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Exposure factors and exposure assessment for toys

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Consumer Exposure Assessment

- Model development (ConsExpo)
- Validation experiments
- Exposure factors (factsheets)
- Consumer behaviour (e.g. children)
- Risk assessment

Exposure Assessment for toys

- RIVM Report prepared for DG Enterprise
- Proposal of a risk assessment methodology
- Tiered approach
- Not limited to certain chemicals (but focussed on elements)

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Basic Principle:

Starting point:

Exposure of children to substances in toys should not exceed a certain health-based level (in mg/kg bw/day)

- Taking into account background levels and other sources of exposure

For elements:

The exposure of children to elements in toys may not exceed X% of the TDI (in mg/kg bw/day)

Responsibility of Industry to assure the safety of products

Only focus on risk assessment, risk management is for the risk managers!

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Options for compliance

1) use of migration data

   Comparable to EN71-3

2) use of product (toy material) composition data

3) use of a quantitative risk based approach

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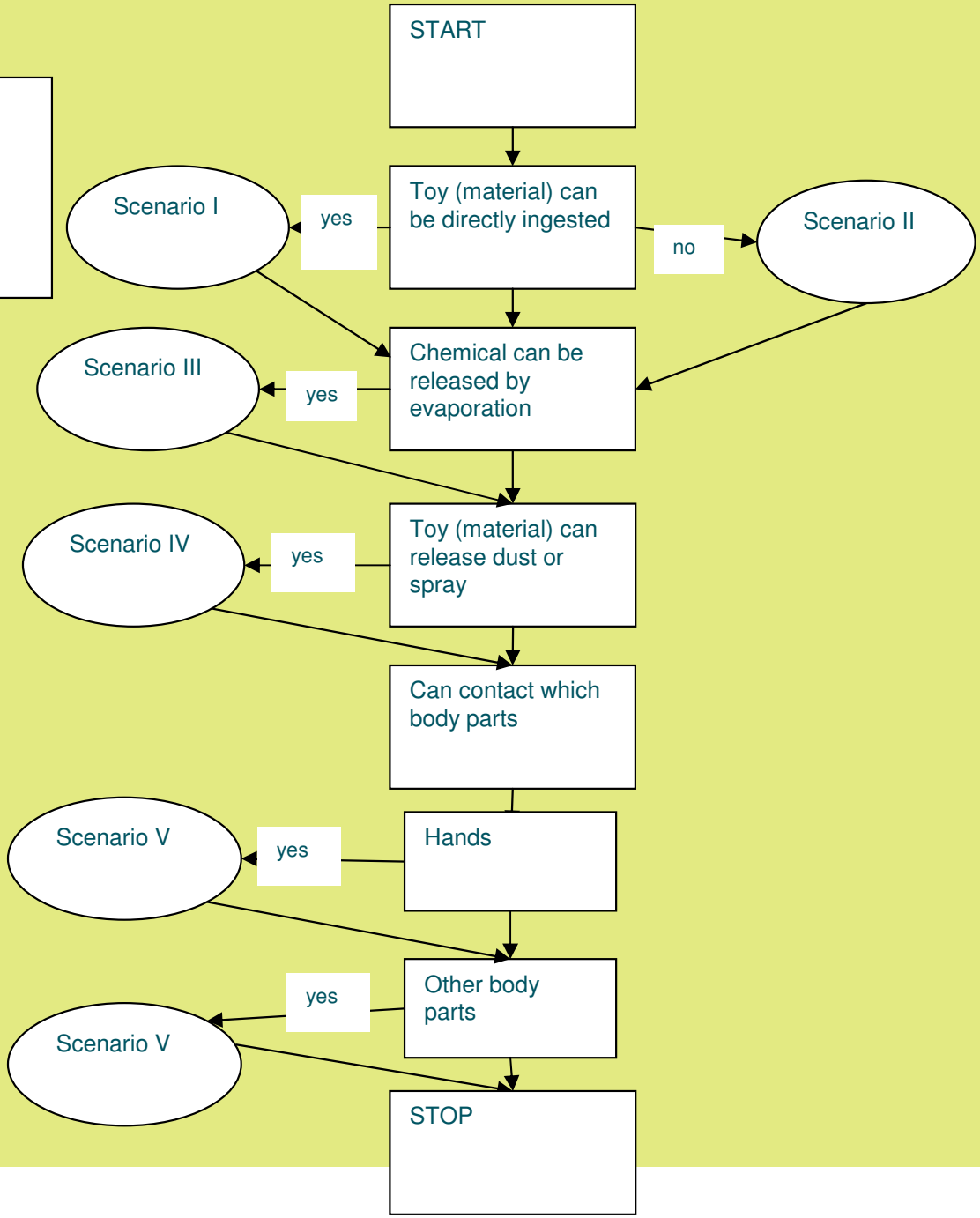
Scenario I:	direct ingestion
Scenario II:	mouthing (sucking/licking)
Scenario III:	inhalation via evaporation
Scenario IV:	inhalation via dust or spray
Scenario V:	skin contact



