

Food consumption data in food allergen risk assessment



Precautionary (“may contain”) allergen labelling

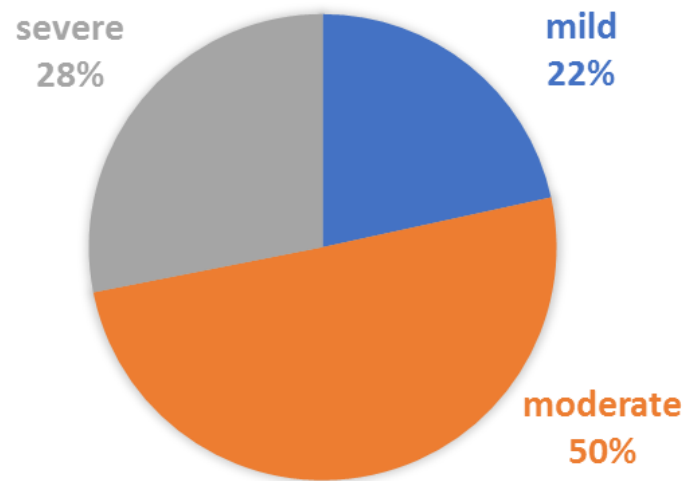
- To warn allergic consumers for possible unintended allergen presence in a product and to protect companies from claims
 - **Lacks correlation with actual risks of presence of non-ingredient allergens in a wide variety of products**
 - Analytical surveys : EU Pele et al, 2007, NL VWA 2007, Spanjersberg 2010; Ireland 2011; USA Remington 2013; Germany Waiblinger 2018; NL Blom 2018, Global overview Allen and Taylor, 2018
- **Products with a warning: 7 - 93 % contained allergen**
- Thus: 7 - 93 % no allergen!*
- **Products without a warning: 11 - 53 % contained allergen**



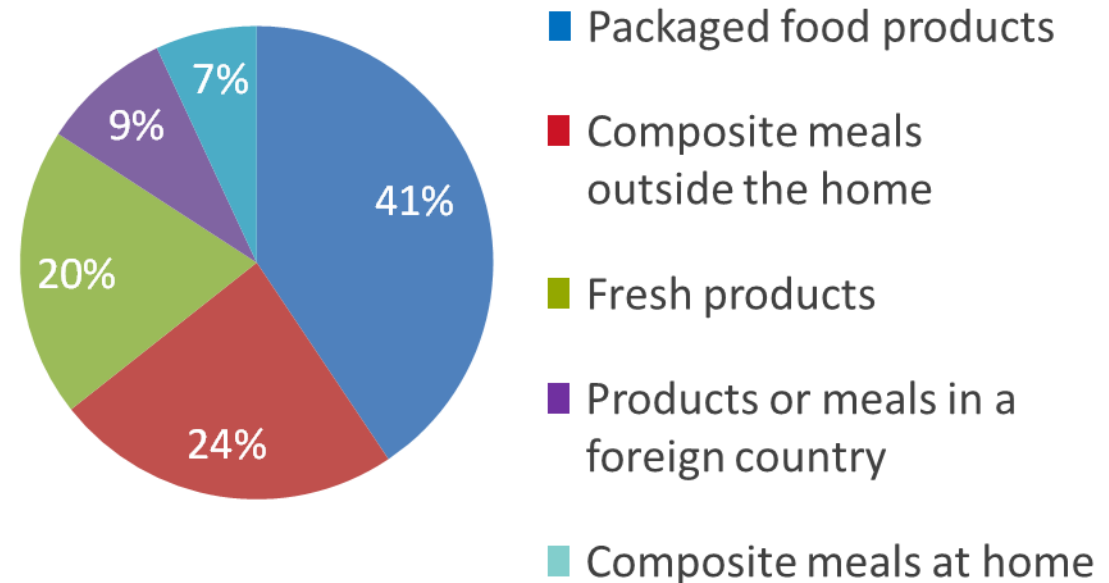
Accidental allergic reactions to products

