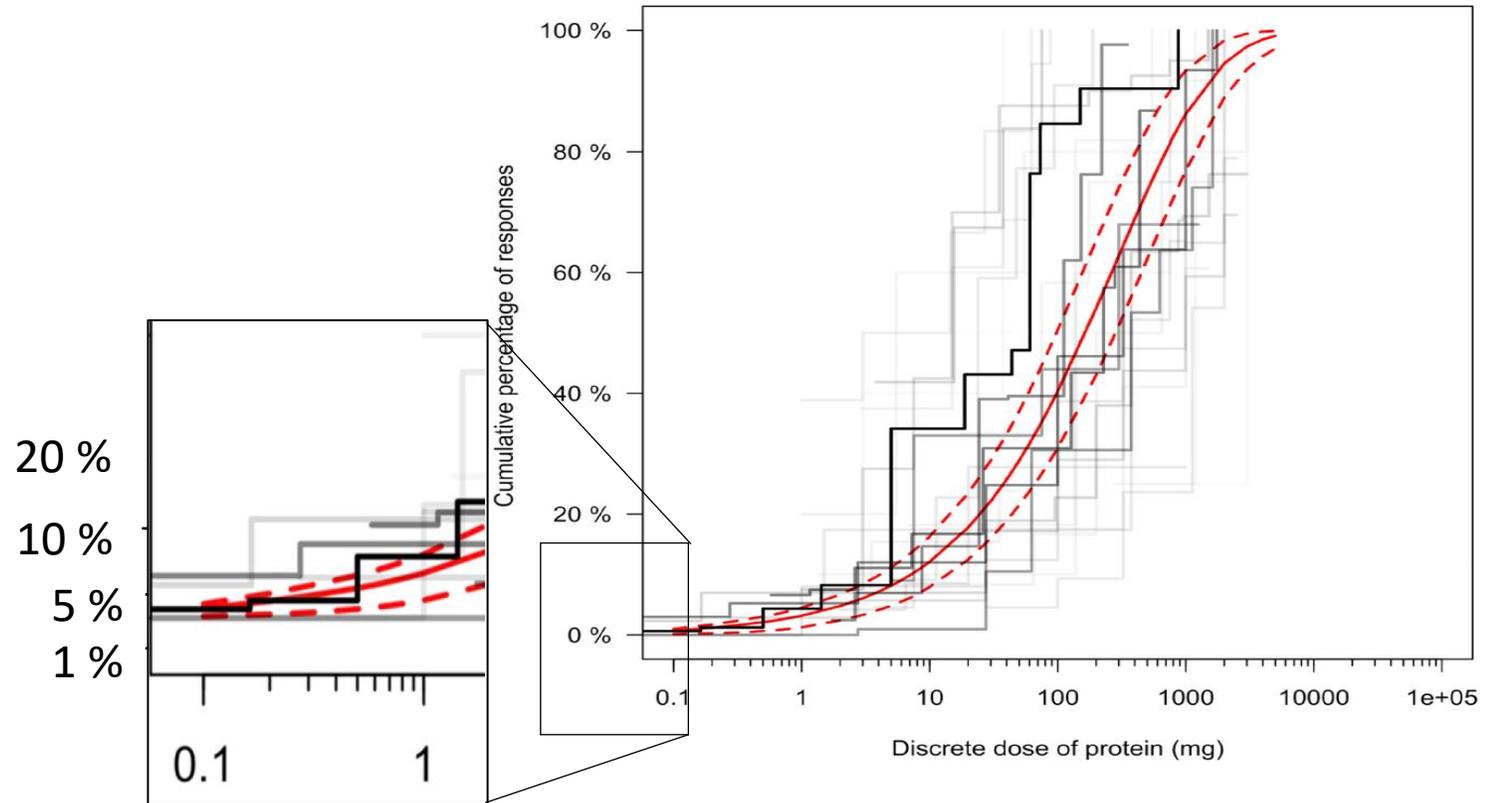


RISK ASSESSMENT OF FOOD ALLERGENS

PART 2: REVIEW AND ESTABLISH THRESHOLD LEVELS IN FOODS FOR THE PRIORITY ALLERGENS

Full 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



Population threshold distributions for 14 priority food allergens

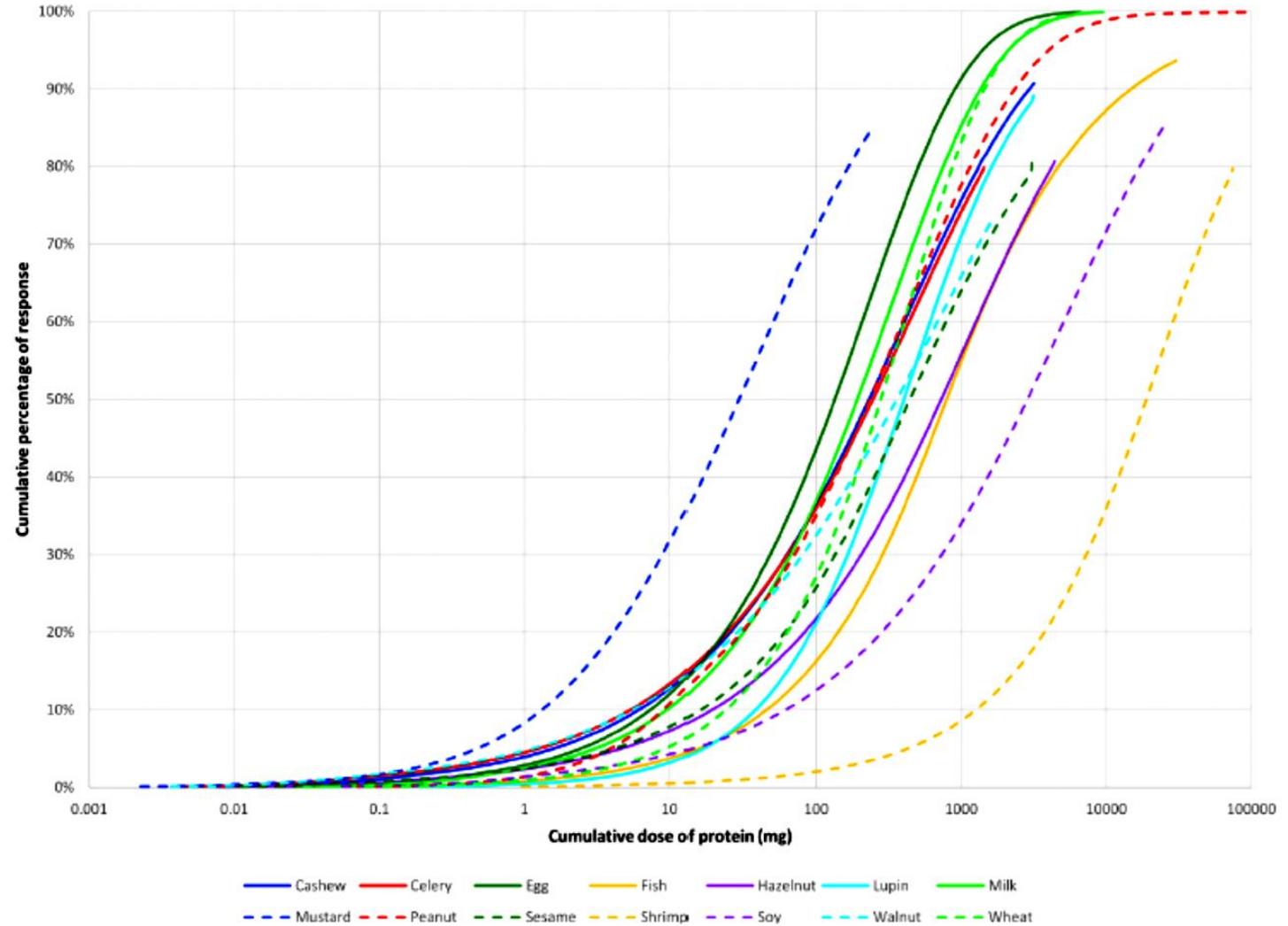
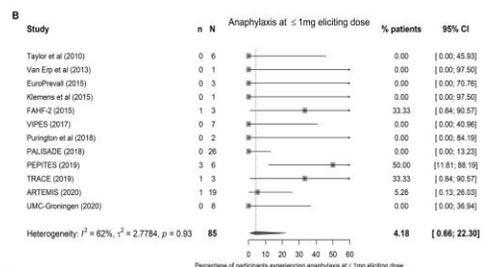
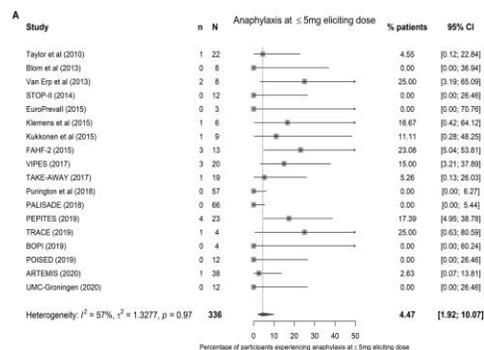


Fig. 1. ED curves from the model averaged population threshold dose distributions for 14 priority allergenic foods, based on discrete (upper