



Food and Agriculture Organization
of the United Nations

Overview of the Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens

Dr Kang Zhou

*Agrifood Systems and Food Safety Division
Food and Agriculture Organization of the United Nations (FAO)*



- The **Food and Agriculture Organization (FAO)** is a specialized agency of the **United Nations** that leads international efforts to defeat hunger.
- Our goal is to achieve **food security** for all and make sure that people have regular access to enough high-quality food to lead active, healthy lives.



- As of 1 May 2020, the Organization has 194 Member Nations, one Member Organization, and two Associate Members.
- Regional office for **Africa** (Ghana, Accra)
- Regional office for **Asia** (Thailand, Bangkok)
- Regional office for **Europe and Central Europe** (Hungary, Budapest)
- Regional office for **Latin America and the Caribbean** (Chile, Santiago)
- Regional office for **Near East and North Africa** (Egypt, Cairo)
- 11 Subregional office
- 6 Liaison offices (Washington, Yokohama, Brussels, Moscow, New York, Geneva)
- 7 Partnership and Liaison Office



Food and Agriculture Organization
of the United Nations

STRATEGIC OUTCOME 1

Inter-governmental and
multi-stakeholder
engagement in intersectoral
coordination

STRATEGIC OUTCOME 4

Public and private
stakeholder collaboration



STRATEGIC OUTCOME 2

Sound scientific advice

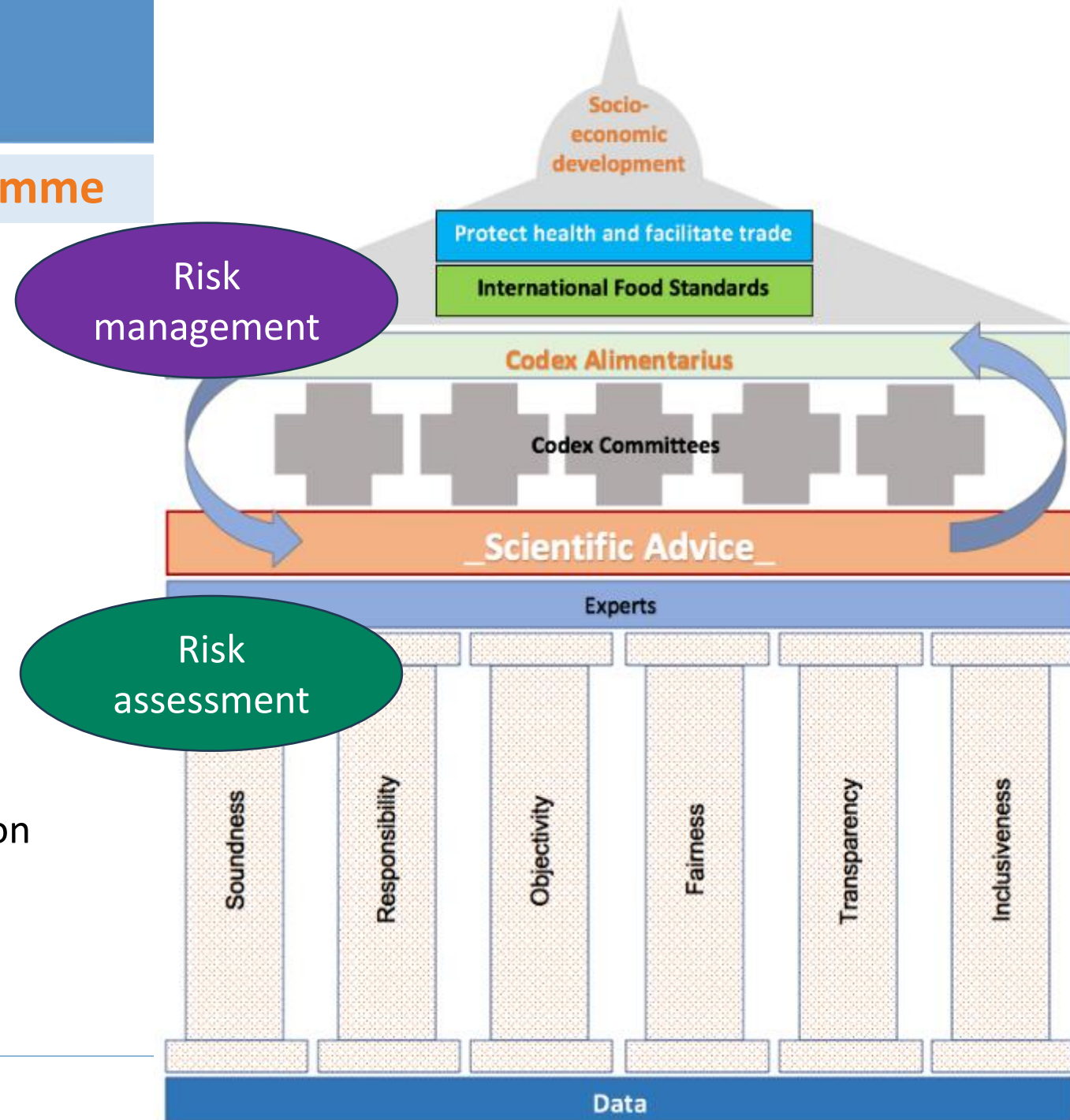
STRATEGIC OUTCOME 3

National food control
systems



Joint FAO/WHO Scientific Advice Programme

- **JEMRA**: Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment
- **JECFA**, Joint FAO/WHO Expert Committee on Food Additives
- **JMPR**, Joint FAO/WHO Meeting on Pesticide Residues
- **JEMNU**, The Joint FAO/WHO Expert Meetings on Nutrition
- **ad hoc** (AMR, food allergens, etc)





CCFH and CCFL requests for FAO/WHO scientific advice (2019)

(i) validate and update the list of foods and ingredients in section 4.2.1.4 of the General Standard for the Labelling of Packaged Foods (GSLPF [1999]) based on risk assessment;

(ii) establish threshold levels in foods of the priority allergens; and

(iii) evaluate the evidence in support of precautionary labelling.