Michelsen-Huisman et al ALLERGY 2018 doi: 10.1111/all.13560

- **Prospective study with Dutch food allergic patients:**
 - 46% of patients had 1 or more unexpected reactions during 1 year follow up
 - Reactions were mostly moderate to severe + 6 Emergency Room admissions



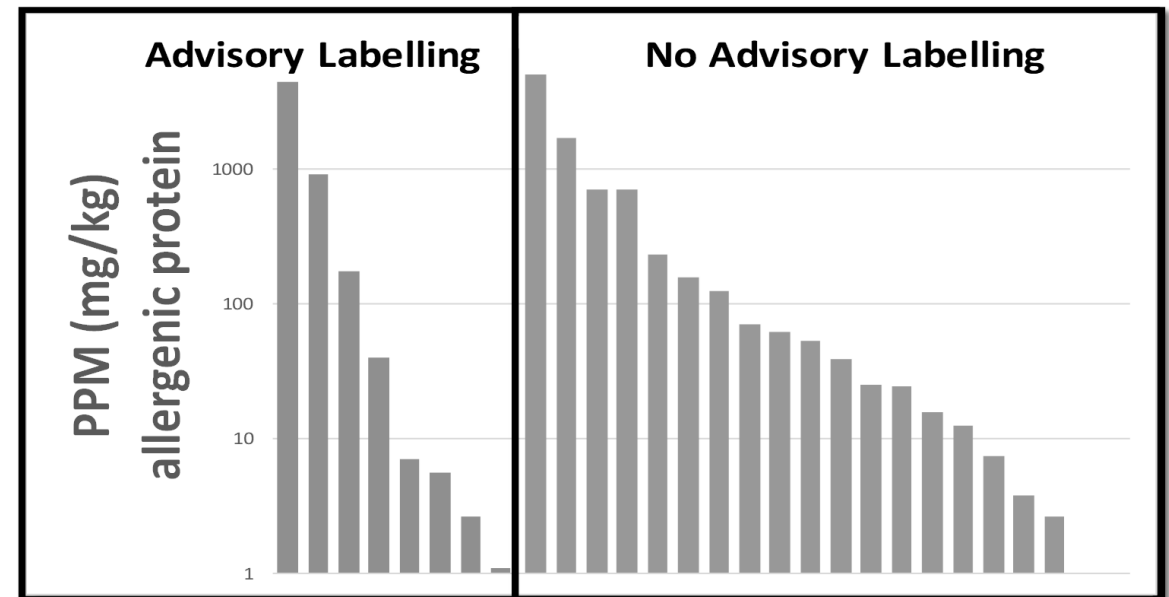
Causal food in accidental reactions



Accidental allergic reactions to products

Blom et. al., J ALLERGY CLIN IMMUNOL 2018, <https://doi.org/10.1016/j.jaci.2018.04.041>

- **Prospective study with Dutch food allergic patients:**
- In 38% of the products, 1 to 4 culprit non-ingredient allergens identified
- PAL was absent for 59% of products causing accidental reaction
- For some products PAL was present for *other allergens* than those identified
- PAL was ignored by part of the patients
- Levels of allergens present was comparable for products with or without PAL
- **Guidance is highly needed!**



Risk based precautionary allergen labelling

Guidance for industry



[Home - Allergen Bureau | Informing Industry](#)

Food allergen management, labelling, and the VITAL® Program

The Allergen Bureau management, labelling, whether and how the...
These best practice approach allergen m...
Are you already prof...

[VISIT VITAL ONLINE](#)


Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment within Food Operations

ILSI Europe Report Series

REPORT

Commissioned by the Food Allergy Task Force

[ILSI-Eu_Guidance-on-QRA-final.pdf](#)



[Precautionary allergen labelling | Food Standards Agency](#)

Food hygiene ratings

to fraud or criminality in food supply chains, or you wish to whistleblow regarding a food business for which you 276 8787 (9am to 4pm Monday-Friday) or [report via our online service](#).