graphs) and cumulative (lower graphs) dose datasets. Doses are expressed in mg total protein from the allergenic food.

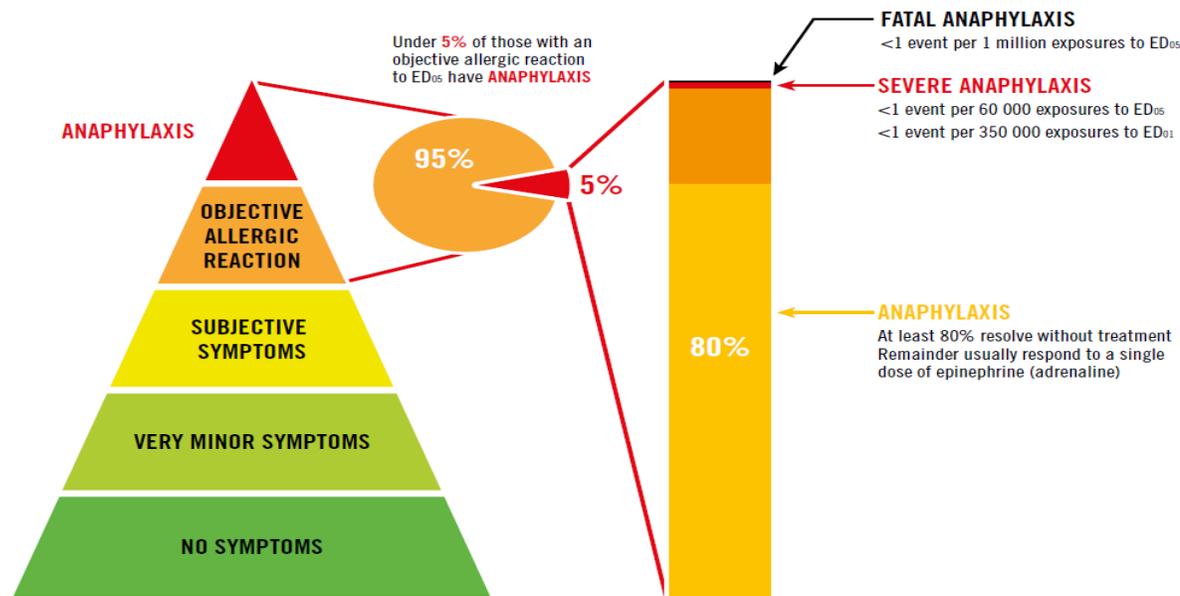
Supporting information for hazard characterization: Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens

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>

FIGURE 3. HIERARCHY OF RISKS FACED BY PEOPLE SUSCEPTIBLE TO IGE-MEDIATED FOOD ALLERGY, PROPORTIONATE TO THEIR ESTIMATED OCCURRENCE FOR PEANUT IN PEANUT-ALLERGIC INDIVIDUALS



Source: Reproduced with permission from Turner *et al.*, 2022a.

