The Task set by Codex

- **Part 1: Review and validation of Codex priority allergen list through risk assessment**
(30 November-11 December 2020, 28 January 2021, 8 February 2021)

- **Part 2: Review and establish threshold levels in foods for the priority allergens**
(15 March-2 April 2021)

- **Part 3: Review and establish precautionary labelling in foods of the priority allergens**
(18-29 October, 3rd November 2021)

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Revision of Codex priority allergen list (GSLPF)

Scope

- Are published **criteria** (FAO/WHO, 2000) still current and appropriate?

- Are there foods and ingredients that should be added to or deleted from the list?

- Are groupings of certain foods and ingredients (e.g. tree nuts) appropriate?

- Can certain ingredients derived from allergenic sources be exempted from mandatory declaration?

Criteria for inclusion on Codex priority allergen list

- List should be limited to:
  - Substances provoking **well-characterised immune-mediated reactions** i.e. IgE-mediated reactions and coeliac disease.
  - Allergenic foods with **global** impact
- Inclusion should be based on
  - *Prevalence*: in unselected populations, global and in different WHO/FAO regions
  - *Severity*: based on proportion of anaphylaxis cases and number of FAO/WHO regions affected
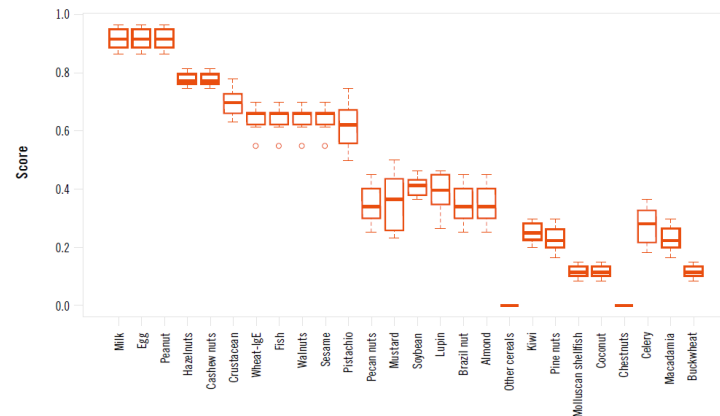 - *Potency*: based on ED_{50} (median population MED) from dose distribution modelling

Criteria for addition to/exclusion from Codex list

Data scoring and normalisation

Recommended global priority allergens

- Cereals containing gluten (i.e., wheat and other *Triticum* species, rye and other *Secale* species, barley and other *Hordeum* species and their hybridized strains)

- Crustacea

- Egg

- Fish

- Peanut

- Milk

- Sesame

- Tree nuts (specific) i.e. almond, cashew, hazelnut, pecan, pistachio and walnut

Other recommendations

- *Insufficient data for*

  - Buckwheat, celery, lupin, mustard, oats, soybean and certain tree nuts (Brazil nut, macadamia, pine nuts) to qualify as global priority allergens but

  - Can be considered for inclusion on regional/country lists of priority allergens

- *Some foods warrant inclusion on a "watch list" owing to dietary trends:*

  - Pulses, insects and other foods such as kiwi fruits

  - To be evaluated for the priority allergen list when sufficient data on prevalence, severity and potency become available

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Terms of Reference (from Codex)

2. Thresholds

- *What are the threshold levels for the priority allergens (e.g. cereals containing gluten, crustaceans, eggs, fish; milk, peanuts, soy, sesame and tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut) below which the majority of allergic consumers would not suffer an adverse reaction?*

    o *Are sufficient data available to establish threshold levels for (all) allergens? If not, what data are needed?*

    o *What are thresholds or levels associated with low, intermediate or high risk for allergic reactions or other adverse health consequences?*

    o *Is there an acceptable level of allergic reaction risk which does not negatively impact public health?*

- *For the priority allergens, what are appropriate analytical methods for testing food and surfaces?*

- *What should be the minimum performance criteria for these different analytical methods?*

Delivery of Terms of Reference (ToR)

- ToR indicate that thresholds should be Health-Based Guidance Values (HBGV), as defined in EHC 240 Chapter 5 i.e. they represent "*exposure without appreciable health risk*"

- After review of several possible approaches, the Committee concluded that Benchmark dose (without MoE) and Probabilistic Hazard assessment are equivalent and best meet the requirements. Operationally, these are based on dose-distribution modelling.

