

ED₀₁ vs. ED₀₅ Explained

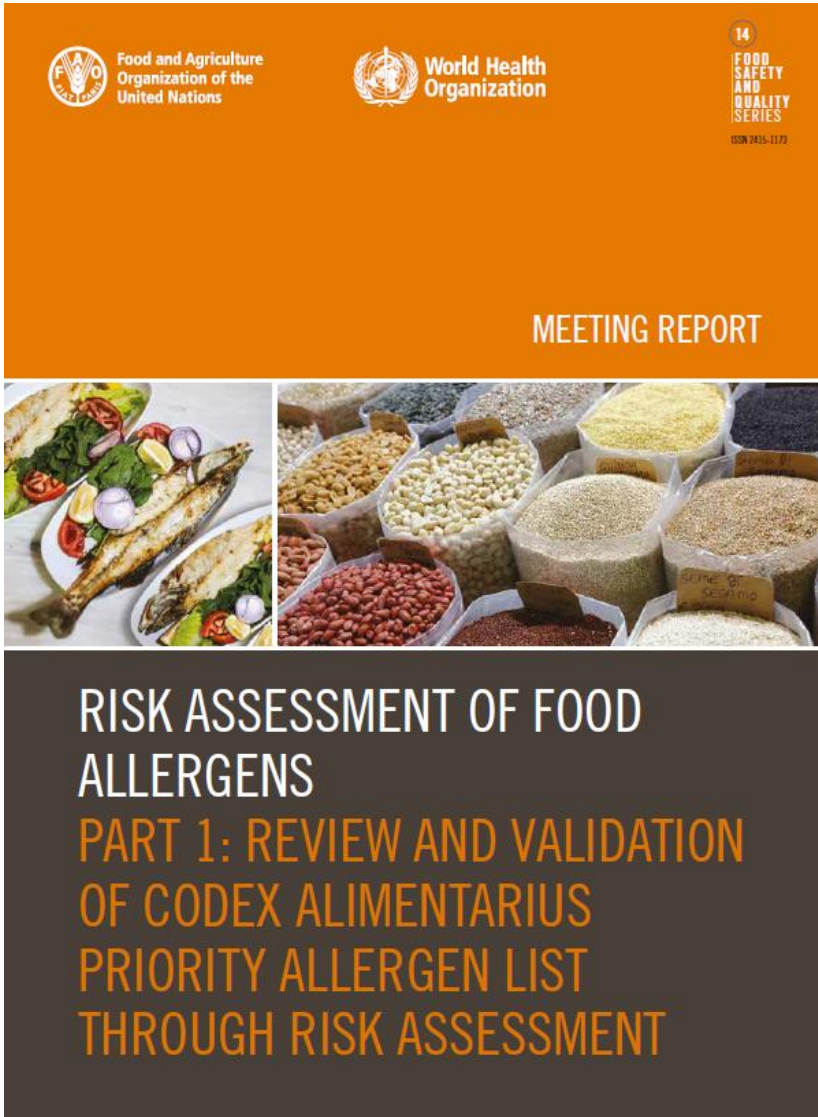
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5th Food Allergen Management Symposium
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Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens

- Part 1: Review and validation of Codex priority allergen list through risk assessment
- Part 2: Review and establish threshold levels in foods of the priority allergens
- Part 3: Review and establish precautionary labelling in foods of the priority allergens
- Part 4: Review and establish exemptions for the food allergens



Criteria for Assessing Priority Allergen Status

Prevalence

Potency

Severity

Potency

Potency: Data Sources

- The Expert Committee noted that the data reported in the publications of Remington, et al., (2020) and Houben, et al., (2020) were the most comprehensive and best described source available, both in terms of content and curation, with supportive peer-reviewed publications.
- Dose-distribution analysis methodology was similarly well-described within this dataset.
- The Committee reviewed the data sources for each priority allergen, taking into consideration both included publications and those which had been collated but excluded, and the extent and type of bias in the data.

Potency: Objective Symptoms

TABLE 8 MOST COMMON SIGNS AND SYMPTOMS OF ALLERGIC REACTIONS TO FOOD, AS REPORTED IN PUBLICATIONS AND UNPUBLISHED CLINICAL DATA

SUBJECTIVE SYMPTOMS	OBJECTIVE SYMPTOMS
Oral cavity	
> Pruritus (itching) and paresthesia (tingling sensation) of the oral cavity, pharynx and/or lips (so called oral allergy symptoms [OAS])	> Lip swelling > Redness/swelling of the oral mucosa > Blisters of the oral mucosa
Skin	
> Pruritus (itching)	> Urticaria > Angioedema > Flush > Erythema (Redness)
Eyes and Nose	
> Pruritus (itching)	> Red eye/conjunctival hyperemia > Tearing > Sneezing > Rhinorrhea
Gastrointestinal	
> Dysphagia > Abdominal/gastric pain* > Cramps > Nausea > Bloating	> Diarrhea > Vomiting**
Neurological	
> Headache > Dizziness > Anxiety > Tension/agitation	> Seizures

SUBJECTIVE SYMPTOMS	OBJECTIVE SYMPTOMS
Respiratory	
> Laryngeal/throat tightness > Thoracic/chest tightness > Dyspnea/shortness of breath	> Laryngeal edema > Dysphonia > Wheezing > Reduced peak expiratory flow/drop in FEV1 > Silence (in lung auscultation) > Breathless to speak > Rapid breath > Chest retractions > Cough
Cardiovascular	
> Faintness > Tiredness	> Change in heart rate/tachycardia > Hypotension/drop of blood pressure > Change in consciousness
Other	
> Uterine cramps/contractions	

*Abdominal pain and gastric pain are considered objective symptoms provided they are observed in children less than three years old.