Note: ED₀₁, the eliciting dose predicted to provoke reactions in 1% of the allergic population; ED₀₅, the eliciting dose predicted to provoke reactions in 5% of the allergic population. Turner, P.J., Patel, N., Ballmer-Weber, B.K., Baumert, J.L., Blom, W.M., Brooke-Taylor, S., Brough, H. *et al.* 2022a. Peanut can be used as a reference allergen for hazard characterization in food allergen risk management: a rapid evidence assessment and meta-analysis. *The Journal of Allergy and Clinical Immunology: In Practice*, 10(1): 59–70. <https://doi.org/10.1016/j.jaip.2021.08.008>

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

Full Report: <https://www.fao.org/documents/card/en/c/cc2946en>

Review of challenge data indicated that all symptoms up to ED05 fell into a mild or moderate category, NO severe symptoms were observed.



RISK ASSESSMENT OF FOOD ALLERGENS
PART 2: REVIEW AND ESTABLISH THRESHOLD LEVELS IN FOODS FOR THE PRIORITY ALLERGENS



RISK ASSESSMENT OF FOOD ALLERGENS
PART 5: REVIEW AND ESTABLISH THRESHOLD LEVELS FOR SPECIFIC TREE NUTS (BRAZIL NUT, MACADAMIA NUT OR QUEENSLAND NUT, PINE NUT), SOY, CELERY, LUPIN, MUSTARD, BUCKWHEAT AND OATS

Global Priority Food Allergens	RfD Recommendation (mg total protein from the allergenic source)
--------------------------------	---

Walnut, Pecan, Cashew, Pistachio, Almond	1.0
Egg, Milk, Peanut, Sesame	2.0
Hazelnut	3.0
Fish, Wheat	5.0
Crustacea	200

FAO/WHO Potential Regional or National Priority allergens	RfD Recommendation (mg total protein from the allergenic source)
---	---

Celery/Celериac	1.0
Soy	10.0
Oats	Oat-specific RfD not appropriate

FAO/WHO Potential Regional or National Priority allergens	Value of risk management (mg total protein from the allergenic source)
---	---

Brazil nuts*, Macadamia or Queensland nuts*, Pine nuts*	1.0
Mustard*	1.0
Lupin*, Buckwheat*	10.0

RfDs are mg total protein NOT a concentration (ppm)



Translating reference doses into action levels (ppm)

$$\text{AL} \begin{array}{l} \text{(in mg total protein from the allergenic food/kg food)} \end{array} = \frac{\text{RfD} \begin{array}{l} \text{(in mg total protein from the allergenic food)} \end{array}}{\text{Amount of food consumed} \begin{array}{l} \text{(in kg)} \end{array}}$$

**TABLE 12 ACTION LEVELS (ALs) FROM TABLE 11 BUT ROUNDED DOWN FOR CLARITY AND EASE OF USE.
ALs ARE EXPRESSED AS mg TOTAL PROTEIN FROM THE ALLERGENIC FOOD PER kg FOOD**

RfD in mg	CRUSTACEA	FISH	WHEAT	HAZELNUT	SESAME	MILK	EGG	PEANUT	CASHEW	WALNUT
RFA in g	200	5	5	3	2	2	2	2	1	1
10	20 000	500	500	300	200	200	200	200	100	100
20	10 000	250	250	150	100	100	100	100	50	50
30	6 500	150	150	100	65	65	65	65	30	30
40	5 000	100	100	75	50	50	50	50	25	25
50	4 000	100	100	60	40	40	40	40	20	20
60	3 000	80	80	50	30	30	30	30	15	15
70	2 500	70	70	40	25	25	25	25	10	10
80	2 500	60	60	35	25	25	25	25	10	10
90	2 000	55	55	30	20	20	20	20	10	10
100	2 000	50	50	30	20	20	20	20	10	10

ppm action levels based on RfD of the ED05

*NOTE: concentrations denoted in units of ppm (mg/kg) of total protein from the allergenic source

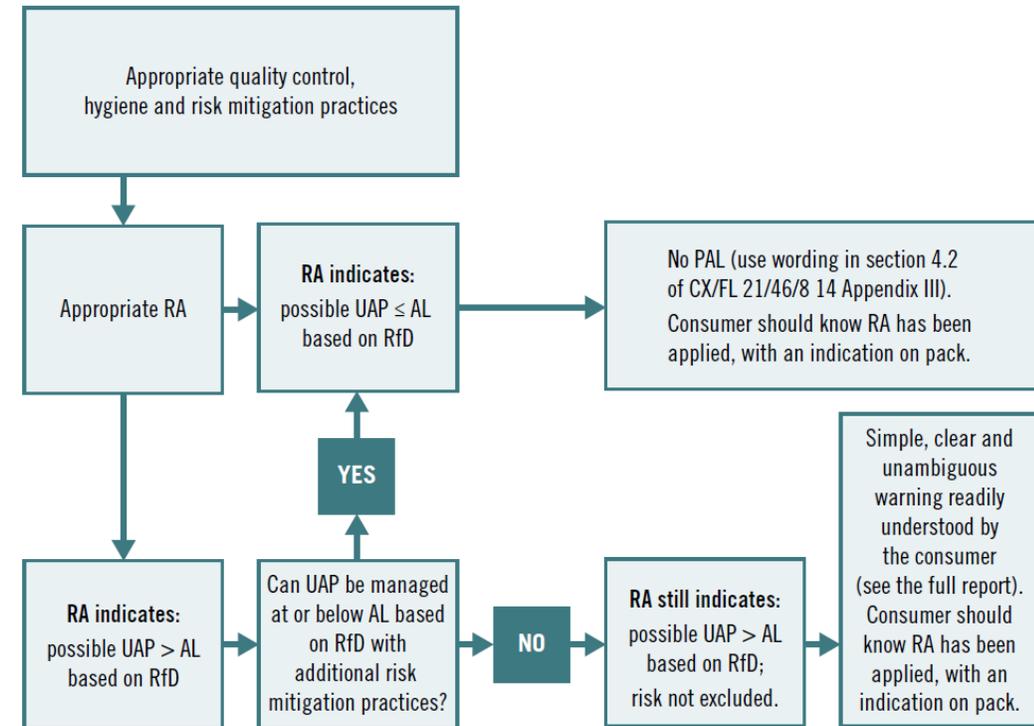
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RISK ASSESSMENT OF FOOD ALLERGENS
PART 3: REVIEW AND ESTABLISH PRECAUTIONARY LABELLING IN FOODS OF THE PRIORITY ALLERGENS