Codex Alimentarius Commission	
CAC	Codex Alimentarius Commission
Executive Committee	
CCEXEC	Executive Committee of the Codex Alimentarius Commission
General Subject Committees	
CCCF	Codex Committee on Contaminants in Foods
CCFA	Codex Committee on Food Additives
CCFH	Codex Committee on Food Hygiene
CCFICS	Codex Committee on Food Import and Export Inspection and Certification Systems
CCFL	Codex Committee on Food Labelling
CCGP	Codex Committee on General Principles
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods



   MEETING REPORT	   MEETING REPORT	   MEETING REPORT	   MEETING REPORT	   MEETING REPORT
 RISK ASSESSMENT OF FOOD ALLERGENS PART 1: REVIEW AND VALIDATION OF CODEX ALIMENTARIUS PRIORITY ALLERGEN LIST THROUGH RISK ASSESSMENT	 RISK ASSESSMENT OF FOOD ALLERGENS PART 2: REVIEW AND ESTABLISH THRESHOLD LEVELS IN FOODS FOR THE PRIORITY ALLERGENS	 RISK ASSESSMENT OF FOOD ALLERGENS PART 3: REVIEW AND ESTABLISH PRECAUTIONARY LABELLING IN FOODS OF THE PRIORITY ALLERGENS	 RISK ASSESSMENT OF FOOD ALLERGENS PART 4: ESTABLISHING EXEMPTIONS FROM MANDATORY DECLARATION FOR PRIORITY FOOD 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

Meeting:

30 November – 11
December 2020

15 March – 2 April
2021

18 – 29 October
2021

14 – 18 November
2022

March 2023

virtual

virtual

virtual

in person

virtual

Report:
2022

2022

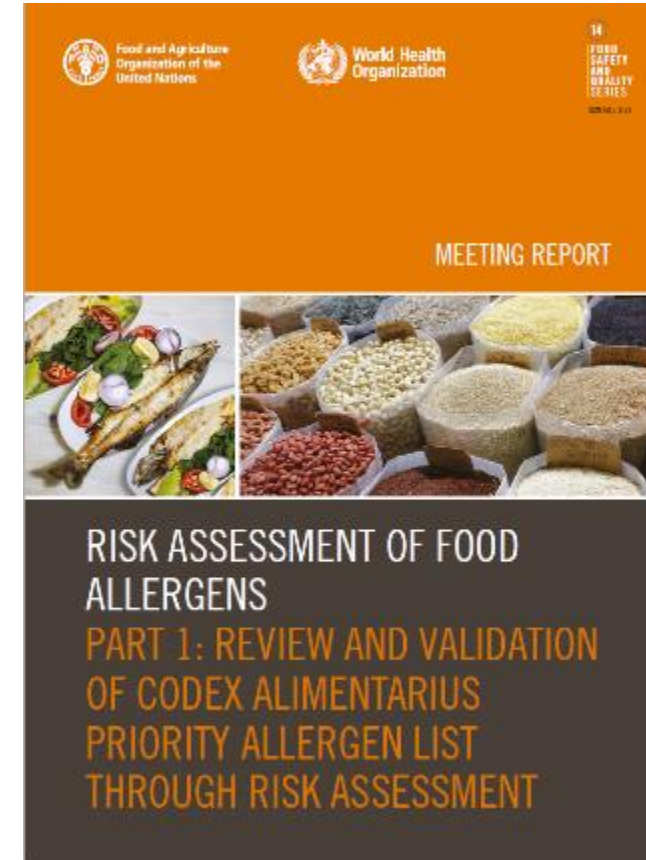
2023

2024

2023

(i) validate and update the **list of foods and ingredients** in section 4.2.1.4 of the General Standard for the Labelling of Packaged Foods (GSLPF) based on risk assessment.

- Immune mediated (IgE, Coeliac);
- three criteria — **prevalence, potency and severity**; and
- **Cereal containing gluten** (i.e. wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species, and their hybridized strains), **Crustacean, Egg, Fish, Peanut, Milk, Tree nuts** (hazelnut, cashew, walnut, pistachio, pecan, almond), **Sesame**.
- **Sesame, soy, oats, Brazil nut, almond, ...?**



Sensitivity analysis

- Systematic and thorough assessments which used all three criteria (prevalence, severity and potency) were done for the sensitivity analysis.