**Vomiting is not considered an objective symptom in children less than one year of age unless the clinician stops the challenge because of vomiting. If vomiting occurs at the final dose of the challenge, it is not considered an objective symptom in children less than one year old, unless additional objective symptoms are present.

Source: Adapted from Westerhout *et al.*, 2019

Potency: Classification Output

FIGURE 4. EDP 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

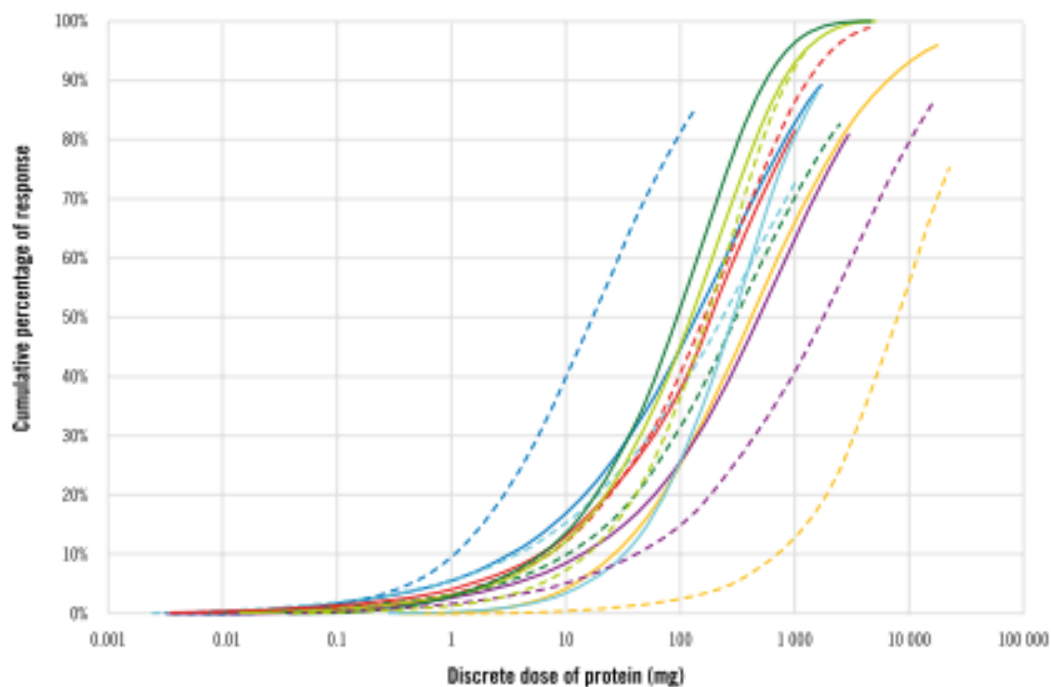


TABLE 9 THE OUTCOME FROM THE SUBGROUP OF THE EXPERT COMMITTEE FOR POTENCY

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

Severity

Severity: Classification Criteria

- The working group considered the outputs from the systematic review undertaken and then categorized allergens into the following groups
- Group A
 - Allergens which cause at least 5–10 percent of anaphylaxis reactions in three or more Codex regions
- Group B
 - Allergens which are considered to cause at least 5–10 percent of anaphylaxis reactions in only one or two Codex regions
- Group C
 - (i) Allergens which cause a lower proportion of anaphylaxis reactions in all regions
OR
 - (ii) Allergens which cause at least 5–10 percent of anaphylaxis reactions in only one CODEX region, but a lower proportion of anaphylaxis reactions elsewhere

Definitions of Anaphylaxis Vary

Cardona et al. *World Allergy Organization Journal* (2020) 13:100472
<http://doi.org/10.1016/j.waojou.2020.100472>