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Guidance on Food Allergen Management for Food Manufacturers Version 2



[Guidance on Food Allergen Management for Food Manufacturers - FoodDrinkEurope : FoodDrinkEurope](#)

e for food

providing allergen information and best

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And many other (local) initiatives...

Risk based precautionary allergen labelling

- Lack of an agreed, consistent approach to quantitative risk assessment for unintended allergen presence.
- This led to variety of standards applied by food business, and by enforcement authorities across Europe and the world.

2020-2023 Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens



Part 1: Global priority allergenic foods list, November-December 2020

Part 2: Health-based guidance values (Reference Doses) for priority allergenic foods, March 2021

Part 3: Guidance for precautionary allergen labeling, October 2021

Part 4: Assessment of exemptions for allergen labeling, November 2022

Part 5: Reference Doses for selected non-global priority allergenic foods, March 2023

Risk based precautionary allergen labelling

2020-2023 Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens

Part 1: Establishment of global priority allergenic foods list

Part 2: Establishment of health-based guidance values (Reference Doses) for priority allergenic foods

Part 3: Guidance for precautionary allergen labeling

“The use of PAL should be restricted and applied to those situations where UAP cannot be prevented and may result in an exposure above the RfD for a priority allergenic food.”

Key step: establishment of Action levels for Precautionary Allergen Labeling:

$$AL = RfD / RfA$$

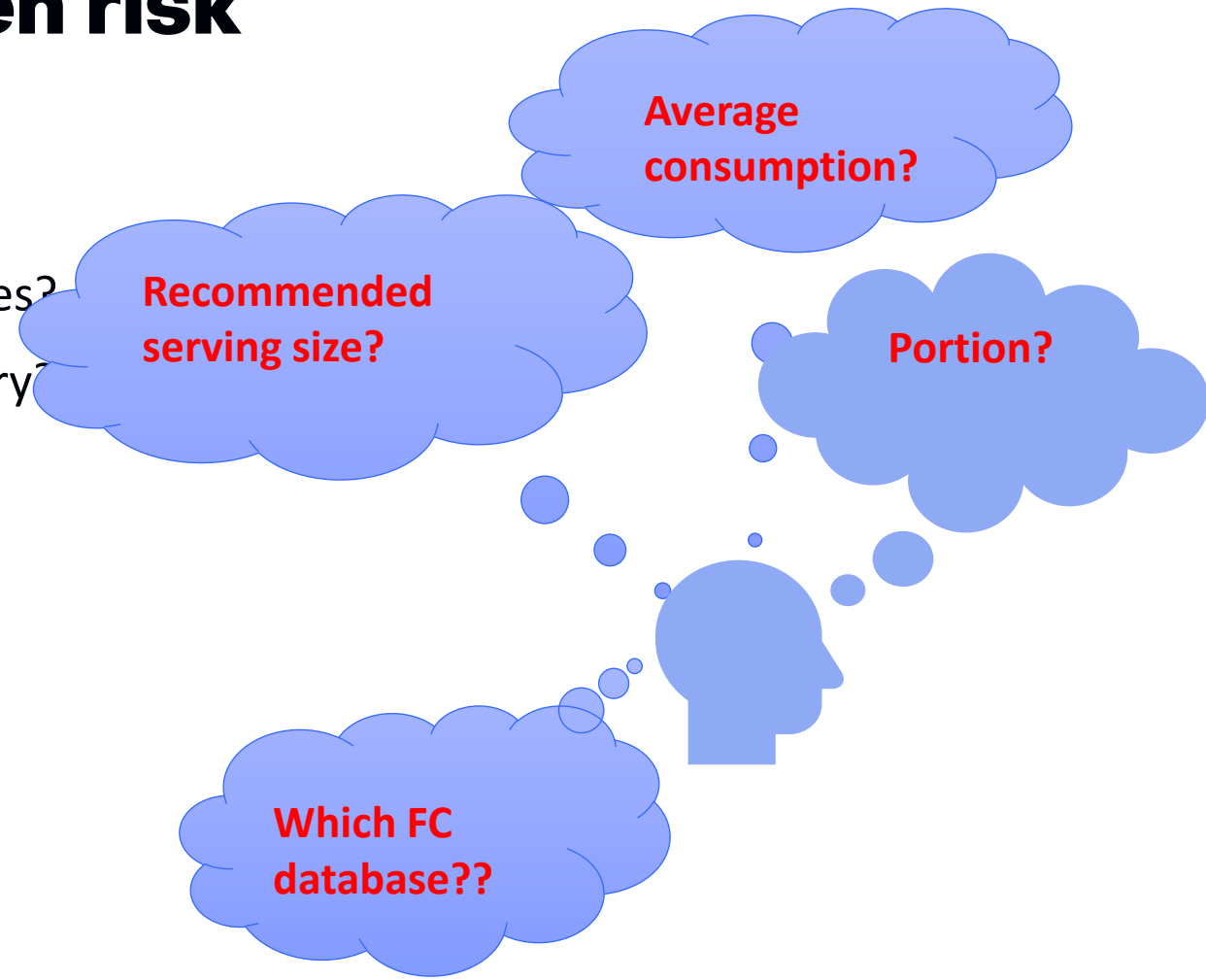
AL: Action Level in mg total protein from the allergenic food/kg food containing the UAP