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Exposure factors

- Different types of toys, different age groups, different exposure routes
- Different age groups (body weight, skin area) and different types of time-activity patterns
- Exposure duration
  - Depends on child, type of toy, scenario – almost no information available (mouthing times)
- Different amounts ingested / mouthed

General information on exposure factors

Large collection of data

- Scattered
- USA Exposure Factors Handbook
- Expofacts
- HERA projects
- Open Literature
- EISChemRisks Toolbox
- RIVM publications

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RIVM publications

- Factsheets for ConsExpo
- Oral exposure of children to chemicals via hand-to-mouth contact (http://www.rivm.nl/bibliotheek/rapporten/320005004.pdf)
- Non-food products: How to assess children's exposure? (body weights, skin areas, inhalation rates, crawling, hand to mouth contact) (http://www.rivm.nl/bibliotheek/rapporten/320005005.pdf)

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Exposure factors

- Different routes of exposure
  - Oral (mouthing/ ingestion)
  - Different types of toys:
    - Scrape off
    - Liquid
    - Powder, dusty

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Exposure Scenarios

For elements in toys: oral route most important

Presently: single value of intake of 8 mg/day

Proposal: default values for oral contact

* 8 mg/day for material that can be scaped off (fibers, paint on pencils)

* 100 mg/day for powder-like material (chalk)

* 400 mg/day for liquid material (e.g. fingerpaint)

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Example: exposure of children to lead in paint on toys

- toys mouthed
- migration paint into salive
- tolerable weekly intake: 25 ug/kg
- the Netherlands: 2 regulations:
  - 0.7 ug bio-available per day per toy 

    <assuming 8 mg ‘toy intake’ a day> Max release rate: 90 ug/g
  - max allowed level 3.5 mg/kg in paint

Case: lead in paint on a top

- lead released from paint: 1970 ug/g in HCl
- lead concentration in paint : 14.8 +/- 0.4 mg/g

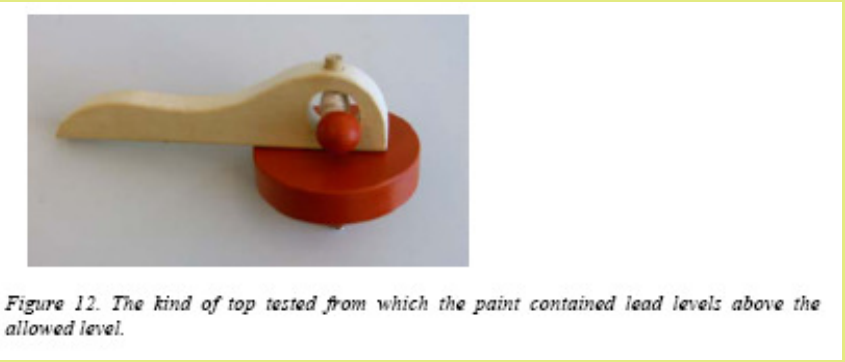

Figure 12. The kind of top tested from which the paint contained lead levels above the allowed level.

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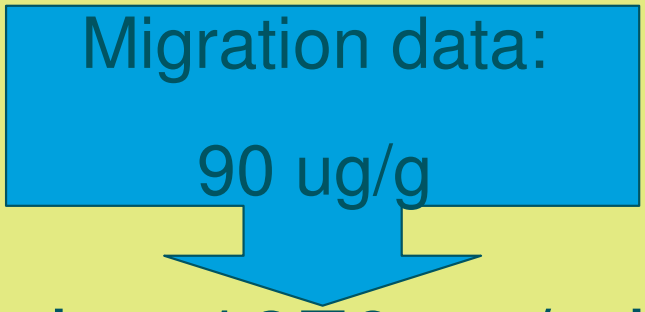
Compliance?