POSITION PAPER

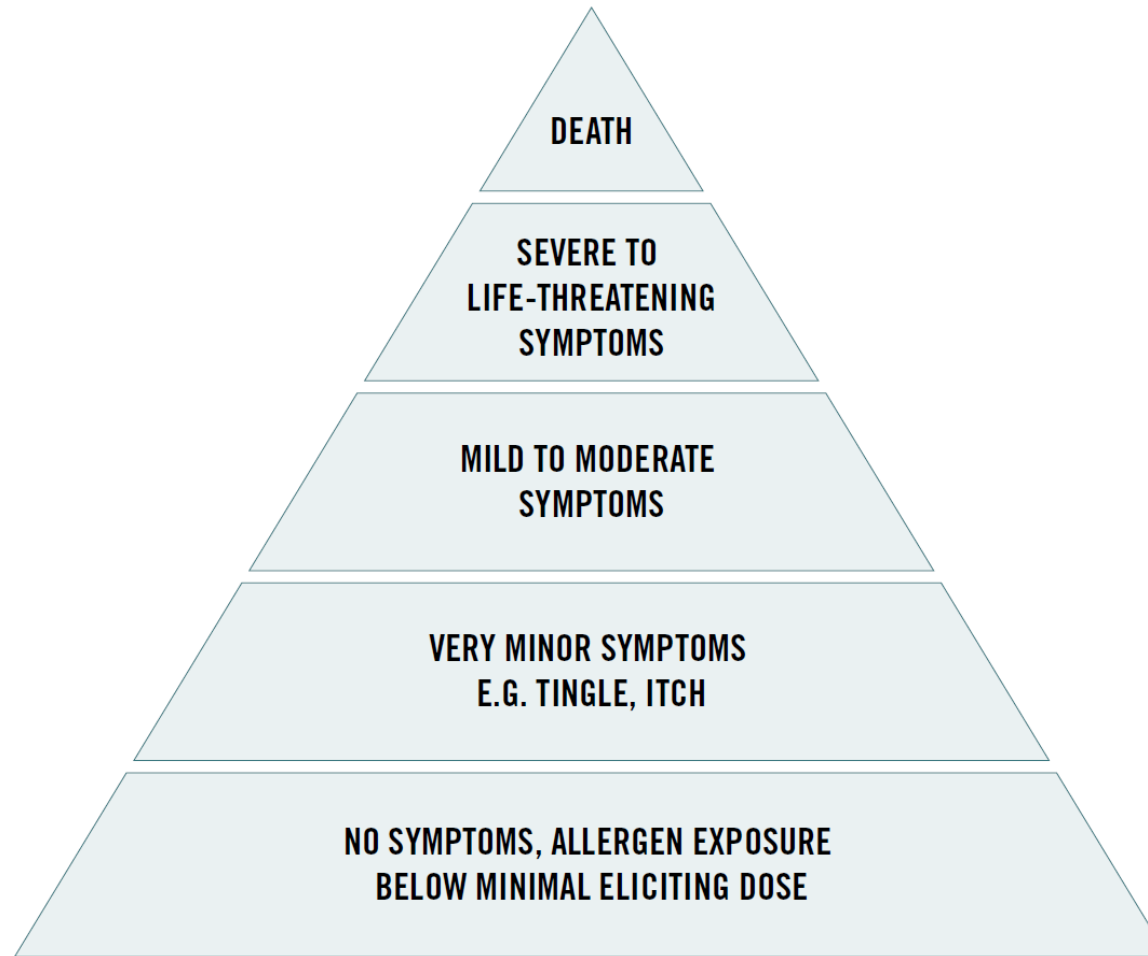
World allergy organization anaphylaxis guidance 2020

Victoria Cardona^{a*}, Ignacio J. Ansotegui^b, Motohiro Ebisawa^c, Yehia El-Gamal^d,
 Montserrat Fernandez Rivas^e, Stanley Fineman^f, Mario Geller^g, Alexei Gonzalez-Estrada^h,
 Paul A. Greenbergerⁱ, Mario Sanchez Borges^j, Gianenrico Senna^k, Aziz Sheikh^l,
 Luciana Kase Tanno^m, Bernard Y. Thongⁿ, Paul J. Turner^{o,1} and Margitta Worm^{p,1}

(Not anaphylaxis)		ANAPHYLAXIS		
Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Symptom(s)/sign(s) from 1 organ system present	Symptom(s)/sign(s) from ≥2 organ	Lower airway	Lower airway	Lower or upper airway
Cutaneous		Mild bronchospasm, eg, cough, wheezing, shortness of breath which responds to treatment	Severe bronchospasm eg, not responding or worsening in spite of treatment	Respiratory failure and/or
Urticaria and/or erythema-warmth and/or pruritus, other than localized at the injection site		And/or	And/or	Cardiovascular
And/or		Gastrointestinal	Upper airway	Collapse/hypotension
Tingling, or itching of the lips ^o or Angioedema (not laryngeal)*		Abdominal cramps* and/or vomiting/diarrhea	Laryngeal edema with stridor	And/or
Or Upper respiratory		Other	Any symptom(s)/sign(s) from grades 1 or 3 would be included	Loss of consciousness (vasovagal excluded)
Nasal symptoms (eg, sneezing, rhinorrhea, nasal pruritus, and/or nasal congestion)		Uterine cramps		Any symptom(s)/sign(s) from grades 1, 3, or 4 would be included
And/or		Any symptom(s)/sign(s) from grade 1 would be included		
Throat-clearing (itchy throat) ^a				
And/or				
Cough not related to bronchospasm				
Or Conjunctival				
Erythema, pruritus, or tearing				
Or Other				
Nausea				
Metallic taste				



FIGURE 2. HIERARCHY OF RISKS FACED BY PEOPLE SUSCEPTIBLE TO IgE-MEDIATED FOOD ALLERGY



Source: Reproduced with permission from Dubois *et al.*, 2018. Dubois, A.E.J., Turner, P.J., Hourihane, J., Ballmer-Weber, B., Beyer, K., Chan, C.-H., Gowland, M.H. *et al.* 2018. How does dose impact on the severity of food-induced allergic reactions, and can this improve risk assessment for allergenic foods?: Report from an ILSI Europe Food Allergy Task Force Expert Group and Workshop. *Allergy*, 73(7): 1383–1392. <https://doi.org/10.1111/all.13405>