RfD: Reference Dose in mg total protein from the allergenic food

RfA: Reference Amount of the food containing the UAP in kg

Food intake data for allergen risk assessment

- General population vs Population with food allergies?
- Can I use data from one country for another country?
- What intake figure to use in allergen risk assessment?
- Frequency of consumption



General population vs Population with food allergies

- Study comparing the food intake levels of the general population showed that these represent those of food allergic patients
- Intake data from food consumption surveys in the general population can be used to estimate the risk from allergens, without under- or overestimating the risk for the population with food allergies
- Blom et al. 2020 - <https://doi.org/10.1016/j.fct.2020.111781>



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Allergen risk assessment: Food intake levels of the general population represent those of food allergic patients

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Check for updates

Intake one country for another country

- National population-based food consumption surveys are used in food allergen risk assessment.
- It would be beneficial if food intake data is interchangeable between countries
 - to bridge potential gaps present in national survey data
 - only possible when risk assessment outcomes for comparable food product groups between countries are fairly similar.
- Recent studies :
 - United States and Dutch population food consumption survey data¹
 - French, Danish and Dutch population food consumption data²
 - Results per country can differ considerably for some food groups.
 - **It is recommended to develop and use a food intake dataset based on the highest intake levels for each food group of the involved countries to facilitate risk management efforts and harmonization.**



¹ Meima et al 2021 - <https://doi.org/10.1016/j.fct.2021.112006>

² Birot et al 2018 - <https://doi.org/10.1016/j.fct.2018.05.042>

Food intake data for allergen risk assessment

- It is crucial to carefully consider the selection of the most appropriate food intake figure when performing an action level calculation or deterministic risk assessment:
 - Data on real intake
 - Food intake distribution created from highest single eating occasion for each individual of the consumer population
 - The optimal point estimate of the food intake distribution for the predefined safety objective :
 - sensitivity analysis to derive this point estimate *Blom et al 2019* - <https://doi.org/10.1016/j.fct.2019.01.025> ; *Blom et al 2023 submitted*
- **Exceptions can be:**
 - When a company has good data on how much is consumed at a single eating occasion of their specific product these data are useful to consider.
 - For some products the exact quantity can more easily be established (e.g. airplane meals)
- If more sophisticated probabilistic risk assessment methods are deemed necessary, the full consumption distribution of products of population-based dietary surveys are the input value.

What intake figure to use in allergen risk assessment?

- It is tempting to choose a portion size or a recommended serving size as they are “single eating occasions”
- Should not be used, because they generally are provided for nutritional purposes, and usually do not reflect actual intakes.
- For example: people typically do not consume one slice of bread or a recommended serving size at an eating occasion
- In fact: Average consumption ~2-3 slices, and can range between less than one slice up to more than 5 slices of bread.



What intake figure to use in allergen risk assessment?