A/B/C	ALLERGEN	POTENCY	PREVALENCE	SEVERITY
A	Milk	Medium	High	Higher proportion of anaphylaxis, 3+ regions
A	Egg	Medium	High	Higher proportion of anaphylaxis, 3+ regions
A	Peanut	Medium	High	Higher proportion of anaphylaxis, 3+ regions
A	Hazelnuts	Medium	Mixed	Higher proportion of anaphylaxis, 3+ regions
A	Cashew nuts	Medium	Mixed	Higher proportion of anaphylaxis, 3+ regions
A	Crustacean	Low (shrimp); N/A for others in group	Mixed	Higher proportion of anaphylaxis, 3+ regions
A	Wheat – IgE	Medium	Low	Higher proportion of anaphylaxis, 3+ regions
A	Fish	Medium	Low	Higher proportion of anaphylaxis, 3+ regions
A	Walnuts	Medium	Low	Higher proportion of anaphylaxis, 3+ regions
A	Sesame	Medium	Low	Higher proportion of anaphylaxis, 3+ regions
A - (with cashew)	Pistachio	N/A (cross with cashew)	Mixed	Higher proportion of anaphylaxis, 3+ regions
A - (with walnut)	Pecan nuts	N/A (cross with walnut)	Very Low	Higher proportion of anaphylaxis, 3+ regions
B - discuss	Mustard	High	Very Low	Higher proportion of anaphylaxis, 1 region
B - discuss	Soybean	Medium/Low	Low	Lower proportion of anaphylaxis, all regions
B - discuss	Lupin	Medium	N/A	Higher proportion of anaphylaxis, 1-2 regions
B - discuss	Brazil nut	N/A	Very Low (regional)	Higher proportion of anaphylaxis, 3+ regions
B - discuss	Almond	N/A	Very Low	Higher proportion of anaphylaxis, 3+ regions
B - discuss	Other cereals	N/A	N/A	N/A
C	Kiwi	N/A	Low	Lower proportion of anaphylaxis, all regions
C	Pine nuts	N/A	Very Low	Higher proportion of anaphylaxis, 12 regions
C	Molluscan shellfish	N/A	N/A	Higher proportion of anaphylaxis, 1 region
C	Coconut	N/A	Not done	Lower proportion of anaphylaxis, all regions
C	Chestnuts	N/A	Not done	N/A
C - (regional)	Celery (regional)	Medium	Very Low (regional)	Higher proportion of anaphylaxis, 1 region
C - (regional)	Macadamia	N/A	Very Low (regional)	Higher proportion of anaphylaxis, 1-2 regions
C - (regional)	Buckwheat	N/A	Very Low	Higher proportion of anaphylaxis, 1 region



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

(ii) establish **threshold levels** in foods of the priority allergens.

- Through risk assessment, reference doses, based on **health-based guidance values** for each of the priority allergens were recommended.
- **analytical,**
- **deterministic safety assessment** (no observed adverse effect level [NOAEL] with uncertainty factor [UF]),
- **deterministic safety assessment** (benchmark dose with/without margin of exposure [MoE]), and
- **probabilistic hazard assessment.**

	RFD Recommendation (mg total protein from the allergenic source)
Walnut (and Pecan*)	1.0
Cashew (and Pistachio*)	1.0
Almond**	1.0
Milk	2.0
Peanut	2.0
Egg	2.0
Sesame	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Crustacea	200

Translating clinical data to RfD

ED_p: the eliciting dose predicted to provoke reactions in a specified percentage (1%, ED₀₁ or 5%, ED₀₅) of the allergic population.

Agreed to use **ED₀₅**, rather than ED₀₁

- The absence of reports of fatal or severe anaphylaxis
- Analytical limitations
- International
- Food security
- PAL and exemption

Grouping allergenic foods according to their ED₀₁/ED₀₅ values and developing group RfDs to facilitate application by risk managers was discussed.

TABLE 2 FOOD-ALLERGIC POPULATION ELICITING DOSES (EDS)

	DISCRETE ED ₀₁ (95% CI)	CUMULATIVE ED ₀₁ (95% CI)	DISCRETE ED ₀₅ (95% CI)	CUMULATIVE ED ₀₅ (95% CI)
CASHEW	0.05 (0.02, 0.3)	0.09 (0.04, 0.5)	0.8 (0.2, 5.0)	1.6 (0.4, 9.4)
EGG	0.2 (0.1, 0.5)	0.2 (0.1, 0.5)	2.3 (1.2, 4.7)	2.4 (1.3, 5.3)
FISH	2.6 (1.0, 12.0)	1.3 (0.4, 12.7)	12.1 (4.5, 43.9)	15.6 (4.6, 102)
HAZELNUT	0.1 (0.07, 0.6)	0.2 (0.09, 0.7)	3.5 (1.3, 12.1)	4.7 (1.7, 15.7)
MILK	0.2 (0.1, 0.5)	0.3 (0.2, 0.6)	2.4 (1.3, 5.0)	3.1 (1.6, 6.6)
Blom <i>et al.</i> (2022)	0.3 (0.2, 0.7)	0.4 (0.3, 0.9)	3.2 (1.8, 6.4)	4.3 (2.4, 9.0)
PEANUT	0.2 (0.1, 0.4)	0.7 (0.5, 1.3)	2.1 (1.2, 4.6)	3.9 (2.8, 7.1)
SESAME	0.1 (0.03, 2.7)	0.2 (0.04, 4.8)	2.7 (0.4, 33.6)	4.2 (0.6, 57.7)
Turner <i>et al.</i> (2022c)	0.2 (0.09, 1.0)	0.2 (0.08, 1.0)	2.4 (1.0, 7.7)	2.5 (0.9, 9.5)
SHRIMP	26.2 (2.7, 166)	30.8 (3.4, 326)	280 (69.3, 880)	429 (94.0, 1854)
WALNUT	0.03 (0.01, 0.5)	0.04 (0.02, 0.6)	0.8 (0.1, 8.9)	1.2 (0.1, 13.0)
WHEAT	0.7 (0.3, 2.5)	1.1 (0.4, 3.8)	6.1 (2.6, 15.6)	9.3 (3.9, 24.9)