TABLE 10 GLOBAL HEAT MAP OF COMMON FOOD ALLERGENS REPORTED TO CAUSE ANAPHYLAXIS, BY CODEX REGION AND COUNTRY/AREA

Severity: Heat Map

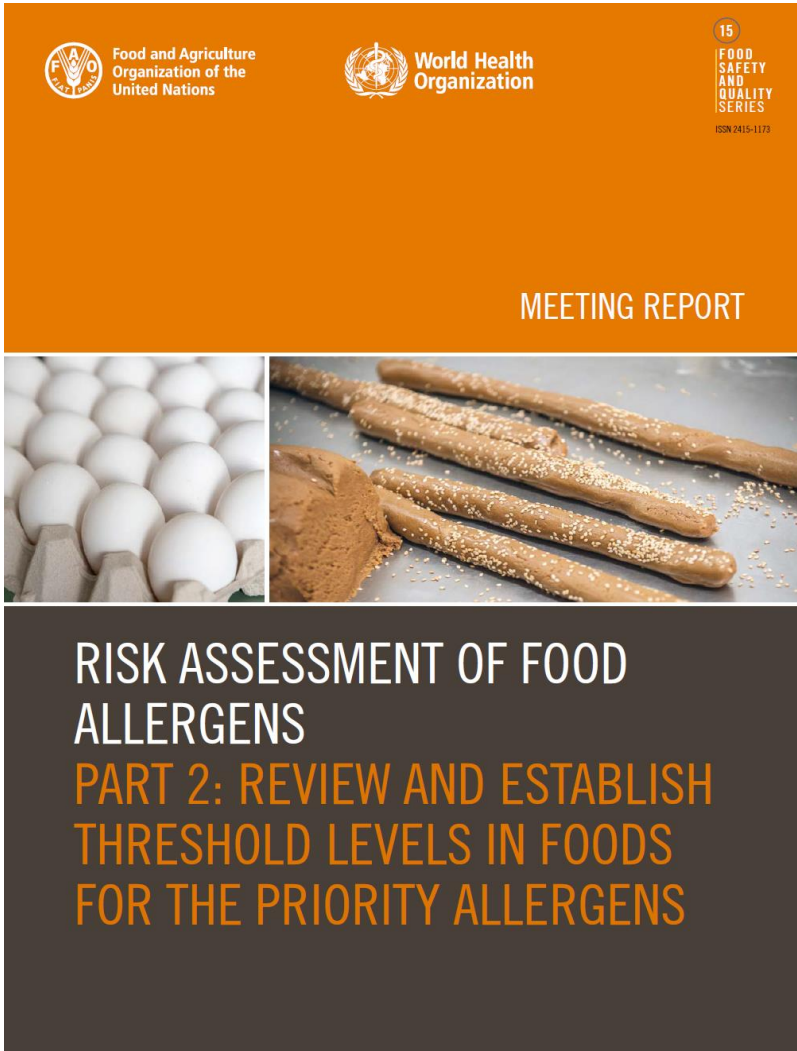
Severity: Classification Criteria

- Initial assignment was based on Table 10, but then included a consideration of the quality of other evidence relating to food allergy severity endpoints and a consensus decision was reached. An assessment of the evidence justifying the above categorization was also made for each allergen:
- Level 1
 - High level of confidence by the working group in the estimate of the proportion of anaphylaxis reactions due to a given food allergen (and thus further data is unlikely to substantially change confidence in this estimate).
- Level 2
 - Lower confidence that the available data indicates that a given allergen causes at least 5–10 percent of anaphylaxis reactions, and thus other evidence relating to fatal food anaphylaxis, allergen cross-reactivity and/or expert judgement required."

	PEANUT	TREE NUTS	SESAME	WHEAT	HEN'S EGG	COW'S MILK	CELERY	CRUSTACEA	MOLLUSCA	FISH	SOYBEAN	LUPINE	OTHER LEGUMES	FRUIT	BUCKWHEAT
CODEX	✓	✓		✓	✓	✓		✓		✓	✓				
AFRICA															
Morocco	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
South Africa	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓				
ASIA															
China	✓	✓		✓	✓	✓		✓		✓	✓			✓	✓
China, Hong Kong Special Administrative Region	✓	✓		✓	✓	✓		✓		✓	✓				
Japan	✓	(✓)		✓	✓	✓		✓		(✓)	(✓)			(✓)	✓
Republic of Korea	✓	(✓)		✓	✓	✓		✓	(✓)	✓	✓			✓	✓
Pakistan	✓	✓		✓	✓	✓		✓		✓	✓				
Philippines	✓	✓		✓	✓	✓		✓		✓	✓				
Singapore	✓	✓		✓	✓	✓		✓		✓	✓				
Sri Lanka															
Thailand	✓	✓		✓	✓	✓		✓		✓	✓				
EUROPE															
EU Member States	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Israel	✓	✓	✓	✓	✓	✓		✓		✓	✓				
Russian Federation	✓	✓	✓	✓	✓	✓		✓		✓	✓				
Switzerland	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Turkey	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
United Kingdom of Great Britain and Northern Ireland	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
LATIN AMERICA/CARIBBEAN (LAC)															
Argentina	✓	✓		✓	✓	✓		✓		✓	✓				
Brazil	✓	✓		✓	✓	✓		✓		✓	✓				
Chile	✓	✓		✓	✓	✓		✓		✓	✓				
Mexico	✓	✓		✓	✓	✓		✓	✓	✓	✓				
Venezuela (Bolivarian Republic of)	✓	✓		✓	✓	✓		✓		✓	✓				
NEAR EAST															
Iran (Islamic Republic of)	✓	✓	✓	✓	✓	✓		✓		✓	✓				
Qatar	✓	✓	✓	✓	✓	✓		✓		✓	✓	✓			
Saudi Arabia	✓	✓	✓	✓	✓	✓		✓		✓	✓	✓			
Tunisia															
NORTH AMERICA/SW PACIFIC (NASWP)															
Australia	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓			
Canada	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓			
New Zealand	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓			
United States of America	✓	✓	(✓)	✓	✓	✓		✓		✓	✓				