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)"*

- Considerations in recommending RfDs:

  - Data quantity, quality, availability and accessibility

  - Contextualisation: taking into account wider and unintended consequences, i.e. would a more stringent (lower) ED value materially improve public health impact? Would it be enforceable?

Data considerations

- **Dose-distribution data**

  - Dataset reported in publications of Remington, *et al*., (2020) and Houben, *et al*., (2020)

  - Most comprehensive and best described

  - Quality criteria described in peer-reviewed publication (Westerhout et al 2019)
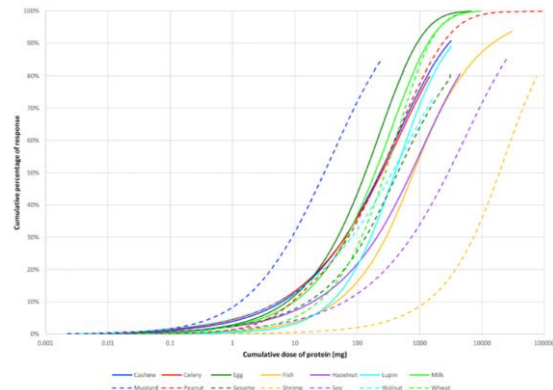
- **Severity data**

  - Based on frequency of anaphylaxis (WAO definition) in controlled clinical challenges at different ED values under consideration as basis of RfD (ED_{01} and ED_{05})

  - Additional analyses of symptom severity at ED_{01}, ED_{05} and ED_{10} in dose-distribution dataset.

  - Using peanut data as an exemplar

After *Houben et al, (2020)*

- Peanut Can Be Used as a Reference Allergen for Hazard Characterization in Food Allergen Risk Management: A Rapid Evidence Assessment and Meta-Analysis

Turner et al., 2021. https://doi.org/10.1016/j.jaip.2021.08.008
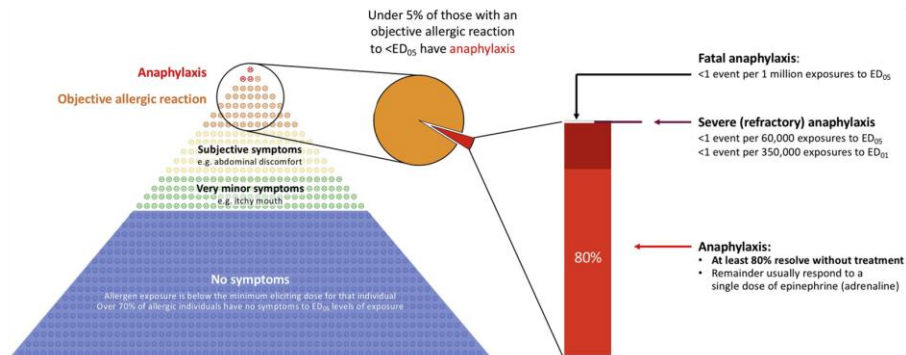
Recommended Reference Doses for priority allergens

- Based on the considerations outlined, the Committee concluded that RfDs *derived from* the ED_{05} would meet the safety objective.

- To simplify application:

    - Derived ED_{05} values rounded down to one significant figure.

    - Foods with close ED_{05} values then grouped together and a single value derived for the RfD.

	Reference Dose (RfD) recommendation (mg total protein from the allergenic source)
Walnut (and Pecan*)	1.0
Cashew (and pistachio*)	1.0
Almond**	1.0
Peanut	2.0
Egg	2.0
Milk	2.0
Sesame	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Shrimp	200

*see considerations in full report

** provisional

Further recommendations

- Provide a table from which action levels can be derived for amounts of the affected food from 10g to 510g in 10g intervals [action level (mg/kg) = RfD (mg)/reference amount (kg)], to be used in conjunction with Reference Amounts.