Source: Reproduced from Remington *et al.* (2020) unless otherwise noted. Remington, B.C., Westerhout, J., Meima, M.Y., Blom, W.M., Kruizinga, A.G., Wheeler, M.W., Taylor, S.L., Houben, G.F. & Baumert, J.L. 2020. Updated population minimal eliciting dose-distributions for use in risk assessment of 14 priority food allergens. *Food and Chemical Toxicology*, 139: 111259. <https://doi.org/10.1016/j.fct.2020.111259>

RfD to (Risk management) action levels

- Reference doses should be expressed as doses of mg total protein from the allergenic food.
- To apply these in the context of action levels for PAL and required limits of quantification of analytical methods to monitor compliance of food products with the RfD:

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

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

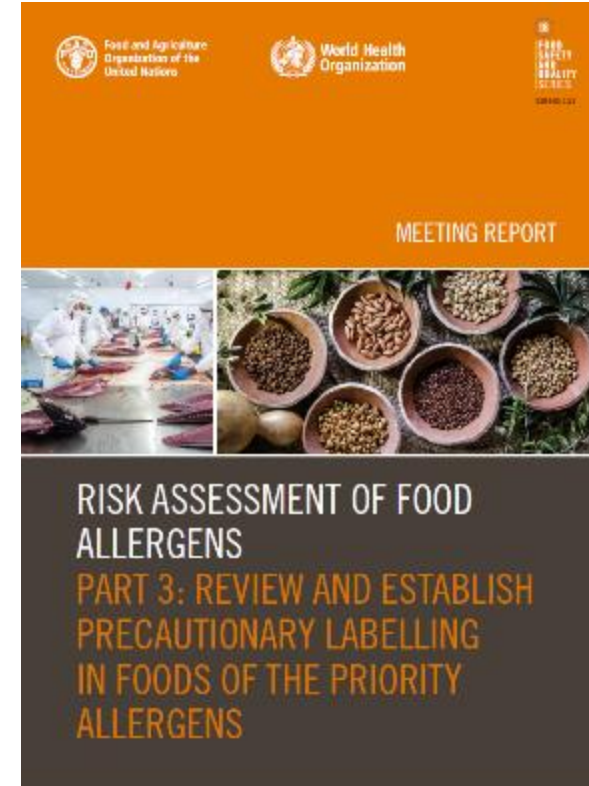
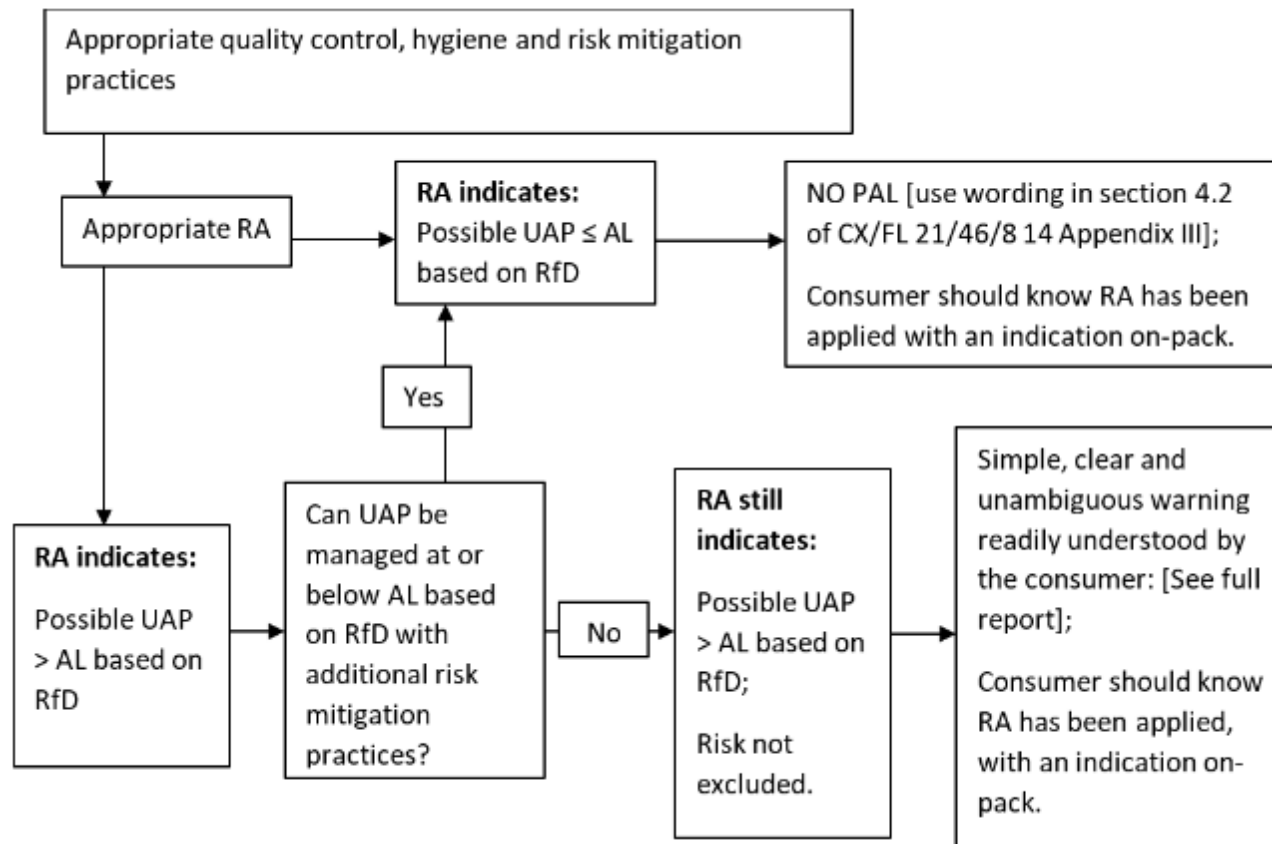
Enzyme-linked immunosorbent assays (ELISA) and mass spectrometry (MS) methods are preferred.

