22 October 2019

Technical stakeholder event on cumulative risk assessment of pesticides in food

Exposure assessment

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Evidence Management Unit

Trusted science for safe food

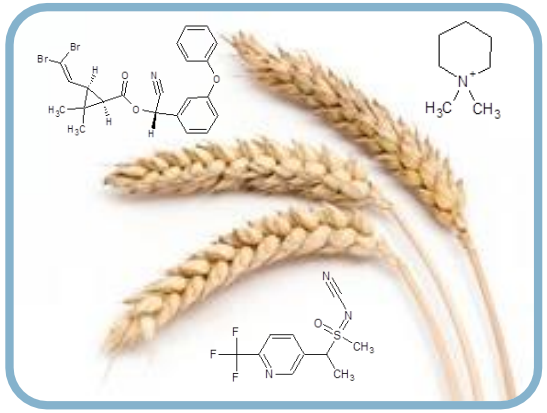
efsa
European Food Safety Authority

Overview

- General methodology
- Assumptions and tiers
- Results and interpretation
- Key observations

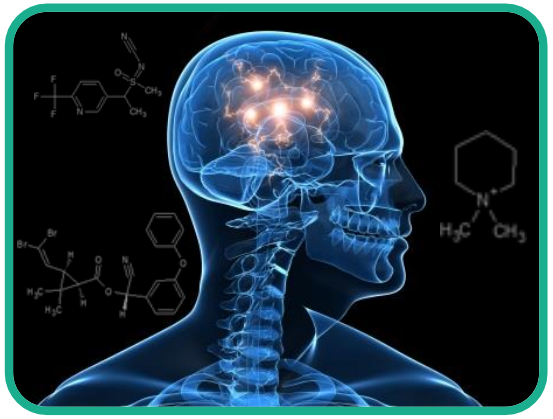
Methodology – Basic principles

Occurrence



Consumption

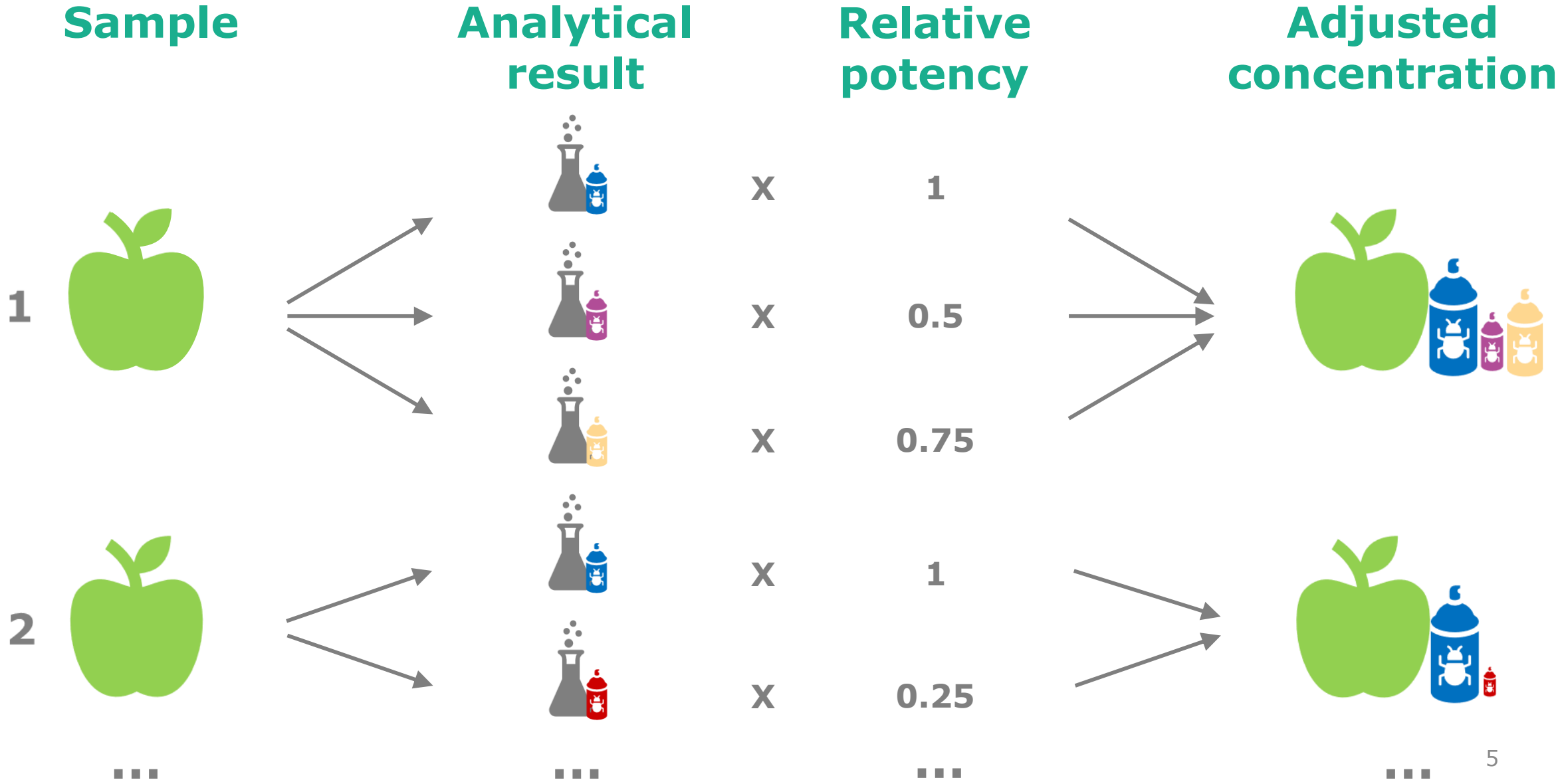
Exposure



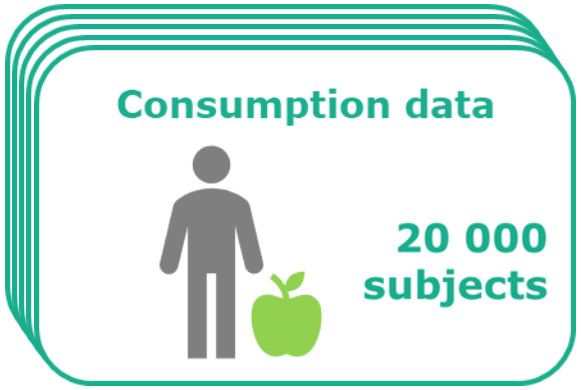
Methodology – Primary input data

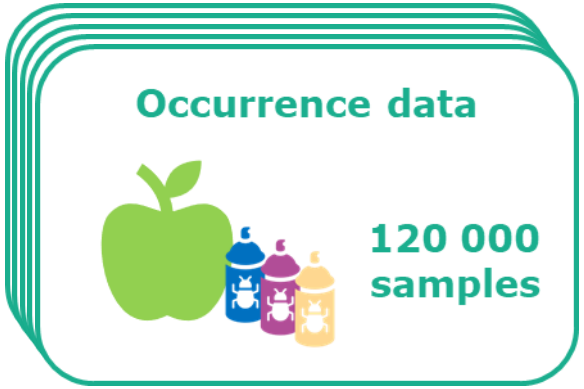
- **Consumption data:**
  - Comprehensive European Food Consumption Database
  - Converted to raw primary commodities
  - Surveys selected for adults (4), children (3) and toddlers (3)
  - Detailed records for 20.000 subjects (2-7 days)
- **Occurrence data:**
  - EU coordinated and national monitoring programs
  - Objective and selective sampling only
  - Reference period 2014-2016
  - 30 raw primary commodities
    + foods for infants and young children
  - Co-occurrence data for 120.000 samples