✓ indicates local legislation requiring disclosure for that allergen; (✓) indicates more limited or voluntary disclosure recommended. Heat map colours indicate relative (rather than absolute) prevalence of that allergen (group) as a common cause of food anaphylaxis in that region/country/area.

Source: Adapted and reproduced with permission from Baseggio Conrado et al., 2021.



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

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

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

Severity Assessment

- Assessment of severity is a critical component of hazard characterization, but the relationship of severity to exposure is complex and depends on many factors other than the amount of allergen (Dubois *et al.*, 2018).
 - Data are currently insufficient and inadequate to describe it mathematically, but clinical and epidemiological observations can provide relevant supporting data in relation to the amounts of allergen protein involved.
 - The expert committee agreed that considerations for reproducibility of thresholds (day-to-day variations in individual thresholds), cofactors, matrix effects, and data confounders should also be considered. Additionally, data on anaphylaxis in controlled challenge studies could be used.
- Based on an understanding that anaphylactic reactions according to accepted definitions (Cardona *et al.*, 2020; WAO) span a wide spectrum of severity/risk to life and include mild/non-severe reactions.

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

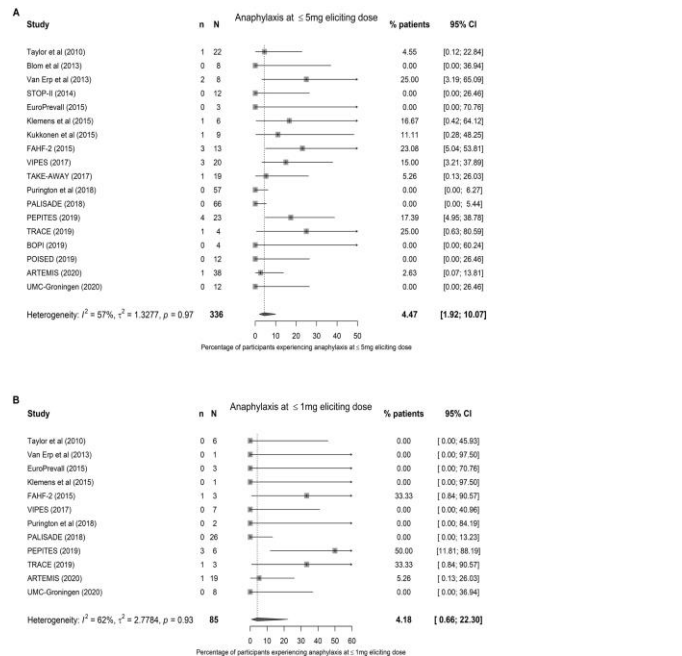
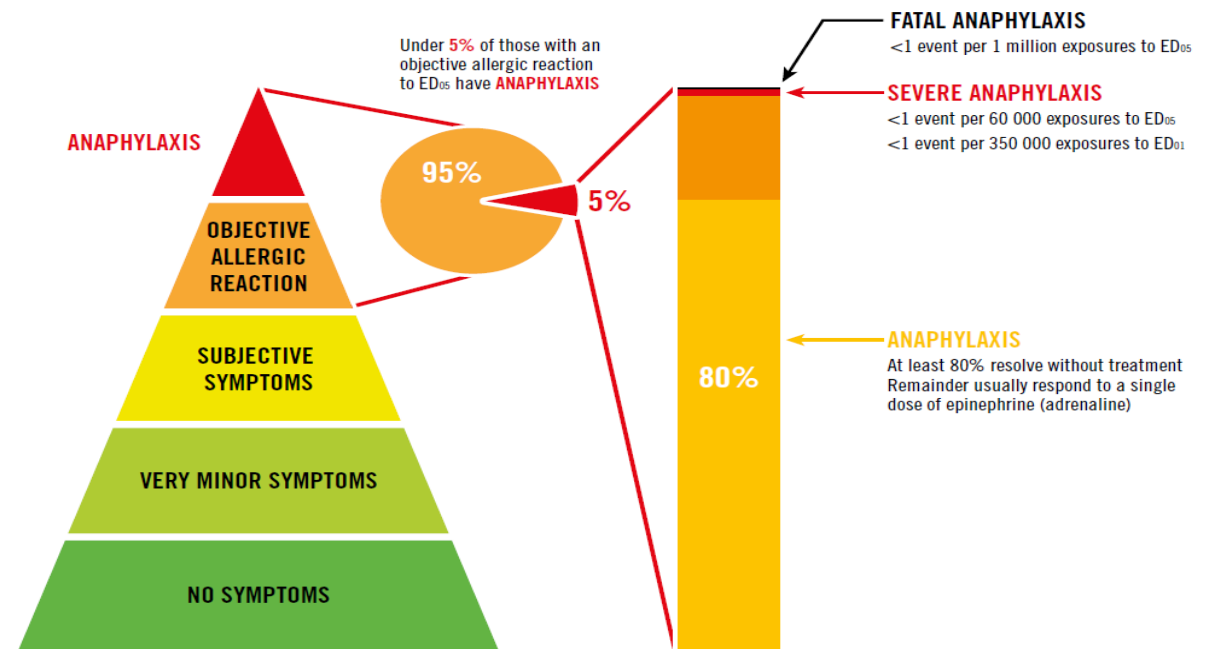