Consideration when choosing an analytical method:

- Assay sensitivity (Limit of Detection (LoD), Limit of Quantitation (LoQ));
- Assay specificity;
- Analytical targets;
- Cross-reactivity issues;
- Method validation;
- Test method reporting units and reference materials;
- Sampling

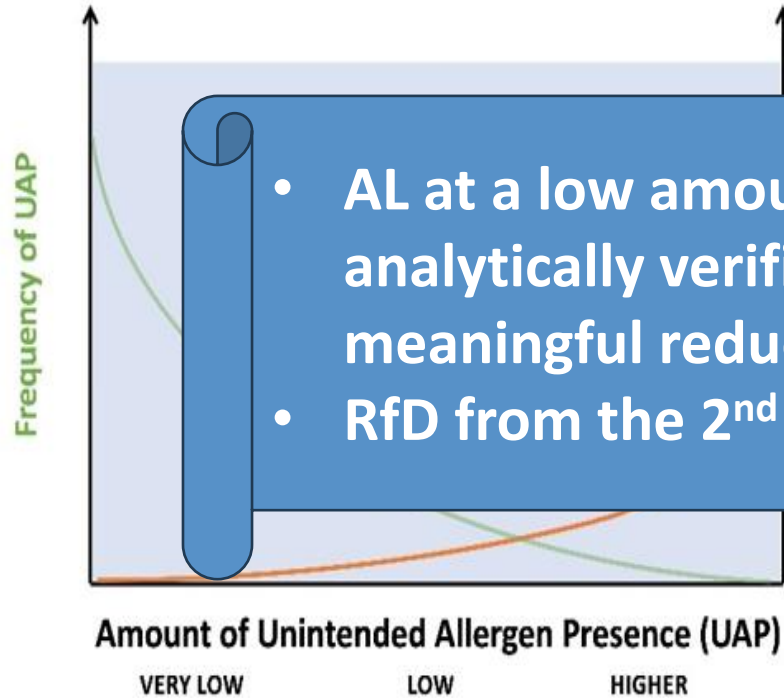
(iii) evaluate the evidence in support of precautionary labelling

Food safety management + Risk Assessment to minimize UAP



RfD, Action level (AL), PAL

STATUS QUO:



- AL at a low amount of allergen exposure, which can be analytically verified, minimizes risk, and below which there is no meaningful reduction in health impact at a population level.
- RfD from the 2nd meeting

PROPOSED APPROACH:

With a lower cut-off 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 cut-off for RfD results in fewer foods with UAP > RfD and therefore less PAL, but a greater population risk of reaction



PAL is informed by whether $UAP > RfD$

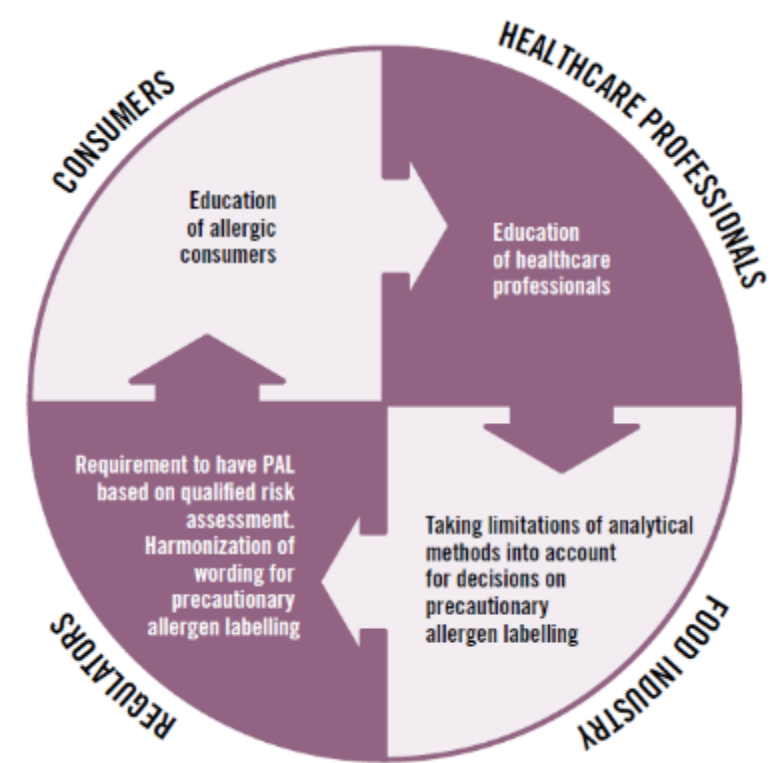
With a lower cutoff for RfD, the risk of reaction is slightly lower, but this does not meaningfully reduce health impact at a population level and would result in more products with PAL.