- Example bread

	Portion size 1 slice *)	Recommended Serving size **)
EU	35-50 gram*)	70-100 gram
US	26-38 gram**)	55 gram

*) www.ncb.nl; www.voedingscentrum.nl

**) example found on a bread; [Food Labeling SECG on Serving Size of Foods \(fda.gov\)](https://www.fda.gov/food/food-labeling-secg-on-serving-size-of-foods);

***) Birot et al 2018; Meima et al 2021

Identify the optimal food intake figure for action level calculation and deterministic food allergen risk assessment

- Principle of the sensitivity analysis to identify the consumption percentile described in Blom et al 2019 FCT
<https://doi.org/10.1016/j.fct.2019.01.025>

Sensitivity Analysis





Deterministic Probabilistic
Risk Assessments Risk Assessments

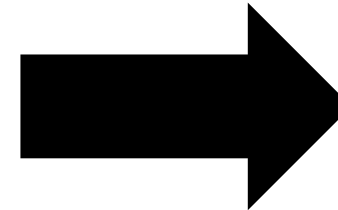
Safety objective, which can be ED01,
ED05, ED10, ...

Identify the optimal food consumption percentile for action level calculation and deterministic food allergen risk assessment

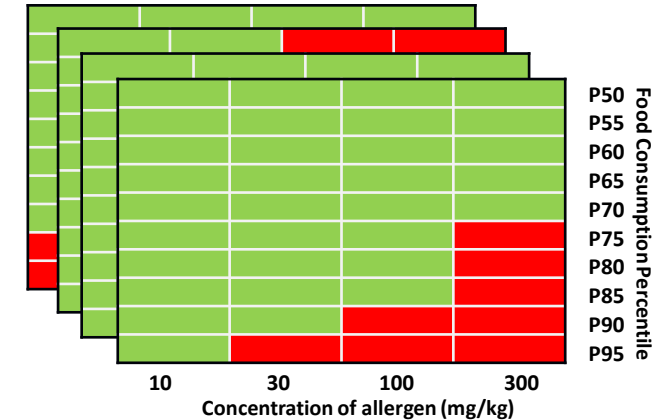
- Principle of the sensitivity analysis in Blom et al 2019

Sensitivity Analysis

	Deterministic Risk Assessments		Probabilistic Risk Assessments
<i>Correct prediction</i>		✓	≤ 1%
<i>Underestimation</i>		✗	> 1%
<i>Overestimation</i>		✓	≤ 1%
<i>Correct prediction</i>		✓	> 1%
	pass or fail		average % risk ± sd

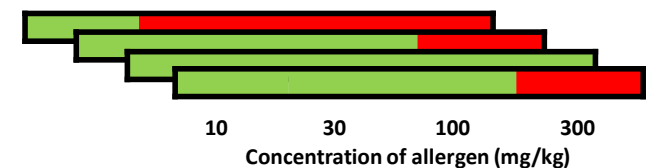


1344 Deterministic Risk Assessment Outcomes



VS

Probabilistic Risk Assessment Outcomes



Identify the optimal food consumption percentile for action level calculation and deterministic food allergen risk assessment

- Applied the sensitivity analysis using the most recent methodology and data on population thresholds
(Wheeler 2021; Remington et al, 2020; Houben et al, 2020)
- Several food survey databases (*United States, North-West Europe and Netherlands*) were analyzed to identify optimal food intake values using this Sensitivity Analysis.
- Predefined safety objective:
 - the risk of an objective allergic reaction at ED01, ED2.5, ED05 or ED10 doses of 14 allergenic foods (Houben et al., 2020).
 - The addressed ED-range covered FAO-WHO recommended Reference Doses



Optimal food consumption percentile - results

- In 99.9% of all 28,784 scenarios, the P50 of food consumption distribution met the criteria.