FIGURE 3. HIERARCHY OF RISKS FACED BY PEOPLE SUSCEPTIBLE TO IGE-MEDIATED FOOD ALLERGY, PROPORTIONATE TO THEIR ESTIMATED OCCURRENCE FOR PEANUT IN PEANUT-ALLERGIC INDIVIDUALS



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

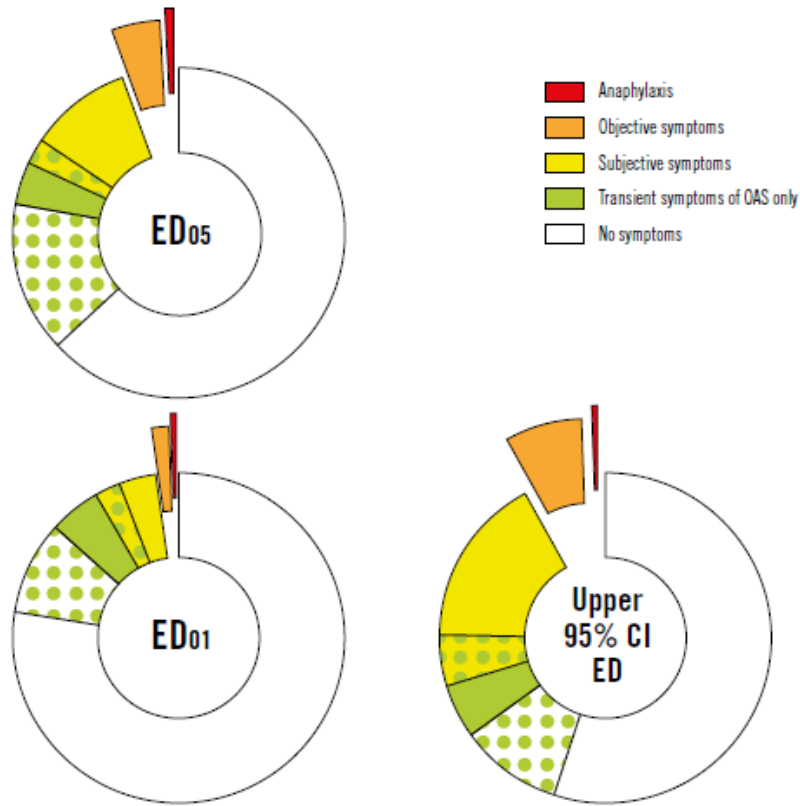
Note: ED₀₁, the eliciting dose predicted to provoke reactions in 1% of the allergic population; ED₀₅, the eliciting dose predicted to provoke reactions in 5% of the allergic population. Turner, P.J., Patel, N., Ballmer-Weber, B.K., Baumert, J.L., Blom, W.M., Brooke-Taylor, S., Brough, H. *et al.* 2022a. 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>

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

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

Virtual meeting, 15 March – 2 April 2021, [More info on Part 2](#) (full report)

FIGURE 4. PROPORTION OF PEANUT-ALLERGIC INDIVIDUALS EXPECTED TO HAVE SUBJECTIVE OR OBJECTIVE SYMPTOMS FOLLOWING EXPOSURE TO AN ED₀₅ OR ED₀₁ AMOUNT OF PEANUT. DATA FROM TABLE 5. (*OAS, ORAL ALLERGY SYMPTOMS)