- Standardise analytical results by expressing them as mg of total protein from the allergenic source per kg of the food product analysed

- Apply a default uncertainty factor to the claimed limit of detection of analytical tests to allow for method performance issues

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Review and establish precautionary labelling in foods of the priority allergens

Conclusions

- Precautionary allergen labelling (PAL) can be an effective strategy to protect consumers from unintended allergen presence (UAP)

- Current use of PAL is voluntary and often not part of a standardized risk assessment process, leading to confusion among consumers

- The available evidence indicates that some manufacturers, consumers and other stakeholders do not understand current strategies to communicate precautionary messages relating to risks posed by UAP in products.

Review and establish precautionary labelling in foods of the priority allergens
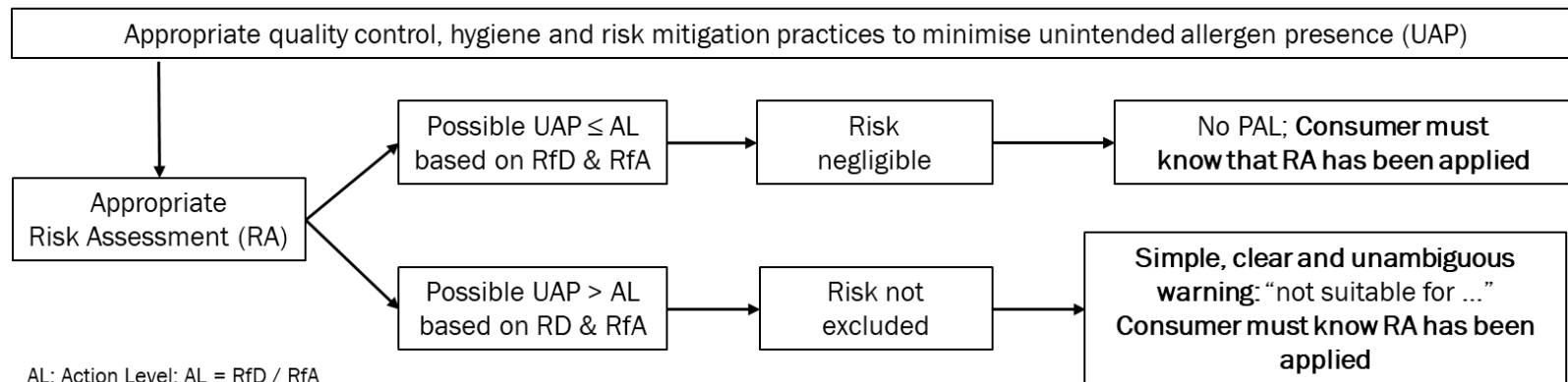
Conclusions (ctd)

- The use of a PAL system based on risk–based reference doses (RfDs) would be protective for the vast majority of food-allergic individuals.

- RfDs recommended in the 2nd meeting are **not** intended to be used for making a claim that a food is **free-from** specified allergens.

Review and establish precautionary labelling in foods of the priority allergens

Recommendations

- The decision whether or not to use a PAL statement should be part of a regulatory framework

Principle of proposed guidance on Precautionary Allergen Labeling

| Appropriate quality control, hygiene and risk mitigation practices to minimise unintended allergen presence (UAP) |

Appropriate Risk Assessment (RA)

Possible UAP ≤ AL based on RfD & RfA → Risk negligible → No PAL; **Consumer must know that RA has been applied**

Possible UAP > AL based on RD & RfA → Risk not excluded → **Simple, clear and unambiguous warning**: "not suitable for ..." **Consumer must know RA has been applied**

AL: Action Level; AL = RfD / RfA
RfD: Reference Dose; as defined by 2nd meeting of FAO/WHO consultation or estimated using the approach as defined by 2nd meeting of FAO/WHO consultation
RfA: Reference Amount; p50 or mean of the single eating occasion general population intake distribution of the food
UAP: Unintended Allergen Presence

What next?

2022:

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

2023:

Next meeting of Codex Alimentarius commission

www.ilsi.eu
www.foodprotection.org

Thank you for your attention