Methodology – Toxicological potency



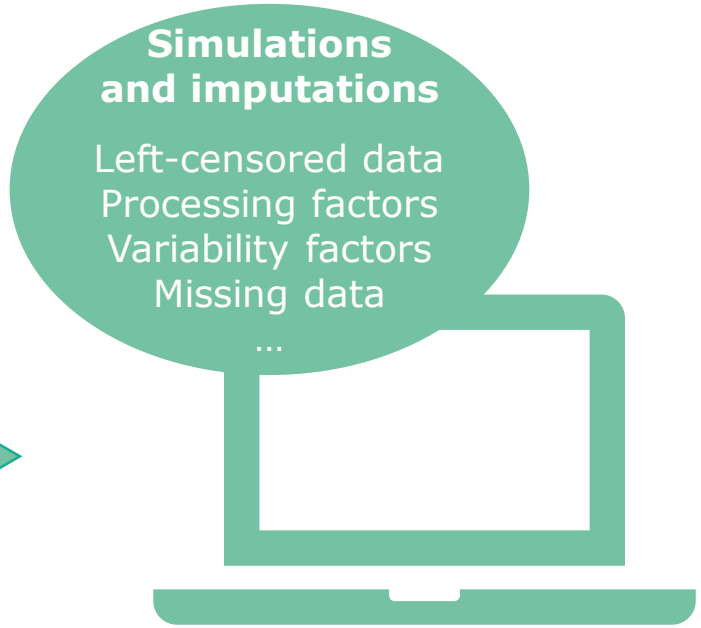
Methodology – Chronic exposure





2-Dimensional

100 bootstraps



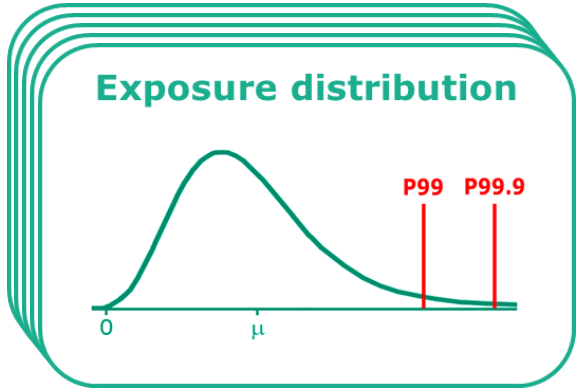
Observed Individual Means (OIM) Approach

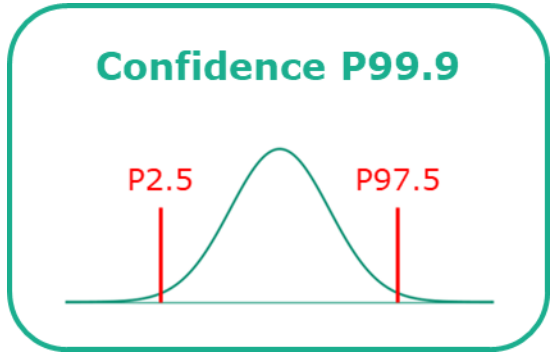
Mean consumption x Mean occurrence

Repeated for each subject (i.e 20 000 times)

