

› **Food consumption estimates for practical application in risk assessments and risk management programs**

Benjamin C. Remington, PhD
Marty Blom, PhD
Geert Houben, PhD

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Introduction

- › Food consumption estimates utilized for food allergen risk assessments and food allergen risk management programs should be:
 - › Easy-to-use,
 - › Conservative in nature,
 - › Representative of consumption patterns of allergic individuals
- › There is no consensus on how to use food consumption data when assessing the risk from unintended allergen presence in food products
- › However, multiple recent studies have investigated different datagaps regarding consumption estimates for food allergen risk assessments, the results of which are presented here

Introduction

- › Three main areas of interest were investigated:
 - › 1) simplification of consumption estimates from governmental dietary surveys for use in industry-guided food allergen management programs;
 - › 2) to investigate whether food consumption amounts at single eating occasions in the allergic population are comparable to those in the general population for use in allergen risk assessment;
 - › 3) if consumption estimates provided from dietary surveys in one country are representative for the population of another country.

Introduction: 3 areas of interest

1. Consumption point estimate

- › Simplification of consumption estimates from governmental dietary surveys for use in industry-guided food allergen management programs

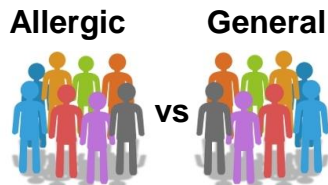


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2. Allergic vs General Pop Consumption Patterns

- › Investigate if food consumption amounts at single eating occasions are comparable for use in allergen risk assessments



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UMC Utrecht



RIVM

3. Global consumption estimate

- › Determine if consumption estimates provided from dietary surveys in one country are representative for the population of another country



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TNO Shared Research Program:

Stakeholder acceptance of risk-based PAL and allergy management for the benefit for the allergic patient

- › Non-profit, Public-Private Partnership
- › SRP aims to solve the two major issues that hamper the global use of a harmonized quantitative allergen management system
 - › (1) development of guidance and a tool to select appropriate consumption data to use in setting Action Levels for Precautionary Allergen Labelling
 - › (2) underpinning the safety and supporting the acceptance and implementation of Reference Doses
- › SRP Participants: the Food Allergy Research and Resources Program (FARRP) of the University of Nebraska, Nestec, MARS, and Dutch Governmental TNO Research Investment Funds



Research



TNO



› **1. Simplification of consumption estimates from governmental dietary surveys for day-to-day use**

Introduction

- › It is well-known that the “serving size” is not an accurate estimation of actual consumption amounts
- › Quantitative risk assessments are sophisticated but knowledge and time intensive, therefore QRA methods are not widely available for day-to-day practice of food allergen risk assessment and management
- › Simpler, deterministic point estimates for consumption at a single eating occasion can be utilized for a first screening
- › This food consumption point estimate should meet the predefined safety objective, yet be adequately conservative from a public health perspective





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Sensitivity analysis to derive a food consumption point estimate for deterministic food allergy risk assessment

W. Marty Blom ^a  , Benjamin C. Remington ^a, Joseph L. Baumert ^b, Luca Bucchini ^c, Amélie Crépet ^d, René W.R. Crevel ^{e, 1}, Charlotte B. Madsen ^f, Steve L. Taylor ^b, Geert F. Houben ^a, Astrid G. Kruizinga ^a

<https://doi.org/10.1016/j.fct.2019.01.025>







ELSEVIER



Food and Chemical Toxicology

Sensitivity and
consumption
deterministic

What should I use as my
consumption estimate in a
VITAL-type program?


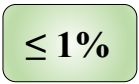

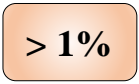

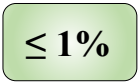

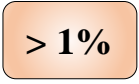
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Identify the optimal food consumption percentile for deterministic food allergy risk assessment

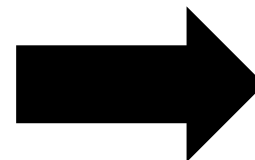
Sensitivity Analysis

	Deterministic Risk Assessments		Probabilistic Risk Assessments	
<i>Correct prediction</i>		✓		Safety objective
<i>Underestimation</i>		X		
<i>Overestimation</i>		✓		
<i>Correct prediction</i>		✓		
	pass or fail		average % risk ± sd	

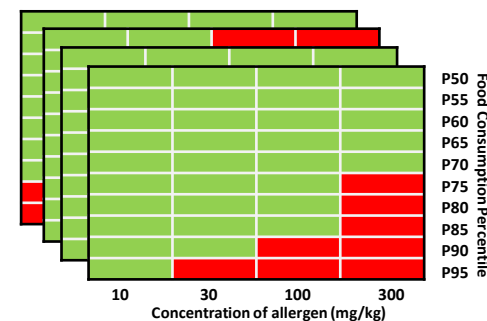
Identify the optimal food consumption percentile for deterministic food allergy risk assessment