Discrete dataset	Food intake database				
	NW EU		United States (US)		Netherlands (NL)
	adults n=728	adults n=742	children n=728	adults n=714	children n=686
ED01					
<i>P50</i>	100%	100%	100%	100%	99.9%
<i>P55</i>					99.9%
<i>P60</i>					100%
ED02.5					
<i>P50</i>	100%	100%	100%	100%	100%
ED05					
<i>P50</i>	100%	100%	100%	100%	100%
ED10					
<i>P50</i>	100%	100%	100%	100%	100%

cumulative dataset	Food intake database				
	NW EU		United states (US)		Netherlands (NL)
	adults n=728	adults n=742	children n=728	adults n=714	children n=686
ED01					
<i>P50</i>	100%	99.6%	99.3%	99.3%	99.7%
<i>P55</i>		99.7%	100%	99.9%	99.9%
<i>P60</i>		100.0%		99.9%	100%
<i>P65</i>				100%	
ED02.5					
<i>P50</i>	99.9%	99.5%	99.6%	99.7%	99.7%
<i>P55</i>	99.9%	100%	100%	99.9%	100%
<i>P60</i>	99.9%			100%	
<i>P65</i>	100%				
ED05					
<i>P50</i>	100%	100%	99.9%	100%	99.9%
<i>P55</i>			100%		100%
ED10					
<i>P50</i>	100%	100%	100%	100%	100%

Optimal food consumption percentile - results

- In 99.9% of all 28,784 scenarios, the p50 of food consumption met the criteria.
- Reference amounts (RfAs) based on the p50 to p65 of the general population distribution of the single-eating occasion intake of foods result in compliance with the safety objective intended by using RfDs based on ED05.
- Recommended to use the p50 as the RfA.
- If the p50 is not available, the mean of the population distribution of the single-eating occasion intake of food would be a good alternative, as analyses of the intake data showed that the mean generally is between the p50 and p65.



The 50th percentile of the general population single eating occasion intake of food is optimal for the calculation of action levels for precautionary allergen labeling.

W. Marty Blom, Joost Westerhout, Geert F. Houben.
Food Chemical Toxicology (submitted)

Part 1: Priority allergen list

Part 2: Threshold levels in foods of the priority allergens

Part 3: Precautionary labelling in foods of the priority allergens

Part 4: Exemption for the food allergens

Part 3: Precautionary labelling in foods of the priority allergens

[FAO/WHO - Part 3 Summary report](#) ; [Full report 3](#)

Key step: establishment of Action levels for Precautionary Allergen Labeling

$$AL = RfD / RfA$$

AL: Action Level in mg total protein from the allergenic food/kg food containing the UAP

RfD: Reference Dose in mg total protein from the allergenic food

RfA: Reference Amount of the food containing the UAP in kg

RfA: p50 or mean of the general population distribution of the single eating occasion intake of a food

based on Blom et al. (submitted)

Frequency of consumption

- Good data on frequency of consumption of products by the food allergic population are lacking
- A consumer with food allergy may completely avoid certain products/categories or eat alternative similar products depending on their allergy profile, e.g.
 - a seemingly safe product in the same food group
 - replace a milk product for drinking with a soy-based milk product for drinking.
- But Blom et al. 2020 showed that in case food allergic individuals choose to eat a product, the amounts consumed are, on a population distribution basis, comparable to those of non-allergic consumers
- **Therefore, it is recommended to conduct risk assessments and express the risks on an allergic user-basis**



TNO Shared Research Program Food Allergy

- Food intake guidance tool – *in development*
- For a company, allergen risk assessment and an allergen management program (such as VITAL) should be broadly applicable with limited repeated effort.
- The SRP Food Allergy program combined knowledge on food intake and developed a Food Intake Guidance tool for use in allergen risk assessment and (VITAL) action level calculations.
 - Guides users to the food group
 - Provides food intake amounts for action level calculations or quantitative risk assessment
 - Based on science
 - Provides reference amounts and harmonization in food intake data
 - Also offers flexibility in choices and allows for company specific food intake data



TNO Food intake guidance tool



Stepwise approach guiding the user to the correct food group and reference amount



- Reference amounts for
- action level calculations
 - allergen risk assessment



Thank you for your attention

For more information :

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Research

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