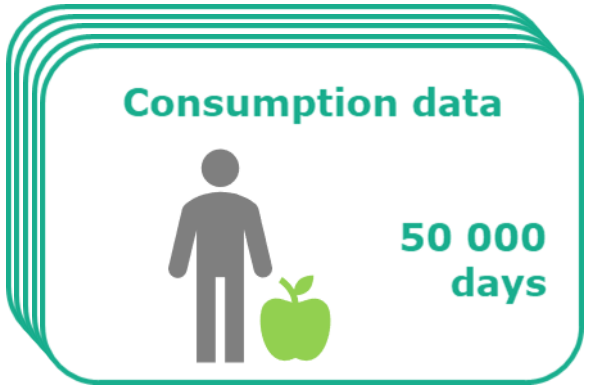
2-Dimensional

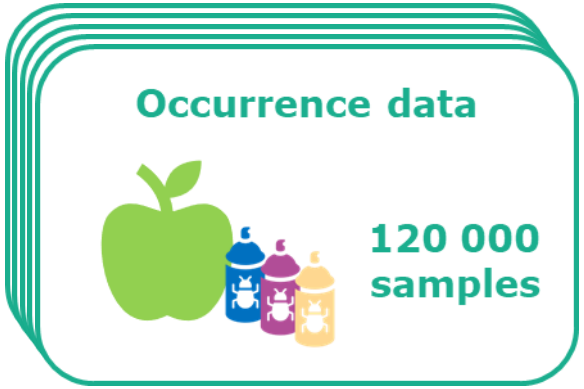
100 distributions





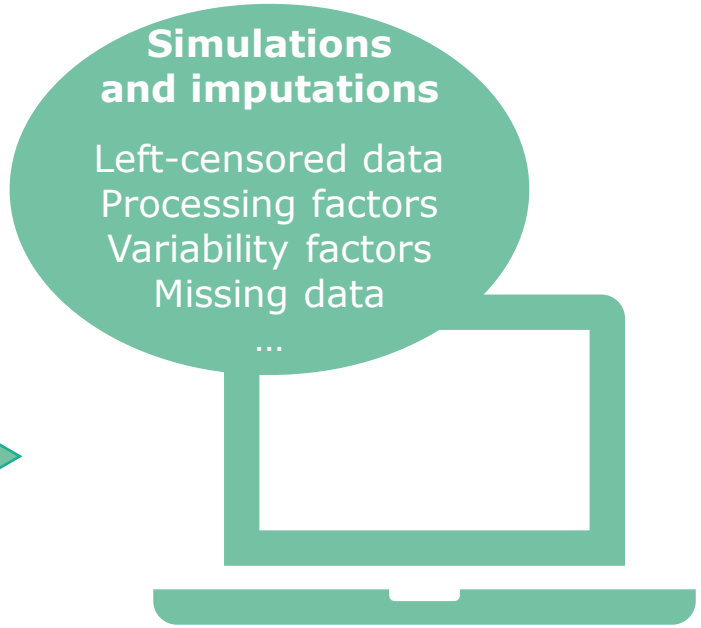
Methodology – Acute exposure





2-Dimensional

100 bootstraps



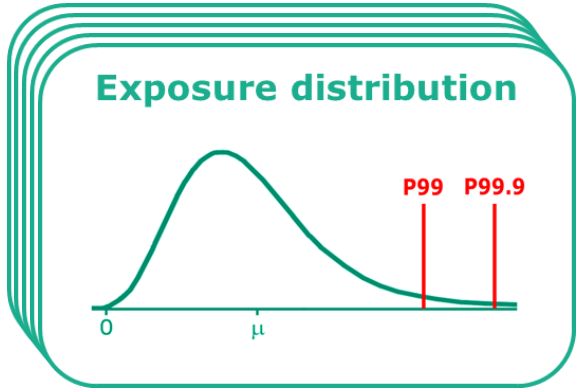
Monte Carlo simulation

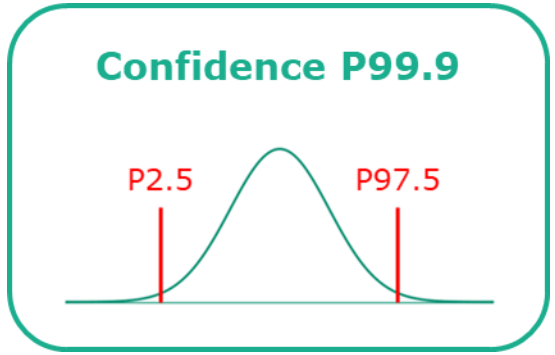
Random day x Random sample

100 000 iterations

2-Dimensional

100 distributions





Overview

- General methodology
- Assumptions and tiers
- Results and interpretation
- Key observations

Assumptions and tiers – General principles

- **Alignment with risk management principles**
  - Standing Committee on Plants, Animals, Food and Feed (SC PAFF)
  - Development of a tiered approach
  - Generic and tier-specific assumptions
  - Discussed and agreed at the meeting of 19 September 2018
- **Tier I**
  - Conservative assumptions which are less resource-intensive
  - Screening of the exposure with low risk for underestimation
- **Tier II**
  - More refined assumptions which are more resource-intensive
  - Still intended to be conservative

Assumptions and tiers – Main simulations

	Tier I	Tier II
Unspecific definitions	Most potent active substance is allocated to each sample	Random allocation of authorized active substances to each sample
Left-censored data	½ LOQ for food-substance combinations with quantifiable findings	½ LOQ based on estimated use frequencies, assuming 100% crop treatment
Missing measurement	Highest values assigned to the most contaminated samples	Random assignment of missing measurements to available samples
Drinking water	Imputed at 0,1 µg/l for the 5 most potent active substances	Imputed at 0,05 µg/l for the 5 most potent active substances
Processed foods	Use processing factors when available. Otherwise, assume all pesticides in the raw primary commodity will reach the end consumer without any loss of residues.	

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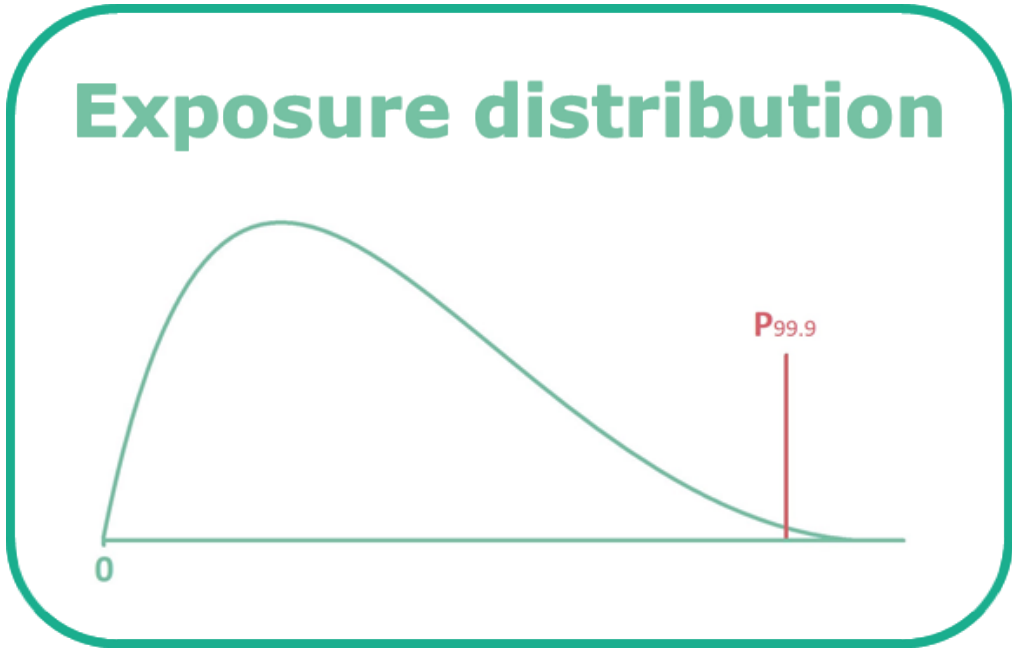
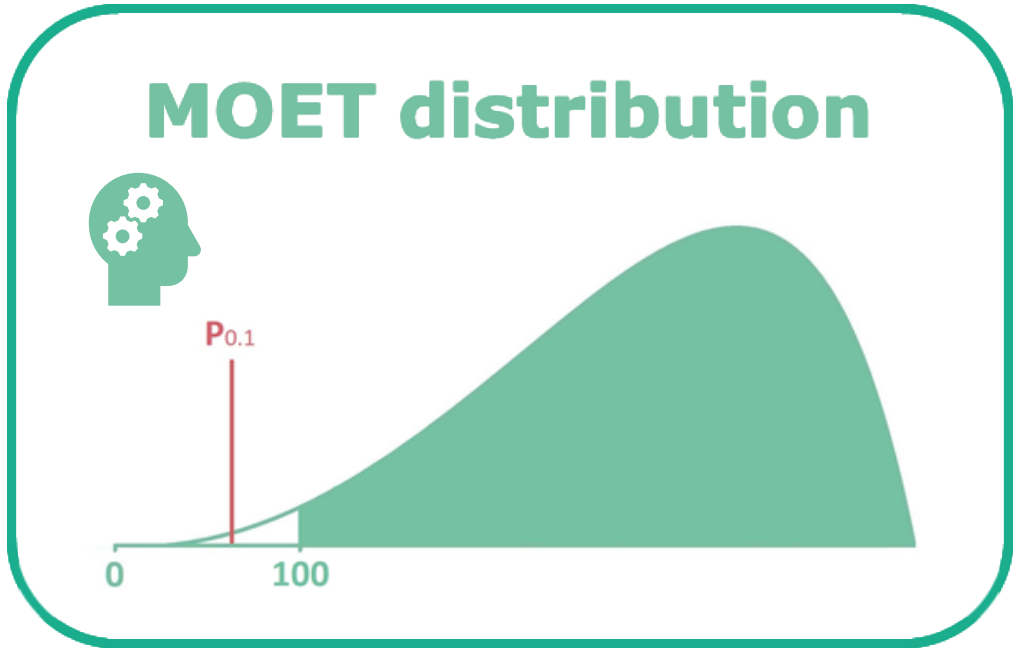
Results – Margin of exposure