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

FIGURE 1. OVERVIEW OF THE RECOMMENDED SINGLE PRECAUTIONARY ALLERGEN LABELLING (PAL) SYSTEM



Note: ^a. RA, risk assessment; ^b. UAP, unintended allergen presence; ^c. AL, action level; ^d. RfD, reference dose.

Source: Authors' own elaboration.

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RISK ASSESSMENT OF FOOD ALLERGENS
PART 3: REVIEW AND ESTABLISH PRECAUTIONARY LABELLING IN FOODS OF THE PRIORITY ALLERGENS

PAL WORDING	“MAY CONTAIN”	“MAY CONTAIN TRACES”	“MANUFACTURED IN A FACILITY THAT ALSO PROCESSES...”	“NOT SUITABLE FOR”	REFERENCE
United Kingdom of Great Britain and Northern Ireland (n=184)	80% avoid	60% avoid	40% avoid	n/a	Noimark, Gardner and Warner, 2009
Canada (n=127)	56% avoid	47% avoid	40% avoid	80% avoid	Ben-Shoshan <i>et al.</i> , 2012
Australia (n=246)	75% avoid	45% avoid	35% avoid	n/a	Zurzolo <i>et al.</i> , 2013a
Netherlands (Kingdom of the) (n=179)	64% avoid	43% avoid	36% avoid	n/a	DunnGalvin <i>et al.</i> , 2015
Ireland (n=87)	67% avoid	59% avoid	49% avoid	n/a	
United Kingdom of Great Britain and Northern Ireland (n=161)	70% avoid	61% avoid	53% avoid	81% avoid	
Germany (n=474)	70% avoid	45% avoid	39% avoid	82% avoid	Marchisotto, Harada and Kamdar, 2017
United States of America (n=5 507)	~90% avoid	n/a	59% avoid	n/a	
Canada (n=1 177)	77% avoid	n/a	64% avoid	n/a	Gupta <i>et al.</i> , 2021
United States of America (n=2 729)	81% avoid	86% avoid	50–80% avoid	n/a*	
Netherlands (Kingdom of the) (n=42)	~90% avoid	~70% avoid	~30% avoid	n/a	Holleman <i>et al.</i> , 2021

Note: *Avoidance numbers were derived from actual study data numbers or related information. Avoidance data not available, but this term (“not suitable for”) was found to be most preferred by consumers (29.3%), followed by “May contain allergen” (22.1%).

Source: Authors’ own elaboration.

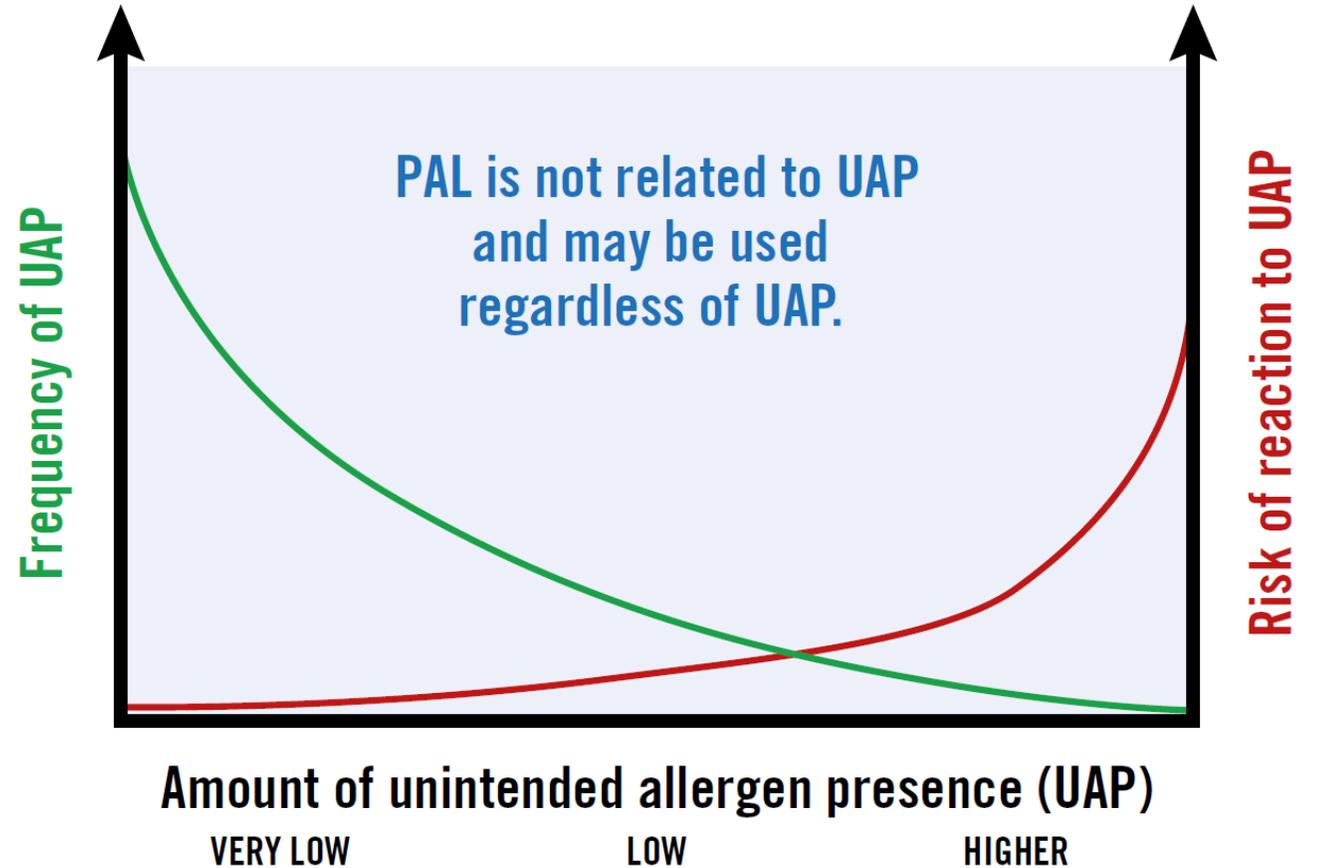
Part 3 Report:
<https://www.fao.org/documents/card/en/c/cc6081en>