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

UAP > RfD, a PAL statement should be used

UAP ≤ RfD (if **UAP is below risk-based reference dose (Rfd)**), No PAL

- **Food allergic consumers avoid foods with PAL**
 - Would be protective for the vast majority
 - Would be overprotective for some
 - Small portion might not be fully protected
- **Restricted to those situations where UAP cannot be prevented and UAP > RfD**
- **RfD are not to be used for allergen-free claims**
- **PAL is not for poor GMP or deviations in allergen controls**
- **Risk-based** (risk management, risk assessment, risk communication)





EDp, RfD, Action level (AL), PAL (holistically)

- The Expert Committee also found that a more stringent RfD (such as ED01) would potentially introduce considerable limitations for **monitoring UAP and for the application of PAL or other risk management strategies**.
- The **mitigation measures** needed to comply with RfDs based on ED01 or lower would be too difficult to achieve in a consistent manner.
- Difficulty in establishing a clear AL based on analytical method could result in a situation similar to the status quo, where food businesses do not make risk-based decisions and default to **using PAL for any potential UAP**.
- The Expert Committee considered the trade-off of using the RfDs proposed in the second meeting (based on ED05), where use of PAL could be informed by existing **analytical capabilities**.
- This would allow a greater number of products to **undergo risk-based assessments and decisions**, and likely **reduce the number of products with PAL statements**.
- This would not only improve risk communication of PAL but would offer consumers a **greater range of safe food choices**.

(iv) evaluate labelling **exemptions for derivatives** of priority allergenic foods.

- The exposure estimates in reasonable worst-case consumption scenarios, based on the scientific data considered for the exemptions approved to date, lead to values around the relevant Reference Doses (RfD) established by the **2nd meeting** divided by 30 (RfD/30). Consequently, the **RfD/30** appears to provide an adequate margin of exposure (MoE) for derivative safety assessment.
- Suitable methods of analysis are available for protein levels based on the RfD/30.
- **A derivative that undergoes the weight of evidence risk assessment as outlined in this report and meets the criterion (RfD/30) may not require clinical studies to establish safety.**





1. Description of the derivative originating from
(or containing) a priority allergenic source.

2. Documentation of history of prior use and safety of use.

3. Characterization of the derivative, which usually includes the source material
process parameters, composition and purity, and quantification of total protein.

4. Specification/description of intended use.

5. Do the documented intended use and
characterization show equivalence to an
already exempted product/derivative
with an established history of safe use?

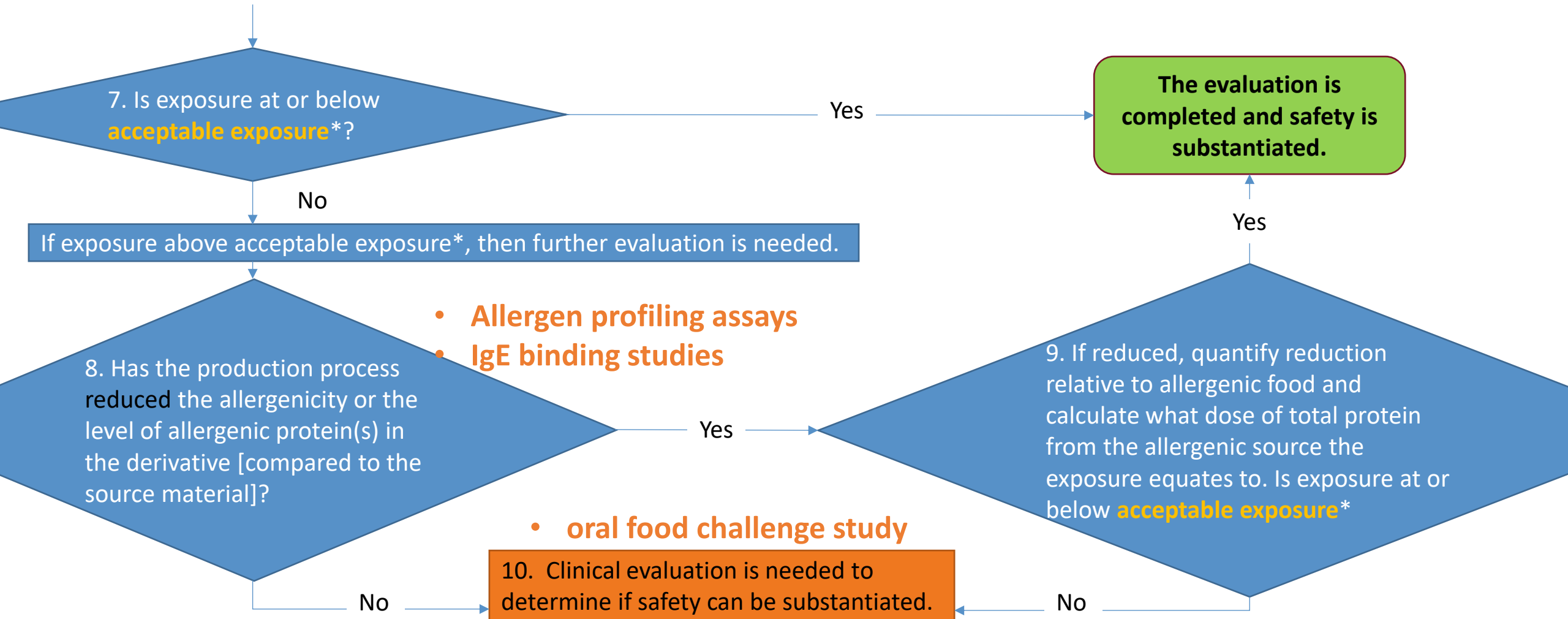
Yes

**The evaluation is
completed and safety is
substantiated.**

No

6. An exposure assessment is needed.

For **total protein quantification** (box 3), to use **more than one test method**, each based on different principles, that are fit for purpose and may include total amino acid analysis as appropriate.



*Acceptable exposure in the context of assessing an exemption application can be derived by applying a Margin of Exposure (MoE) to the Reference Dose (RfD) proposed in the 2nd meeting of this expert consultation (i.e. RfD divided by MoE; RfD/MoE). The RfD/30 appears to provide an adequate MoE for derivative safety assessment. For comparison with the acceptable exposure, exposure should be calculated into and expressed as the equivalent of dose of total protein from the priority allergenic source.