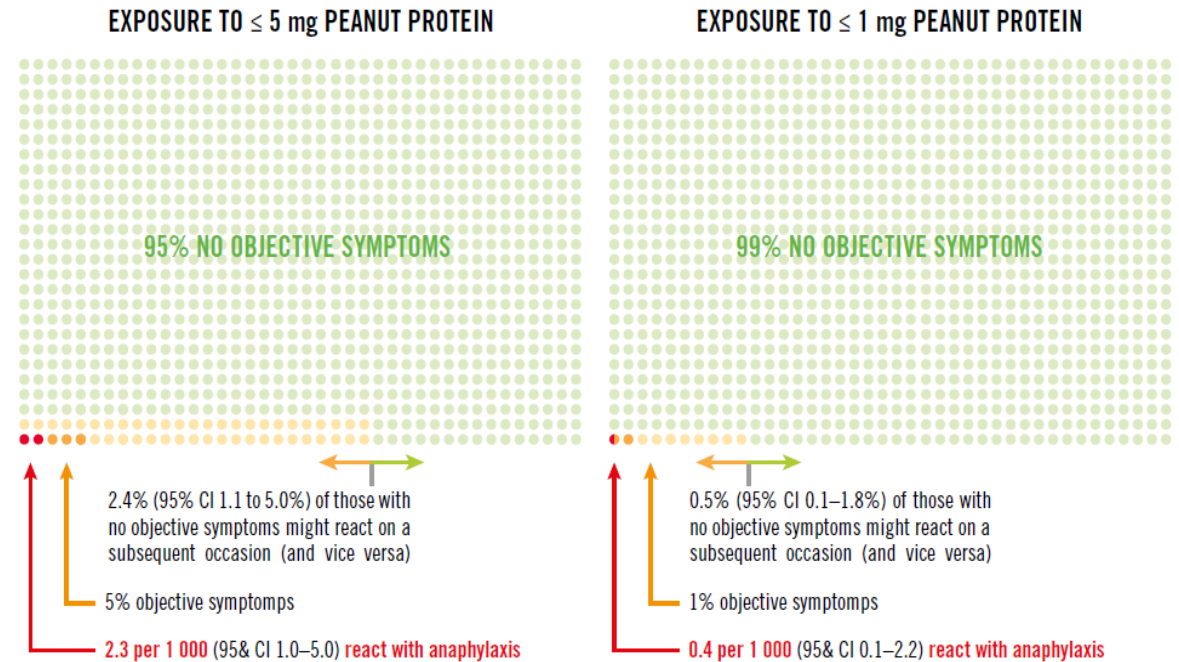


Source: Adapted with permission from Turner *et al.*, 2022a.

Note: OAS = oral allergy symptoms.

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>

FIGURE 5. PROPORTION OF PEANUT-ALLERGIC INDIVIDUALS WHO WOULD BE EXPECTED TO HAVE OBJECTIVE SYMPTOMS (INCLUDING ANAPHYLAXIS) FOLLOWING EXPOSURE TO ≤ 5 mg OR ≤ 1 mg AMOUNT OF PEANUT, AND AN INDICATION OF REPRODUCIBILITY, I.E. PROPORTION OF INDIVIDUALS WHO DO NOT EXPERIENCE OBJECTIVE SYMPTOMS ON ONE OCCASION WHO MIGHT REACT ON A SECOND SUBSEQUENT EXPOSURE



Source: Adapted with permission from Patel *et al.*, 2021a. Patel, N., Adelman, D.C., Anagnostou, K., Baumert, J.L., Blom, W.M., Campbell, D.E., Chinthrajah, R.S. *et al.* 2021a. Using data from food challenges to inform management of consumers with food allergy: a systematic review with individual participant data meta-analysis. *Journal of Allergy and Clinical Immunology*, 147(6): 2249–2262.e7. <https://doi.org/10.1016/j.jaci.2021.01.025>

TABLE 10 SUMMARY TABLE FOR THE RATE OF ANAPHYLAXIS TO ED05 LEVELS OF EXPOSURE IN ALLERGIC INDIVIDUALS. IT SHOULD BE NOTED THAT THE UPPER LIMIT OF THE 95 PERCENT CI FOR THE CUMULATIVE ED05 FOR SESAME SEED IS NOW ESTIMATED TO BE LESS THAN 58 MG SESAME SEED PROTEIN. AS SUCH, THE RESULTS FOR SESAME SEED IN THIS TABLE ARE CONSIDERED CONSERVATIVE

ALLERGEN	EVIDENCE BASE (number of FC included in dataset)	UPPER LIMIT OF THE 95% CI FOR CUM ED05 (mg protein)	EXPECTED RATE OF SYMPTOMS TO A LEVEL OF ALLERGEN EXPOSURE ≤ UPPER 95% CI FOR THE CUM ED05		EXPECTED RATE OF ANAPHYLAXIS TO AN ALLERGEN EXPOSURE ≤ UPPER 95% CI FOR THE CUM ED05, AS A PROPORTION OF	
			Any symptoms	Objective symptoms	Individuals reacting to ED05 exposure with objective symptoms	All individuals allergic to this food
PEANUT	3 151 DBPCFC	7.1 mg	35–45%	8%	4.5% (95%CI: 1.9% to 10%)	2.3 per 1 000 (95%CI: 1.0 to 5.1 per 1000)
CASHEW	323 DBPCFC 421 Open FC	9.4 mg	32%	12%	4.9% (95%CI: 2.2% to 10.5%)	2.5 per 1 000 (95%CI: 1.1 to 5.3 per 1000)
HAZELNUT	391 DBPCFC 43 Open FC	15.7 mg	~75%	9%	2.5% (95%CI: 0.3% to 15.8%)	1.2 per 1 000 (95%CI: 0.2 to 7.9 per 1000)
WALNUT	194 DBPCFC 156 Open FC	13.0 mg	~60%	14%	5.3% (95%CI: 2.0% to 13%)	2.7 per 1 000 (95%CI: 1.0 to 6.7 per 1000)
SESAME	59 DBPCFC 214 Open FC	58 mg	Not reported	20%	3.0% (95%CI: 0.8% to 11%)	1.5 per 1 000 (95%CI: 0.4 to 5.7 per 1000)
COW'S MILK	728 DBPCFC 317 other FC	6.6 mg	20%	9%	4.9% (95%CI: 2.1% to 11%)	2.5 per 1 000 (95%CI: 1.1 to 5.5 per 1000)
EGG	637 DBPCFC 543 other FC	5.3 mg	14%	9%	1.5% (95%CI: 0.02% to 55%)	0.8 per 1 000 (95%CI: 0 to 27 per 1000)
WHEAT	123 DBPCFC 23 Open FC	25 mg	Not reported	11%	2.2% (95%CI: 0.02% to 75%)	1.1 per 1 000 (95%CI: 0 to 38 per 1000)
FISH	59 DBPCFC	102 mg	58%	25%	Insufficient data for meta-analysis	
SHRIMP	12 DBPCFC 46 Open FC	1 850 mg	57%	19%		
SOYA	89 DBPCFC 51 Open FC	76 mg	Not reported	Not reported	0% (95%CI: 0% to 16.8%)	0 per 1 000 (95%CI: 0 to 8.4 per 1000)