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RISK ASSESSMENT OF FOOD ALLERGENS
PART 3: REVIEW AND ESTABLISH PRECAUTIONARY LABELLING IN FOODS OF THE PRIORITY ALLERGENS

Status quo



 Food and Agriculture Organization of the United Nations
  World Health Organization

 16
 FOOD SAFETY AND QUALITY SERIES
 ISSN 2415-1173

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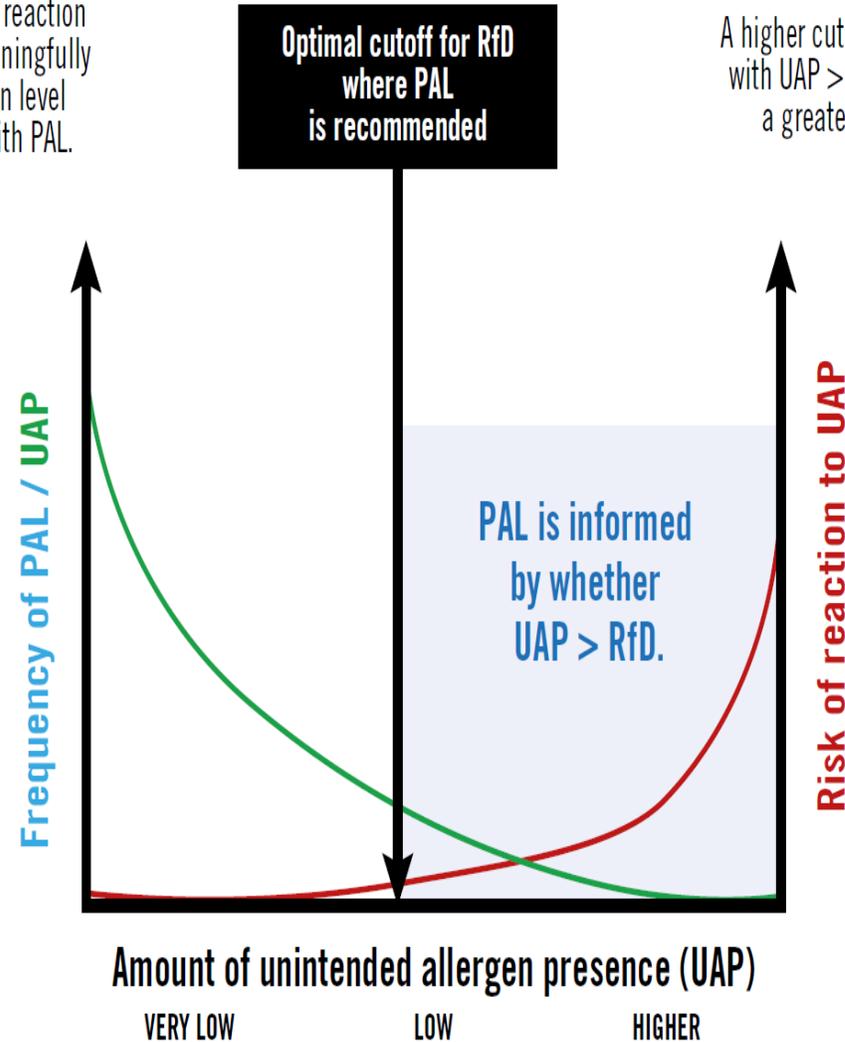


RISK ASSESSMENT OF FOOD ALLERGENS
PART 3: REVIEW AND ESTABLISH PRECAUTIONARY LABELLING IN FOODS OF THE PRIORITY ALLERGENS

Proposed approach

With a lower cutoff for RfD, the risk of reaction is slightly lower, but this does not meaningfully reduce health impact at a population level and would result in more products with PAL.

A higher cutoff for RfD results in fewer foods with UAP > RfD and therefore less PAL, but a greater population risk of reaction.