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



Optimal food consumption percentile

- › Analysis showed that for 99% of the food groups, the P50 of food consumption met our criteria
- › The P75 met our criteria for 100% of the food groups

Optimal food consumption percentile

- › In this analysis, the P75 is the optimal point estimate for use in deterministic food allergy risk assessment
 - › P75 meets the safety objective
 - › P75 is adequately conservative for a public health context
 - › P75 is not overly conservative

- › The sensitivity analysis developed can be applied to any ED-value chosen as a safety objective

Remaining work: P75 availability for the public

- › P75 is not always reported in summary statistics of available consumption databases
 - › Still requires calculation
- › Incorporation into online tools envisioned in the future

P75??



Country	Pop Class	Foodex L3	% Consuming days	Mean	STD	P5	P10	Median	P95
Austria	Adults	Cereal bars	0.8%	58.11	63.31	20.00	20.00	41.00	300.00
Austria	Adults	Cereal bars	1.7%	37.08	25.54	20.00	20.00	25.00	100.00
Belgium	Adults	Cereal bars	0.5%	23.44	3.43	16.70	20.00	25.00	30.00
Czech Republic	Adults	Cereal bars	1.6%	37.13	21.66	15.00	23.50	30.00	100.00
Germany	Adults	Cereal bars	1.2%	48.16	24.34	30.00	38.00	38.00	80.00
Spain	Adults	Cereal bars	0.4%	34.15	16.06	21.50	21.50	25.50	64.50
Spain	Adults	Cereal bars	1.4%	31.13	10.37	21.00	21.00	30.75	43.00
Finland	Adults	Cereal bars	0.5%	32.58	19.07	9.00	24.00	30.00	90.00
Finland	Adults	Cereal bars	0.8%	34.38	14.58	21.00	21.00	30.00	60.00
France	Adults	Cereal bars	1.4%	36.98	31.97	20.00	20.00	25.00	84.00
United Kingdom	Adults	Cereal bars	2.0%	42.37	21.65	25.00	25.00	37.00	75.00
United Kingdom	Adults	Cereal bars	4.9%	39.42	18.62	22.00	23.00	35.00	80.00

› 2. Food consumption of Allergic Patients (FoodCAP)

Introduction

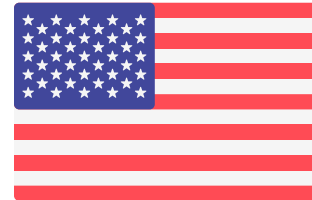
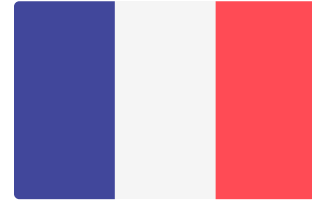
- › Risk assessments are conducted using national consumption data
- › Assumption: if consuming a product, the allergic consumer eats and drinks the same amount of a product as a consumer from the generic population
- › Is this assumption valid?



Introduction

- › Is this assumption valid?
- › Previous research attempts:
 - › MIRABEL (French - Study for Allergic risk/benefit analysis)
 - › Different dietary survey methods than in general population
 - › Not enough general population controls participated for analysis
<https://www.sciencedirect.com/science/article/pii/S0273230014002992>
 - › NHANES (USA - rolling population survey)
 - › Self-reported allergy or IgE screening
 - › Criteria for allergy were not strong enough and non-allergic individuals were mixed with the allergic population
 - › i.e. liquid milk consumption similar for “milk-allergic” and general population

http://www.eaaci.org/meetings/FAAM2016-Abstracts/abstracts/FAAM_2016_PP046.pdf



Introduction

- › Risk assessments are conducted using national consumption data
- › Assumption: if consuming a product, the allergic consumer eats and drinks the same amount of a product as a consumer from the generic population
- › Is this assumption valid?
- › AIM: Perform a study to investigate if the consumption pattern of the generic population is different from that of the allergic population



Note: this study is not investigating the frequency of consumption, the number of participants needed would be >1000

Food Consumption of Allergic Patients (FoodCAP)

- › Collaboration between TNO, University Medical Center Utrecht and the National Institute for Public Health and Environment (RIVM)
- › Acknowledgements:



University Medical Center
Utrecht



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

W. Marty Blom
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FoodCAP: Conduct of food consumption survey

- › A cross-sectional cohort study with food allergic adult patients:

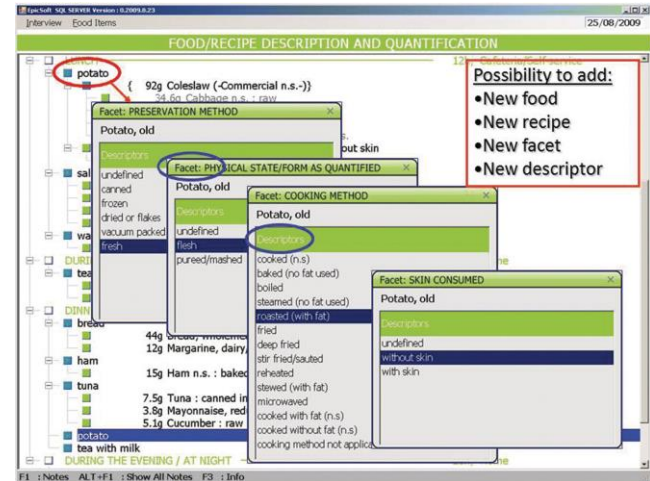
Group allergic individuals*)		Food consumption survey completed
		N=
Milk/Egg	Milk/Egg (n=16)	38
	Milk/Egg/ Peanut/tree nuts (n= 22)	
Peanut/tree nuts		35

*) Mean number of confirmed food allergies 4.2 +/- 2.4 (range 1-11)

FoodCAP: Conduct of food consumption survey

- › Consumption data were collected similar to the Dutch National Food Consumption Survey (DNFCS)
 - › 24-hour recall method on two non-consecutive days
 - › by phone by trained dieticians UMCU
 - › using GloboDiet software program

- › Data were compared to the adult group selected from the Dutch National Food Consumption Survey DNFCS performed in 2007-2010 (van Rossum et al 2011).



FoodCAP: Products consumed -> food grouping

- › All products consumed were assigned to food groups previously developed for food allergy risk assessment by iFAAM (Biro et al 2018)
 - › Some food groups were adjusted

Biro et al. (<https://www.sciencedirect.com/science/article/pii/S0278691518303429>)



FoodCAP: Statistical comparison

- › Using an ANOVA model on max consumption data it was statistically tested if there was a difference between allergy groups (*milk/egg* and *peanut/tree nut*) and the general population
- › The model was corrected for the following background variables ('co-variates'):
 - › age-range
 - › gender
 - › season
 - › education
- › False discovery rate (FDR) correction was applied

FoodCAP: General Results

- › The overwhelming majority of food groups did not show a statistical significant difference
- › Three (3) food groups reported statistically different amounts consumed between the allergic and general population
- › Only “Fruit and vegetables, unprocessed” is expected to have an impact on the risk assessment results
 - › Eaten more by allergic population

FoodCAP: Remaining Activities

- › Finalization of the “impact on risk assessment” results
- › Preparation and submission of the manuscript to peer-review journal

› 3. Global Consumption Estimate





Global consumption estimate: Introduction

- › For a multinational company, an allergen management program (such as VITAL) should be broadly applicable with limited repeated effort

- › The optimal, simplified food consumption estimate for a food product would be:
 - › Conservative across the different markets/countries where a food is available
 - › Easy-to-use

- › Thus to investigate different market applications, food consumption databases from different countries were grouped and analyzed in similar fashion to determine if consumption databases of different countries effected the results of the food allergen risk assessment

Global consumption estimate: Status

Past

- › Comparison of Danish, Dutch and French consumption data



Ongoing

- › Comparison of USA and Dutch consumption data



Future directions

- › Addition of Australian consumption data
- › Addition of more Asian consumption patterns





Global consumption estimate

Past

- › Danish, Dutch and French combination indicated that 53 of 61 food groups could be combined across countries
 - › 8 country-specific food group recommendations
- Birot et al. (<https://www.sciencedirect.com/science/article/pii/S0278691518303429>)

Ongoing

- › USA vs Dutch consumption comparisons indicate similar results, i.e. a large number of categories, but not all, have similar consumption patterns
 - › Country-specific food groups needed in some cases

Future Directions

- › A conservative, cross-country consumption estimate will be determined to simplify application of RM programs across different markets

Conclusions

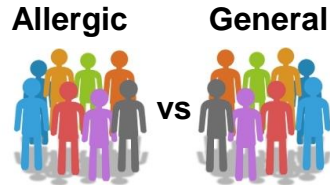
1. Consumption point estimate

- › P75 was optimal for deterministic risk assessments in food allergy



2. Allergic vs General Pop Consumption Patterns

- › Nearly all food groups showed no difference
- › Exception: Unprocessed fruits and vegetables



3. Global consumption estimate

- › Some differences due arise between countries
- › A conservative, cross-country consumption estimate would be optimal to simplify application of RM programs across different markets