Source: Reproduced with permission from Turner *et al.* (2022a). 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>

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- The latter indicated that all symptoms up to ED05 fell into a mild or moderate category,
- Analysis of clinical data indicated that up to 5% of reactions at both ED01 and ED05 could be classed as anaphylaxis, although none were severe, based on the World Allergy Organization definition.
- Furthermore, the Committee noted the extreme rarity of fatal food anaphylaxis (1 per 100,000 person-years in the allergic population) and observed that no fatal reactions had been observed following exposure to doses at or below those considered for RfD (i.e. the ED01 and the ED05).

SCIENTIFIC RATIONALE FOR RfD

- The RfD meet the criterion of “*exposure without appreciable health risk*”
 - This was defined as a probability of objective symptoms of <5 percent in the population of individuals with a relevant IgE-mediated food allergy when ingesting a dose not exceeding the RfD;
 - In those who do develop objective symptoms to a dose not exceeding the RfD, a probability of non-severe anaphylaxis (according to the World Allergy Organization definition) of <5 percent;
 - a risk of severe anaphylaxis (according to the World Allergy Organization definition) of <1:100 000 person years in the population of individuals with a relevant IgE-mediated food allergy; and
 - a risk of fatal reaction of <1 per million in the population of individuals with a relevant IgE-mediated food allergy when ingesting a dose not exceeding the RfD.
 - **Note: No severe or fatal anaphylaxis events have been reported following exposure to a dose not exceeding the RfD.**
- When non-severe anaphylaxis was observed in clinical studies, at least 80 percent resolve without any treatment, and >98 percent of the remainder respond to first line treatment (epinephrine/adrenaline).

TABLE 17 CONSENSUS REFERENCE DOSE (RfD) RECOMMENDATIONS FOR CODEX PRIORITY ALLERGENS

	RFD RECOMMENDATION (mg total protein from the allergen c 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 Reference Doses into Action Levels

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

Method performance criteria indicate that the limits of quantification (LoQ) of any method utilized for a specific food should be approximately 3-fold lower than the action level for that food in order to account for real-world performance variability and to assure that the analytical result is truly at or below the action level.

TABLE 13 LIMITS OF QUANTIFICATION (LoQ) REQUIRED FOR ANALYTICAL METHODS TO MEET CALCULATED ALs (TABLES 11 AND 12), TAKING INTO ACCOUNT METHOD PERFORMANCE

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	6 666	166	166	100	66	66	66	66	33	33
20	3 333	83	83	50	33	33	33	33	16	16
30	2 166	50	50	33	21	21	21	21	10	10
40	1 666	33	33	25	16	16	16	16	8.3	8.3
50	1 333	33	33	20	13	13	13	13	6.6	6.6
60	1 000	26	26	16	10	10	10	10	5	5
70	833	23	23	13	8.3	8.3	8.3	8.3	3.3	3.3
80	833	20	20	11	8.3	8.3	8.3	8.3	3.3	3.3
90	666	18	18	10	6.6	6.6	6.6	6.6	3.3	3.3
100	666	16	16	10	6.6	6.6	6.6	6.6	3.3	3.3

ppm action levels based on RfD of the ED05

RfD in mg	Crustacea	Fish	Wheat	Hazelnut	Sesame	Milk	Egg	Peanut	Cashew	Walnut
RFA in grams	25	1.3	0.7	0.1	0.2	0.2	0.2	0.2	0.05	0.03
10	833	43	23	3	7	7	7	7	2	1.0
20	417	22	12	2	3	3	3	3	0.8	0.5
30	278	14	8	1.1	2	2	2	2	0.6	0.3
40	208	11	6	0.8	2	2	2	2	0.4	0.3
50	167	9	5	0.7	1.3	1.3	1.3	1.3	0.3	0.2
60	139	7	4	0.6	1.1	1.1	1.1	1.1	0.3	0.2
70	119	6	3	0.5	1.0	1.0	1.0	1.0	0.2	0.1
90	93	5	3	0.4	0.7	0.7	0.7	0.7	0.2	0.1
100	83	4	2	0.3	0.7	0.7	0.7	0.7	0.2	0.1

ppm action levels based on RfD of the ED01

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

Thank You For Your Attention

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