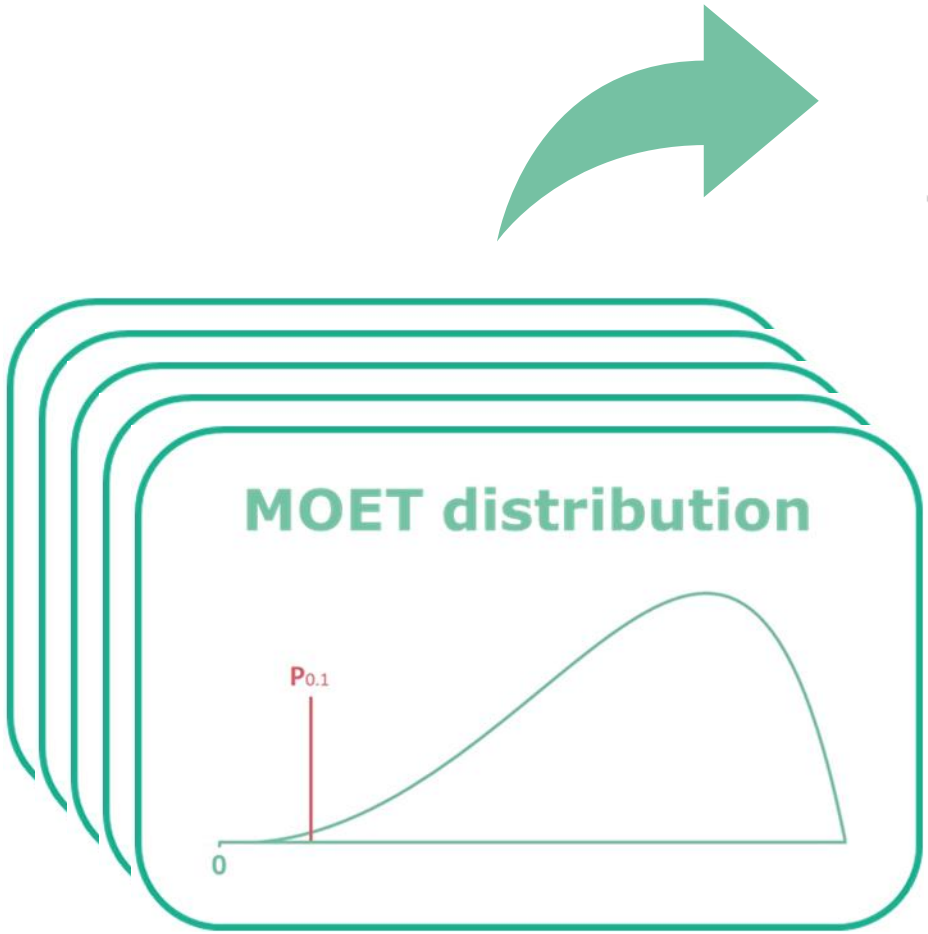
Threshold for regulatory consideration

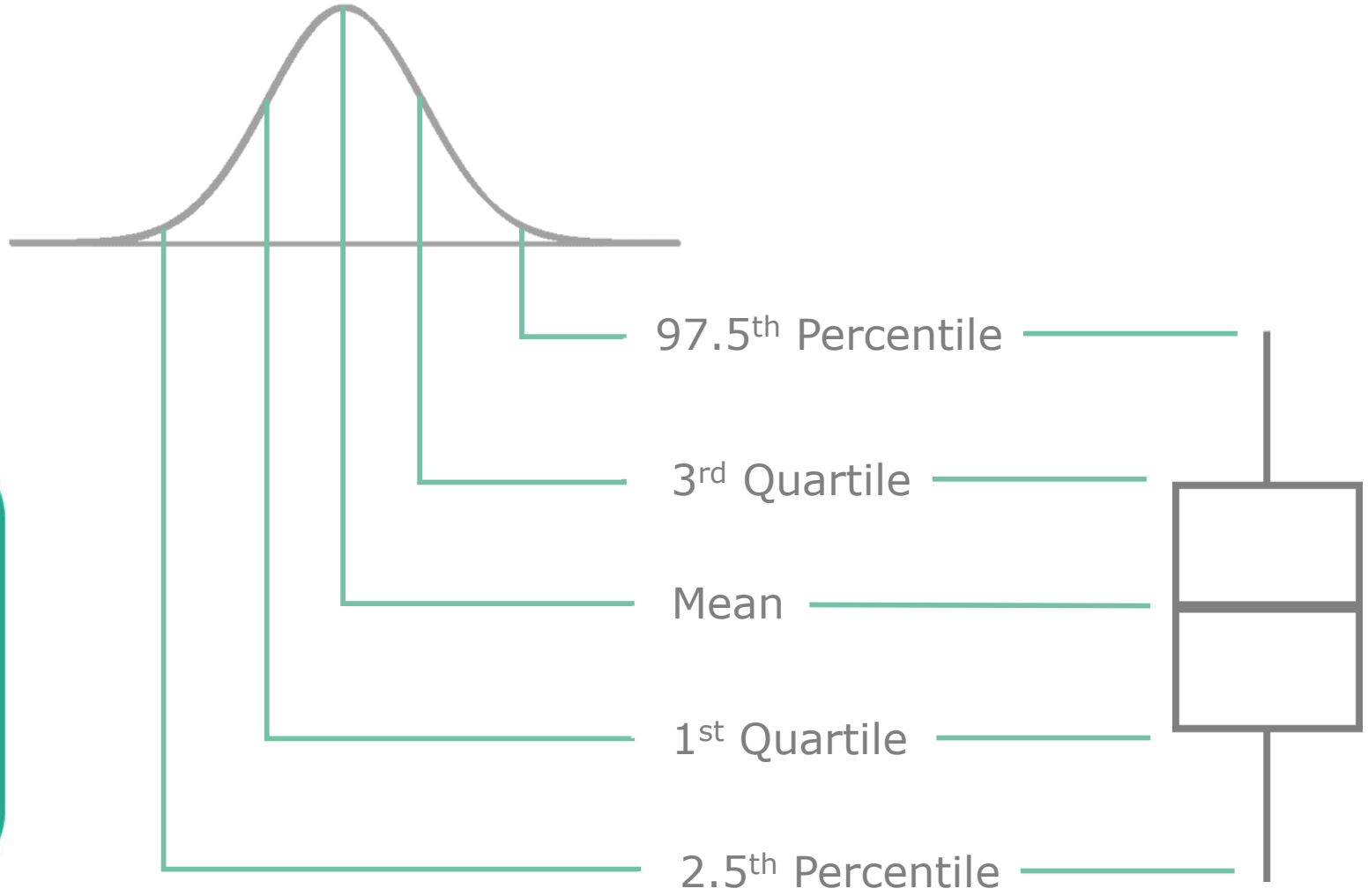
Who defined it?	Standing Committee on Plants, Animals, Food and Feed (SC PAFF)
How is it calculated?	Total margin of exposure (MOET), i.e. toxicological reference dose/estimated exposure
Reference point?	99.9th percentile of the exposure distribution
Numerical threshold?	Should be ≥ 100
Additional conditions?	Assumptions used under Tier II should be "sufficiently conservative"