Note: Establishment of safety based upon this weight of evidence approach is dependent upon consideration of data quality, outcome of the exposure assessment and review by competent authorities (as needed). When safety is established, a labeling exemption can be granted.



Observations:

1. Ice structuring protein (ISP)
2. Glucose syrup derived from wheat starch
3. Soy phytosterols/tocopherols
4. Soy oil
5. Peanut oil
6. Soy lecithin
7. Whey ethanol
8. Fish gelatine
9. Hypoallergenic infant formula (extensively hydrolysed casein [EHC])



(v) establish **threshold levels** which are **not** of the priority food allergens.

- Transparency
- Harmonization
- Capacity
-



A/B/C	ALLERGEN	POTENCY	PREVALENCE	SEVERITY
A	Milk	Medium	High	Higher proportion of anaphylaxis, 3+ regions
A	Egg	Medium	High	Higher proportion of anaphylaxis, 3+ regions
A	Peanut	Medium	High	Higher proportion of anaphylaxis, 3+ regions
A	Hazelnuts	Medium	Mixed	Higher proportion of anaphylaxis, 3+ regions
A	Cashew nuts	Medium	Mixed	Higher proportion of anaphylaxis, 3+ regions
A	Crustacean	Low (shrimp); N/A for others in group	Mixed	Higher proportion of anaphylaxis, 3+ regions
A	Wheat – IgE	Medium	Low	Higher proportion of anaphylaxis, 3+ regions
A	Fish	Medium	Low	Higher proportion of anaphylaxis, 3+ regions
A	Walnuts	Medium	Low	Higher proportion of anaphylaxis, 3+ regions
A	Sesame	Medium	Low	Higher proportion of anaphylaxis, 3+ regions
A - (with cashew)	Pistachio	N/A (cross with cashew)	Mixed	Higher proportion of anaphylaxis, 3+ regions
A - (with walnut)	Pecan nuts	N/A (cross with walnut)	Very Low	Higher proportion of anaphylaxis, 3+ regions
B - discuss	Mustard	High	Very Low	Higher proportion of anaphylaxis, 1 region
B - discuss	Soybean	Medium/Low	Low	Lower proportion of anaphylaxis, all regions
B - discuss	Lupin	Medium	N/A	Higher proportion of anaphylaxis, 1-2 regions
B - discuss	Brazil nut	N/A	Very Low (regional)	Higher proportion of anaphylaxis, 3+ regions
B - discuss	Almond	N/A	Very Low	Higher proportion of anaphylaxis, 3+ regions
B - discuss	Other cereals	N/A	N/A	N/A
	Kiwi	N/A	Low	Lower proportion of anaphylaxis, all regions
	Pine nuts	N/A	Very Low	Higher proportion of anaphylaxis, 12 regions
C	Molluscan shellfish	N/A	N/A	Higher proportion of anaphylaxis, 1 region
C	Coconut	N/A	Not done	Lower proportion of anaphylaxis, all regions
C	Chestnuts	N/A	Not done	N/A
C - (regional)	Celery (regional)	Medium	Very Low (regional)	Higher proportion of anaphylaxis, 1 region
C - (regional)	Macadamia	N/A	Very Low (regional)	Higher proportion of anaphylaxis, 1-2 regions
C - (regional)	Buckwheat	N/A	Very Low	Higher proportion of anaphylaxis, 1 region



Brochures

In brief: Priority food allergens

Food allergen reference doses

Exemptions from mandatory food allergen declaration

Precautious allergens labelling (PAL)

Food and Agriculture Organization of the United Nations

World Health Organization

Food and Agriculture Organization of the United Nations

World Health Organization

Food and Agriculture Organization of the United Nations

World Health Organization

Food and Agriculture Organization of the United Nations

World Health Organization

Food and Agriculture Organization of the United Nations

World Health Organization

Food and Agriculture Organization of the United Nations

World Health Organization

Food and Agriculture Organization of the United Nations

World Health Organization

Food and Agriculture Organization of the United Nations

World Health Organization

Food and Agriculture Organization of the United Nations

World Health Organization

3-fold version

1. Priority food allergens

2. Food allergen reference dose

3. Precautionary labelling

4. Exemption

[illegible][illegible][illegible][illegible]

Food allergens of concern

The Risk Assessment of Food Allergens Part 1 Review and Validation of the Global Allergen Priority Allergens List Through Risk Assessment provides a structured, quantitative assessment framework and recommendations for which foods should be included in a global priority list of allergens. It was developed after the global consultation of scientists and risk assessors, and the risk managers of other responsible for food decision-making and/or communication. The report:

- updates the list of priority food allergens of concern;
- defines qualitative criteria for assessing the addition or exclusion of foods from the priority list;
- provides a generic approach to assess and prioritize food allergens of concern; and
- ensures transparency and repeatability, and facilitates any future evaluation.

This work represents among the first comprehensive global quantitative risk assessment for food allergens it can serve as the scientific basis for the Codex Alimentarius to involve and update its related texts and decisions leading on the available global data and risk assessment; it provides a generic approach for the countries to include the food allergen with the same priority. This harmonization represents the international consensus recommendation for food safety and facilitating for trade).

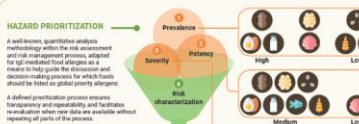


Hazard Prioritization

In 2020, allergic foods were assessed within a structured, transparent and repeatable process and recommendations were made regarding their potential inclusion or exclusion in a global priority list of food allergens.