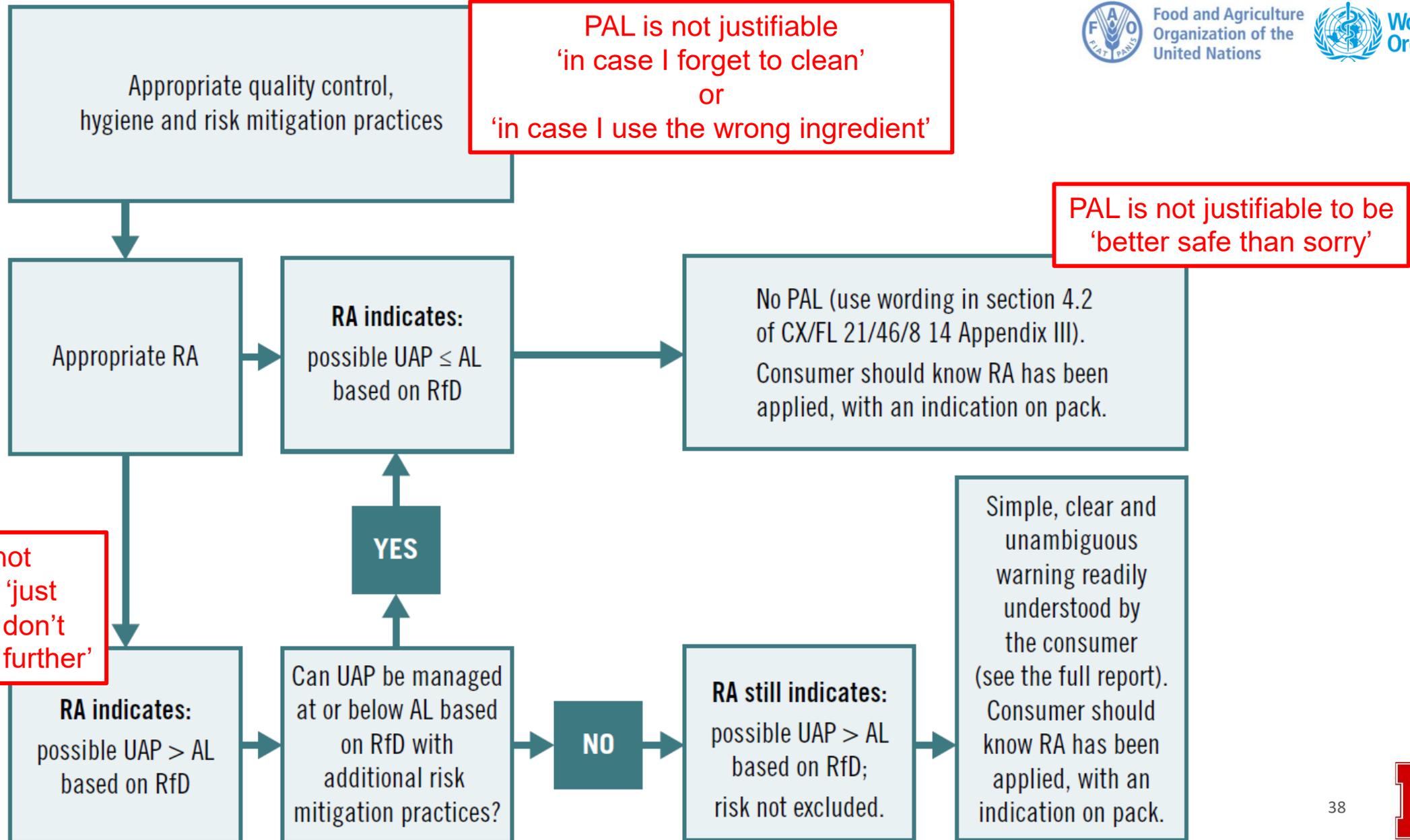
Part 3: Review and establish precautionary labelling in foods of the priority allergens



Food and Agriculture Organization of the United Nations



World Health Organization



PAL is not justifiable
'in case I forget to clean'
or
'in case I use the wrong ingredient'

PAL is not justifiable to be
'better safe than sorry'

PAL is not justifiable 'just because I don't want to look further'





Food and Agriculture
Organization of the
United Nations



World Health
Organization

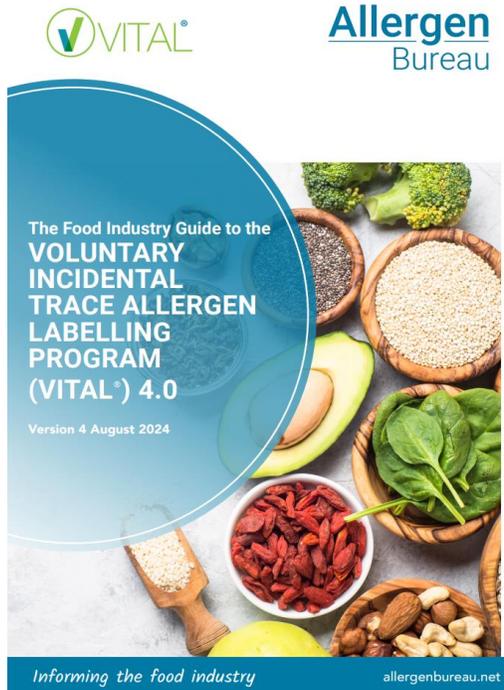
Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens



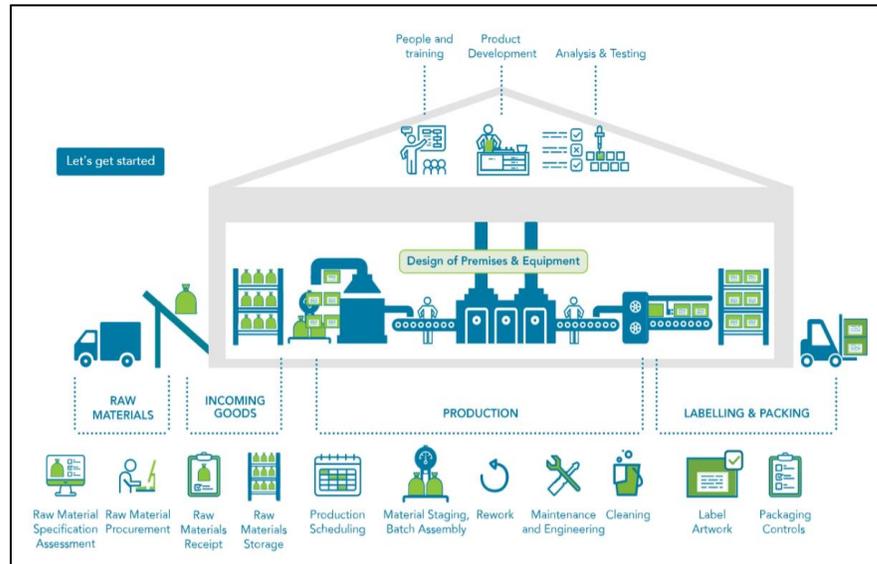
- The recommendations of the expert committee are currently being reviewed by the CCFL
 - Agreement by the member countries would be needed before moving forward with a revised list of priority allergens and use of reference doses in a risk assessment framework for PAL

Transitioning to RfDs for risk-based decisions on PAL

- The Netherlands:
 - Since January 1, 2024, there is a new policy for cross-contact and Precautionary Allergen Labeling (PAL). Companies have a transition period of two years to comply with the new policy, so until January 1, 2026.
 - Recommended reference doses (RfD) largely based on FAO-WHO reports.
 - FNLI, CBL, & NVWA. (2024). [Guidelines on cross-contact of allergens](#).
- Belgium:
 - SciCom opinion given on the reference doses to be used in the context of the surveillance of allergen labelling
 - Recommended reference doses (RfD) largely based on FAO-WHO reports.
 - [2022](#), update SciCom opinion 24-2017
- Allergen Bureau of Australia & New Zealand:
 - VITAL 4.0 transitioned to default ED05 values on August 13th, 2024



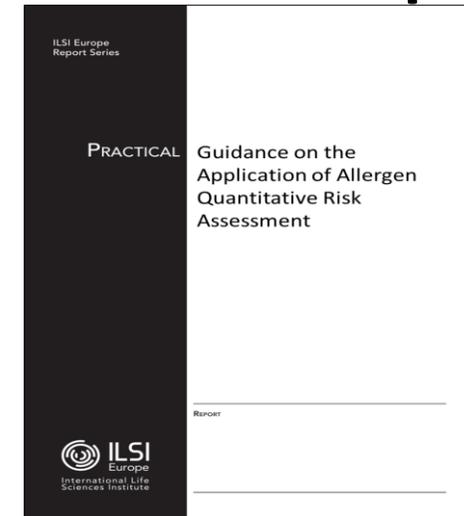
<https://vital.allergenbureau.net/vital-program/>



VITAL® Risk Review Tool

<https://info.allergenbureau.net/infographic/>

ILSI-Europe



<https://ils.eu/scientific-activities/food-safety/food-allergy/>

Exponent®

x



The what, how, & why of risk-based allergen management

October 2024

Dr. Rachel Ward FIFST

Food Allergens are a HAZARD

- Allergens are a **HAZARD** requiring HACCP controls
 - Priority allergens for intended market of sale
- Single eating occasion enough to do harm
- Amount needed to trigger an allergic reaction?
 - Very small, milligrams
 - A drop of milk or a few sesame seeds enough to cause severe allergic reactions



Food Operations Allergen Risk Management

- Effective risk management needs accurate allergen information
 - Available before product recipe development
 - Consistent (common terminology and approach across industry)
 - Type of allergenic derivative – particulate, powder, highly refined derivative
 - Quantitative – total protein levels
 - Accurate vs. likelihood of allergen presence – based on risk assessment
 - Relevant to intended market and mandatory allergens labelling list

Food Supply Chain - Raw Materials

- Allergen status clearly declared?
 - Intentional presence
 - Unintentional presence
 - PAL
 - Free-From claims
 - On packs
 - In signed specifications / contracts
- Allergen risk profile determined?
 - Based on transparent risk assessment
 - No alibi labelling!
 - Quantified levels of potential cross-contamination
- Allergen risk management effective?
 - Each supplying site
 - Each contingency site
 - For all EU food allergens
 - Validated to a known level of control
 - Ongoing verification checks

Food Supply Chain - Raw Materials

- Primary producers often less aware of food allergen risks
 - Not involved in finished product labelling / risk communication
 - Don't receive consumer queries / complaints
 - Not familiar with EU allergen labelling lists, especially ex-EU sources
- Commodity crop standards can legally permit other materials
 - How much? Of what? Why?
- Co-mingling difficult to avoid in agricultural products
 - In the field
 - During harvest
 - During storage / transport
 - During primary processing – cleaning, shelling, chopping, milling



Food Supply Chain - Product

- Recipe allergen risk profile / declaration
 - Which allergens? From what source?
 - Amount present? For what purpose?
 - How much protein present from each allergenic derivative?
- Production allergen risk profile / declaration
 - Which allergens on site and where?
 - In same production area?
 - On shared production line or equipment?
 - Allergen cross-contamination level
 - How much?
 - How often?



Minimising Cross-Contamination

- Presence On Site
 - Peanut shellers also shell tree nuts and seeds
 - Maize mills also mill wheat/barley
 - Bakeries handle multiple flours, seeds, other inclusions
 - Oil processors handle different oilseeds and grades of unrefined/refined oil
- Form of Allergenic Derivative
 - Particulates (seeds, pieces, clumps, clusters)
 - Homogenous powders
 - Sticky? Oily?
 - Dust / airborne



Minimising Cross-Contamination

- Avoidance of cross-contamination
 - Dedication – site, line, equipment, WIP bins
 - Segregation – time (scheduling) and place (separation)
 - Air handling
 - Equipment hygienic design
 - Cleaning and sanitation
- Excellent industry guidelines exist



Change & Allergen Risk Management

- Daily change management
 - Changeover – products, people, equipment
 - Impact of maintenance / breakdown
 - Impact of cleaning
- Overall business change management
 - New product development and trials
 - New raw material supply sources
 - New lines / equipment
 - Rebranding
 - New suppliers: transport, storage, artwork, etc.