Results – Confidence interval

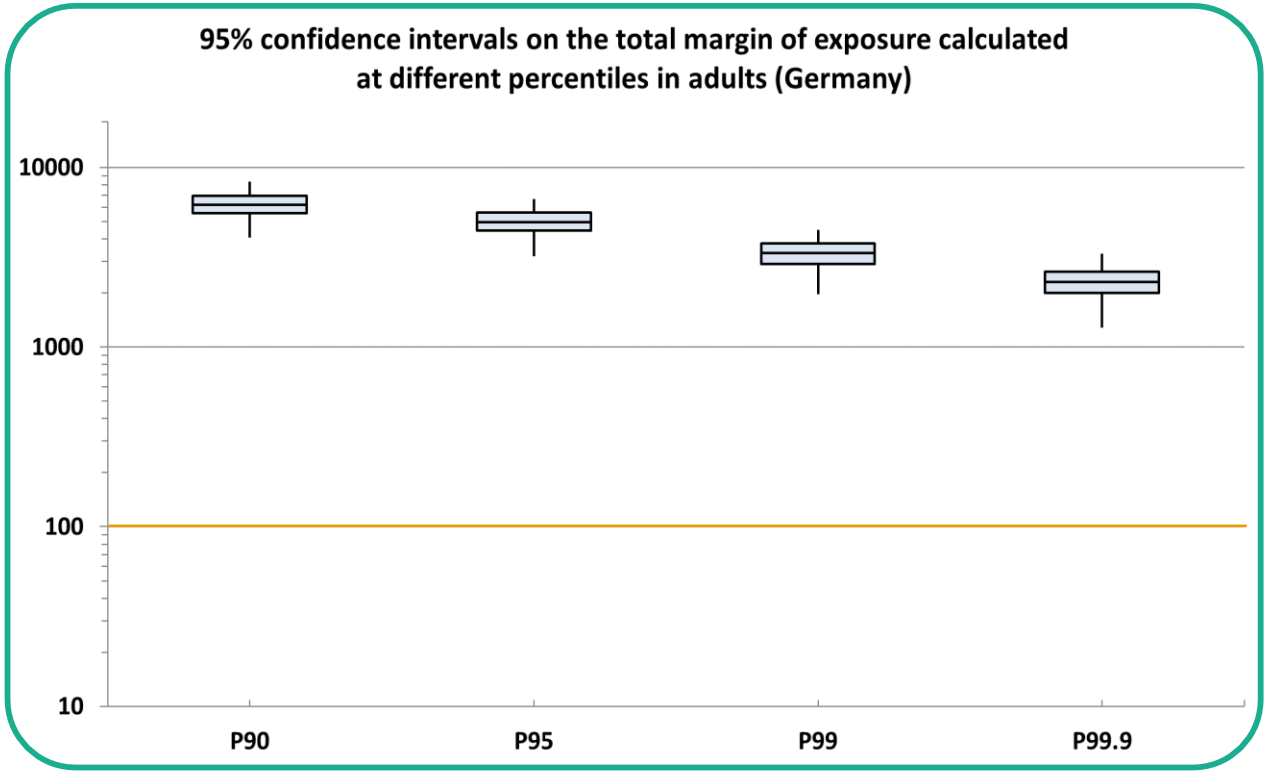




Hypertrophy, hyperplasia and neoplasia of C-cells

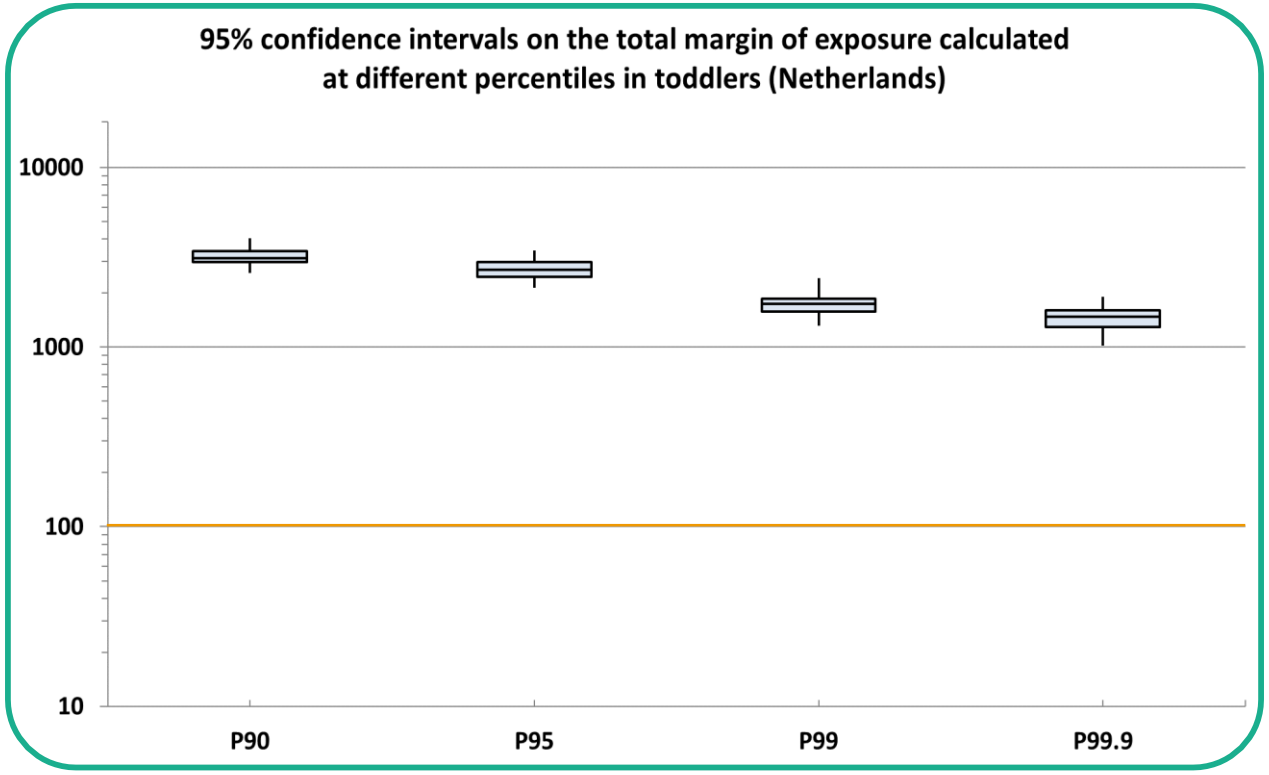
German adults

Tier II



Dutch toddlers

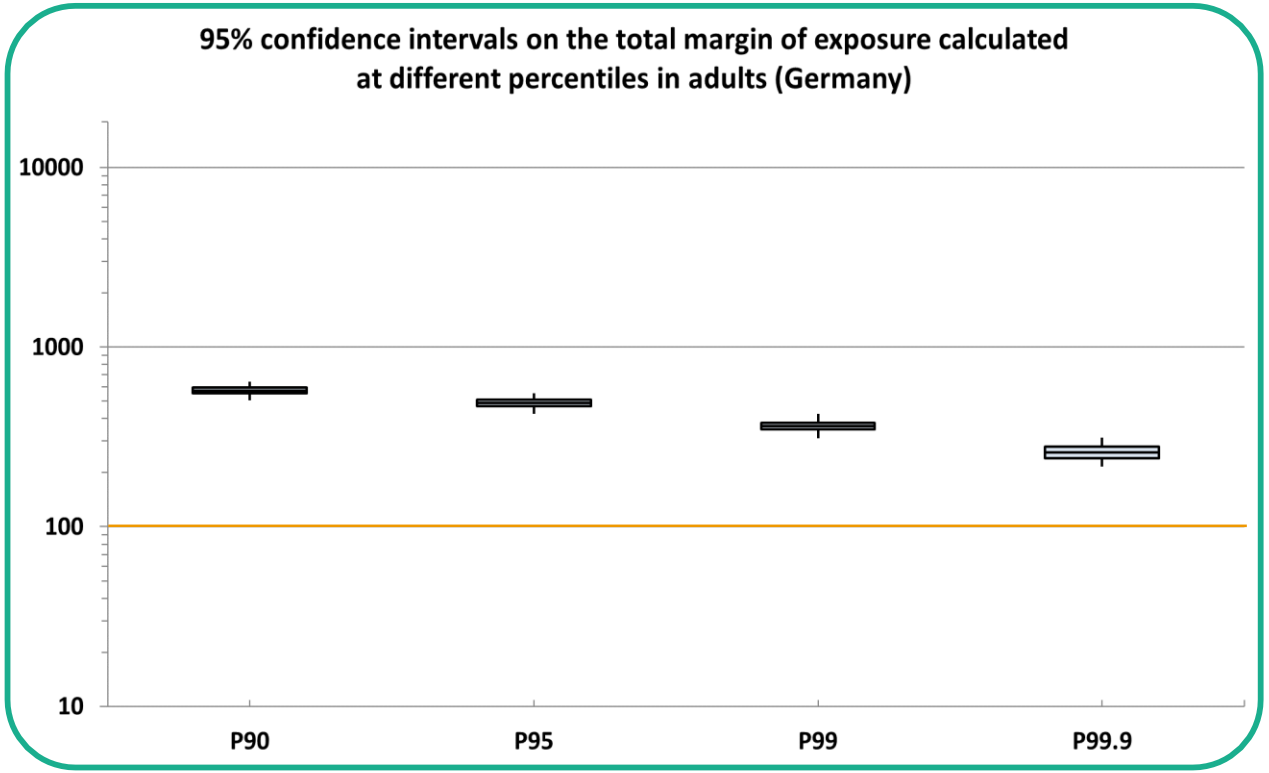
Tier II



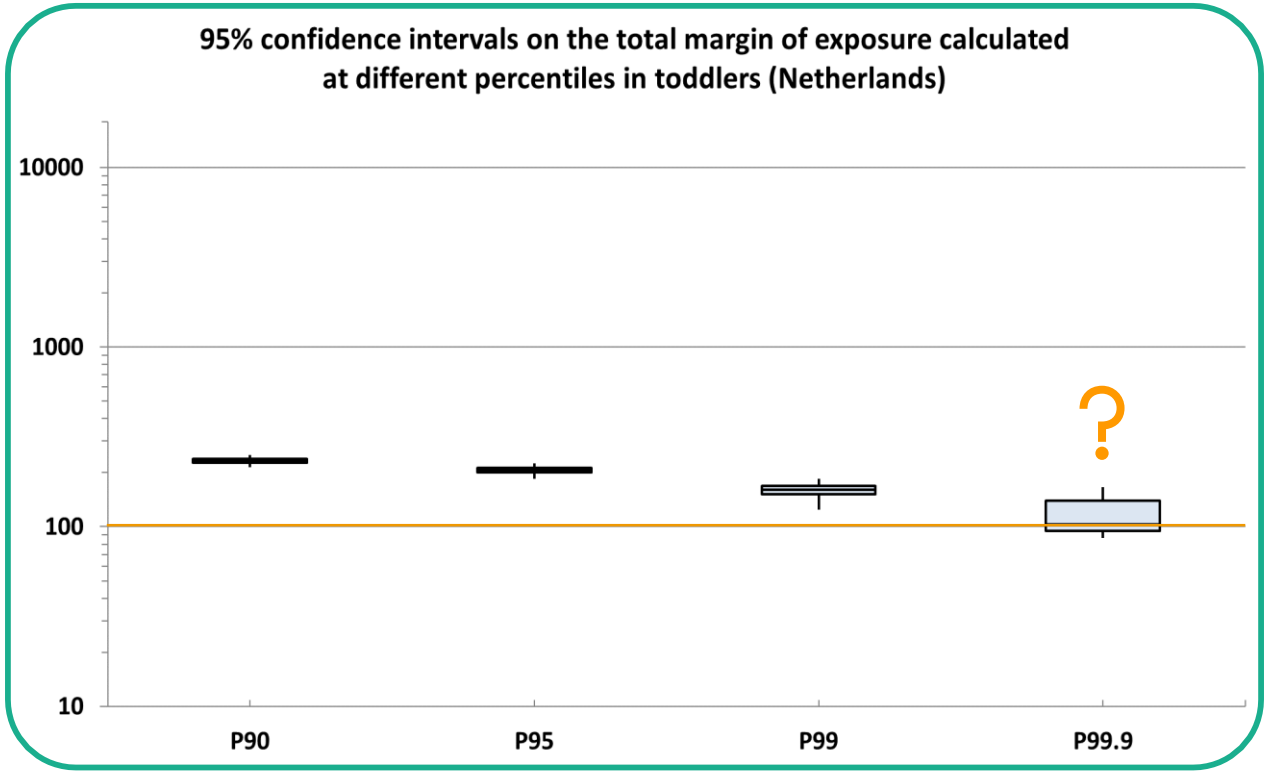
Results – Chronic exposure

Hypothyroidism

German adults
Tier II



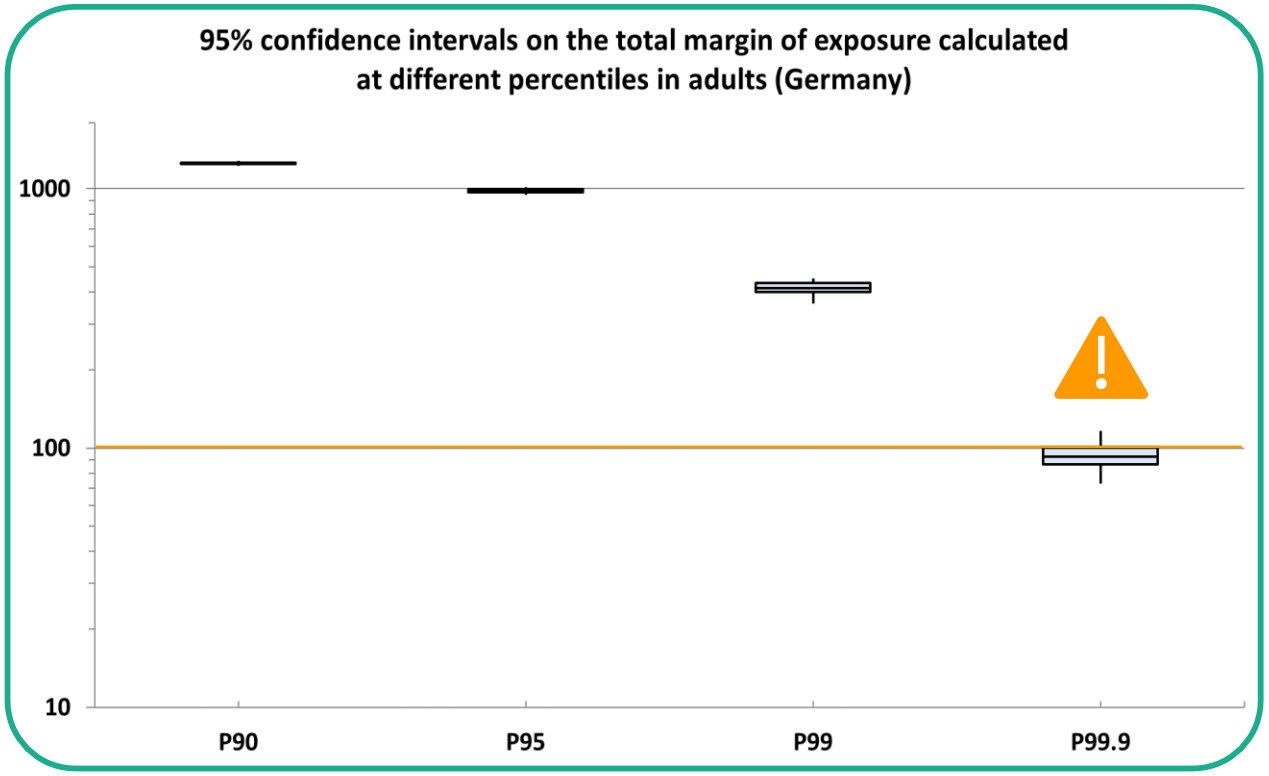
Dutch toddlers
Tier II



Brain and/or erythrocyte AChE inhibition

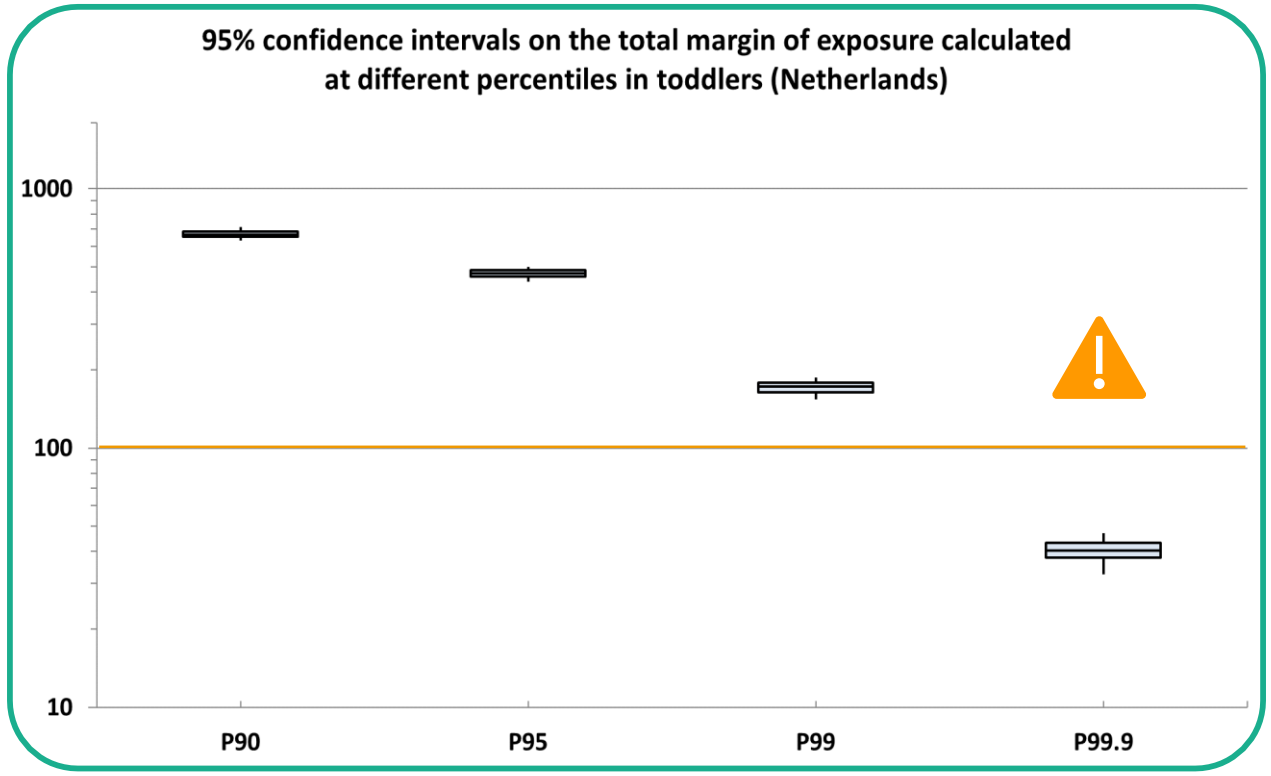
German adults

Tier II



Dutch toddlers

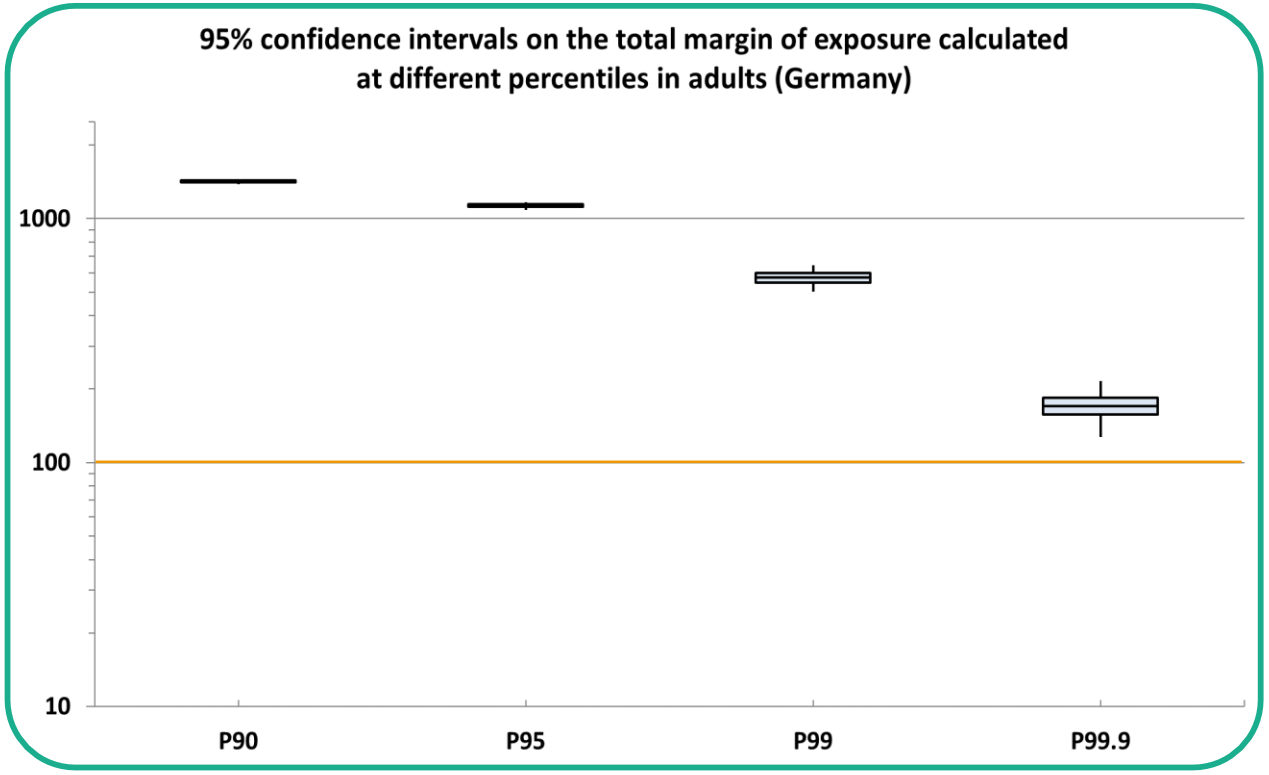
Tier II



Alterations of the motor division

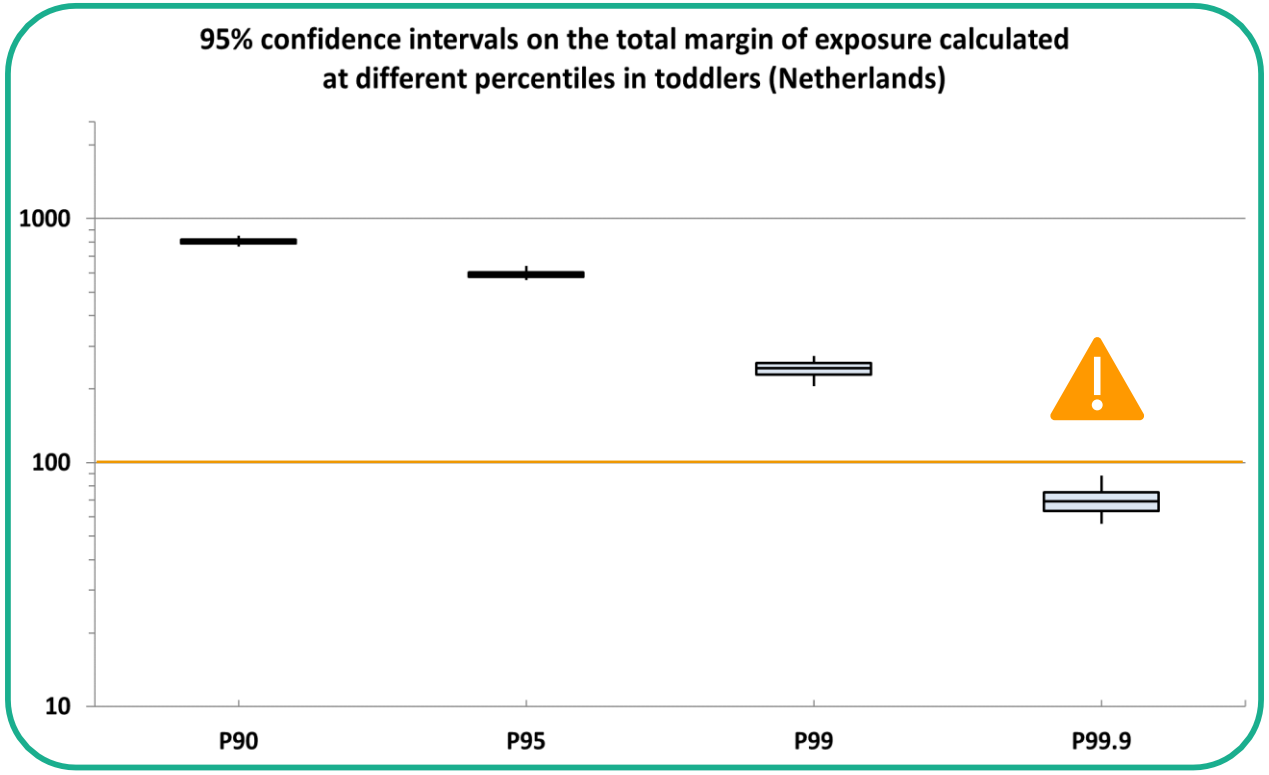