The following sections provide Assessments on food allergens by allergenicity, prevalence, quantified and prioritized risks across different food categories and food items.

1. Prevalence: the proportion of a population known to have experienced an immune-mediated adverse reaction to food allergens supported by studies from different geographic regions and in unrelated populations, representative with regards to genetic age and ethnicity, and sex and diet.



A defined prioritization process ensures transparency and repeatability, and facilitates re-evaluation when new data are available without repeating any part of the process.

GLOBAL PRIORITY FOOD ALLERGENS

Milk, eggs, peanut, tree nuts (almond, coconut, walnut, pistachio, hazelnut, cashew, pecan, Brazil nut, macadamia nut, pine nut, etc.), soybean, wheat, rye, barley, oat, rice, corn, sorghum, quinoa, buckwheat, lupine, chickpea, lentils, broad beans, fava beans, kidney beans, black beans, green beans, and other leguminous species, and other hydrolyzed strains)



Potentially important on a regional or national level

Eggs, brown rice (brown, medium and grey milled), yellow bushclover, lupine, mustard and

[illegible][illegible]

Framework for exemptions from required mandatory allergen declaration

The Risk Assessment (RA) of Allergens Part 4: Establishing the framework for exemptions from required mandatory allergen declaration is a risk framework for assessing whether foods are regarded as posing a negligible risk to allergic individuals and, when derived from the list of priority food allergens can be exempted from mandatory food allergen labelling.

The framework was developed for the global community of scientists and risk assessors, and the risk managers are responsible for risk decision-making and/or communication to provide a general approach to assess and exempt allergen derivatives from mandatory food allergen labelling requirements.

Additionally, the report highlights that a framework utilising scientific evidence is provided, and that the RA framework provides a general approach to assess and exempt allergen derivatives of exposure to allergens suitability for allergen labelling exemptions.

Establishment of safety based upon this weight of evidence approaches is dependent upon consideration of data quality evidence of a conservative exposure assessment for all intended ingested exposure to allergens (consumption) and review by competent authorities.

The process provides an exemption and transparent risk-based rationale for exemptions from mandatory allergen labelling to be consistent on a national, regional and global basis.

Exemptions from mandatory food allergen declaration and "allergens free" labelling claims are separate concepts, with distinct considerations.

"Allergen-free" claims are not covered within the framework for exemptions. Further, this report is the basis for exempting "allergen-free" labelling.

History of safe consumption

The report concludes that for the current accepted exemptions, there is an established history of safe consumption. As part of mandatory food allergen labelling requirements, the report:

- summarizes past studies that have been conducted from developing the food allergen labelling requirements were granted.
- summarizes past studies that have been conducted to not grant.
- found exposure estimates for the current accepted exemptions to be always consistent in amounts of total protein from allergenic foods above the relevant reference dose (RFD) established by the second meeting of the WHO (2003) in reasonable worst-case consumption scenarios.
- concludes that the RFDs appear to provide an adequate margin of safety (MOS) for derivative safety assessment.
- emphasizes suitable methods of analysis are available for the RFDs.
- concludes that the RFDs appear to be protective of the most sensitive risk thresholds such as RFD100 or RFD1300.

Practical considerations

Advances to safety assessment principles make reference to concerns for exempting individuals from labelling requirements based on reasonable worst-case exposure to allergen safety under an reasonably foreseeable consumption. To facilitate these assessments, the report:

- provides considerations for analysis regarding protein determination and methods of interest allergen profiling.
- estimates of exposure for exemption assessments should use maximum levels of intended use of the (derivative) and food consumption data from the 95th, 90th, 80th, or 97.5th percentiles of consumers, and if applicable, of exposure from a combination of multiple food exposures consumed on a single eating occasion, and
- provides a summary of the methods for the purposes of exemption efforts from calculations of exposure during assessment of an anticipated allergen safety under a worst-case context, which uses the 95th percentile of consumers.

Other activities

- Promotion
- Capacity building
 - Workshop during the FAO/WHO Coordinating Committee for Asia (CCASIA), September 2025
 - Workshop in other regions in 2026.



<https://www.youtube.com/watch?v=sSSI549bgkQ>



Following activities

- **Risk assessment**

- 48th session of Codex Committee on Food Labelling, 27 October to 1 November 2024

(v) request FAO/WHO to provide:

- (a) guidance for qualitative risk assessment;
- (b) scientific advice on the level of RfDs or concentrations for cereals containing gluten or gluten; and
- (c) capacity building activities to countries on the PAL and risk assessment.

- 16-20 June 2025, joint FAO/WHO expert consultation on qualitative risk assessment.
- Late 2025, joint FAO/WHO expert consultation on gluten RfD.



**Joseph Baumert,
Simon Brooke-Taylor,
Hongbing Chen,
René Crevel,
Geert Houben,
Lauren Jackson,
Symeon Kyriakidis,
Sébastien La Vieille,
Alice Lee,
María Cristina López,
Stefano Luccioli,
Patrick O'Mahony,
Gustavo Polenta,**

**Bert Pöpping,
Benjamin Remington,
Eva Södergren,
Sirinrat Srikulnath,
Stephen Taylor,
Paul Turner,
Markus Lacorn,
Clare Mill,
Huilian Che,
Simon Flanagan,
Stephan Walch,
Carmen Diaz-Amigo**

For more information

<https://www.fao.org/food-safety/scientific-advice/food-allergens/en/>

• kang.zhou@fao.org