Allergen Risk Communication

Avoidance by consumers requires accurate allergen information

- Easily visible and clearly legible
- Available before choices made (online, on pack label, on menus, verbally in restaurants, etc.)
- Comprehensible (simple clear descriptors)
- Consistent (common terminology and approach across industry)
- Accurate vs. levels of food allergen presence / risk



Allergen Status Categories

'Free From' claim	No 'free-from' claim No allergens declared No PAL warning	No 'free-from' claim No allergens declared PAL warning	Allergenic ingredient declared
<p><u>Only</u> 'free-from' materials used in the product recipe or manufacture</p> <p>Manufacturing environment <u>strictly</u> managed so as to <u>eliminate</u> risk of allergen cross-contamination</p>	<p>Allergenic food derivative is <u>not</u> used in the product recipe or manufacture</p> <p>Unintentional allergen cross-contamination <u>unlikely</u> or <u>can be managed</u> to acceptable levels</p>	<p>Allergenic food derivative is <u>not</u> used in the product recipe or manufacture</p> <p>Unintentional allergen cross-contamination assessed as <u>likely</u> and <u>cannot be managed</u> to acceptable levels</p>	<p>Allergenic food derivative is <u>used</u> in the product recipe or manufacture</p> <p>AND</p> <p><u>No exemption from labelling</u></p>
<p>Implies a higher standard of safety</p> <p>Can be consumed by allergic consumer under any circumstances</p>	<p>Implies safe to consume by allergic consumers</p>	<p>Implies should not be chosen for consumption by allergic consumers</p>	<p>Implies <u>unsafe</u> for consumption by allergic consumers</p>

Allergen Status Risk Communication

Where food allergens intentionally present in foodstuffs...

- Labelling declaration mandated for allergenic foods
 - Specified allergenic foods and derivatives
 - Must label all deliberately added allergenic ingredients, additives, and processing aids, and any carry-over

BUT...

- Required whether allergenic protein present or not, unless regulatory exemption given
- Required irrespective of amount allergenic derivative present
- Not proportional to the level of allergenic food (protein) present



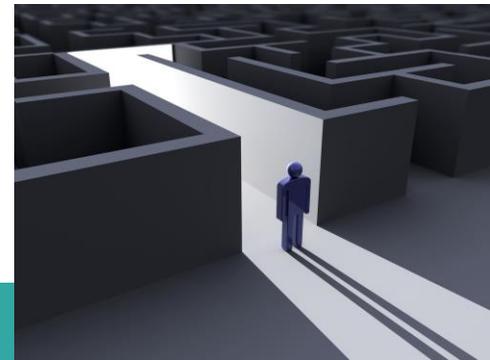
Allergen Status Risk Communication

Where food allergens unintentionally present in foodstuffs...

- Risk communication via precautionary advisory labelling (PAL)
 - Lack of harmonised approaches amongst national authorities (Voluntary in most countries; Some countries mandate PAL; Some ban PAL)
 - Lack of agreed quantitative action levels produced 'fail-safe' approaches, e.g., any potential presence triggers warning
 - Analytical non-detect used as trigger for PAL - but no evidence these levels have clinical relevance
 - Use of PAL not consistent and does not reflect level of allergen presence

BUT...

- Active global discussions
 - Consistent risk assessment and enforcement approaches
 - No PAL without previous risk assessment
 - Consistent use of PAL based on reference doses and action levels
 - Uniform wording for PAL



Allergen Status Risk Communication

Where free-from allergen claims are made

- Strict controls must guarantee absence of specific named allergens
- Risk communication through free-from claims
 - Permitted in most countries – provided not misleading
 - Globally aligned conditions for making gluten-free claims

BUT...

- No agreement on quantitative levels – except for gluten
- Analytical non-detect used as threshold to confirm absence, no evidence that these levels have clinical relevance
- Inconsistency in supply chain free-from standards

VEGAN
DOES NOT EQUAL
FREE FROM
MILK, EGG, ETC.

Questions?

Further information and support



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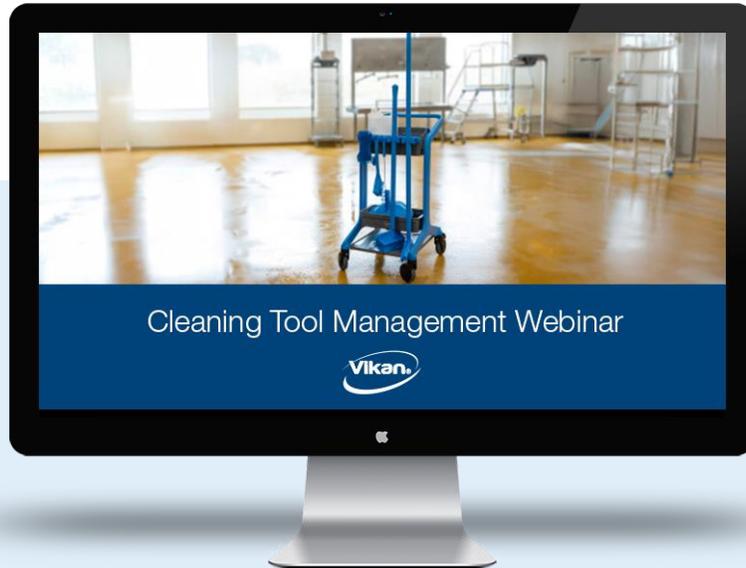
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Vikan's Food Safety Webinar Series

What's next?



Topic:

Cleaning tool management:
An essential factor for food safety

Date & Time:

20 February 2025
3 p.m. CEST (9 a.m. EST)

Presenter:

Deb Smith, Vikan