German adults

Tier II



Dutch toddlers

Tier II



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Key observations – Risk drivers

- **Limited number of substances**
  - Hypertrophy, hyperplasia and neoplasia of C-cells: thiram
  - Hypothyroidism: bromide ion
  - AChE inhibition: chlorpyrifos, triazophos, omethoate
  - Motor division: triazophos, thiram, deltamethrin
- **Other factors driving the acute exposure distribution**
  - Single substances in a specific commodity (75% of the upper part)
  - Samples exceeding the MRL (40 to 95% of the upper part)
- **What about 2017-2019 (retrospective assessment)?**
  - Single substance assessments have revealed similar risks
  - Measures already taken by risk managers for chlorpyrifos

Key observations – Main uncertainties (1)

- **Missing processing factors**
  - Sensitivity analysis assuming no residues in processed foods
  - Potential overestimation by a factor of 2 to 5 (!)
  - Need for consolidation of EU Processing Factor Database
- **Left-censored (LC) data**
  - Sensitivity analyses assuming LC data equal 0 or ½ LOQ
  - Most relevant for chronic exposure assessment
  - Data on use frequency to be collected

Key observations – Main uncertainties (2)

- **Foods for infants and young children (FIYC)**
  - Sensitivity analysis excluding FIYC
  - Contribution of FIYC to the exposure is negligible
  - Consistent with previous opinion of the PPR Panel
- **Unspecific residue definitions**
  - No sensitivity analysis was carried out…
  - … but several risk drivers (e.g. thiram and omethoate) resulting from unspecific residue definitions
  - Data on use frequency to be collected

Key observations – Software

Exposure calculated with two different software

- EFSA used SAS® Software
- RIVM used MCRA Software
- Minor divergencies attributed to random effects of probabilistic methodologies

What are the advantages?

MCRA

- Scope
- Accessibility
- Usability

SAS®

- Flexibility
- Openness
- Data integration

Action plan for MCRA under elaboration

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