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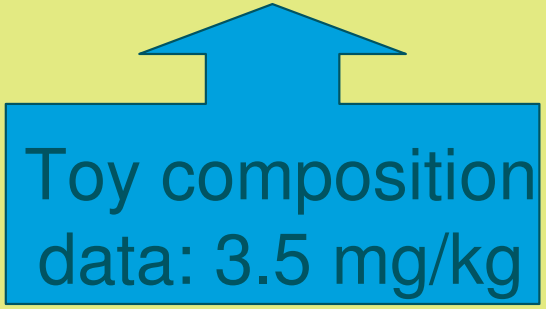

Exposure scenario

- mouthing/chewing : pieces of paint migrate into saliva/gastro-intestinal tract
- population : children of 1.5 years
- time scale: week average exposure
- background levels are not considered (but may be relevant)

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Use of a quantitative approach

1. deterministic evaluation using worst case values
2. refine assessment using more ‘realistic’ data and experiments
3. include quantitative evaluation of uncertainty and variability in probabilistic assessment

1rst step: deterministic evaluation

- exposure evaluation for hypothetical ‘worst case’ exposed child, representing entire population
- conservative assumptions exposure factors/parameters
- single values
- estimation of maximum exposure, no information on uncertainty/variability (distribution of exposure in population)

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Exposure model & deterministic evaluation

E = (frequency x migrated amount of paint x uptake fraction) / body weight

ConsExpo defaults:

- body weight : 10 kg
- uptake fraction : 100%
- exposure frequency: 3x a week
- amount paint migrated into saliva: 0.1 g

Exposure:

1) E = 0.45 mg/kg/week = 450 ug/kg per week, based on concentration
2) E = 0.06 mg/kg/week = 60 ug/kg per week, based on HCl leaching test

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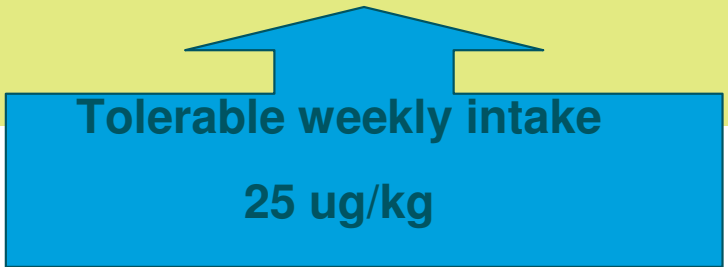


Refining the deterministic assessment

- Experimental determination
  - bioaccessible fraction
- Variability
  - body weight
- uncertainties
  - frequency
  - migration fraction paint (dependent on mouthing time)
  - fraction of lead in paint (experimental error)

Bioaccessibility and bioavailability

External exposure

⇩

mouth

⇩

oesophagus, stomach, small intestine

⇩

small intestine portal vein

⇩

liver

⇩

systemic circulation

Internal exposure

Exposure to contaminant in a matrix

Ingestion of matrix + contaminant

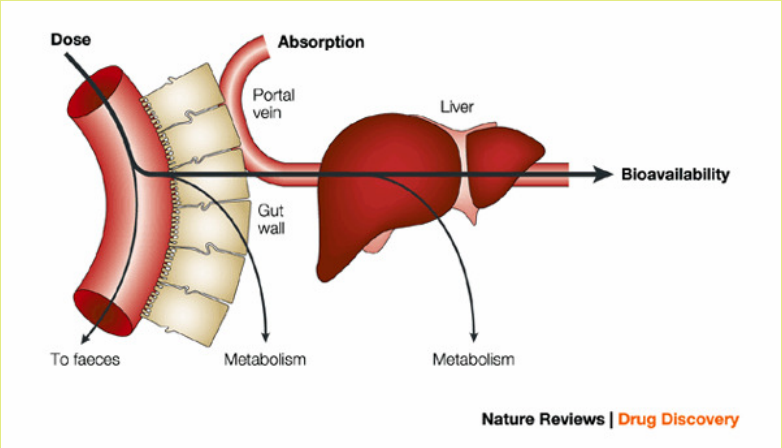
F_B = Fraction released from matrix = **bioaccessible fraction**

F_A = Fraction of F_B absorbed by small intestine

F_H = Fraction of F_A passing liver without being metabolised

F = Fraction reaching systemic circulation = bioavailable fraction

$F = F_B \times F_A \times F_H$



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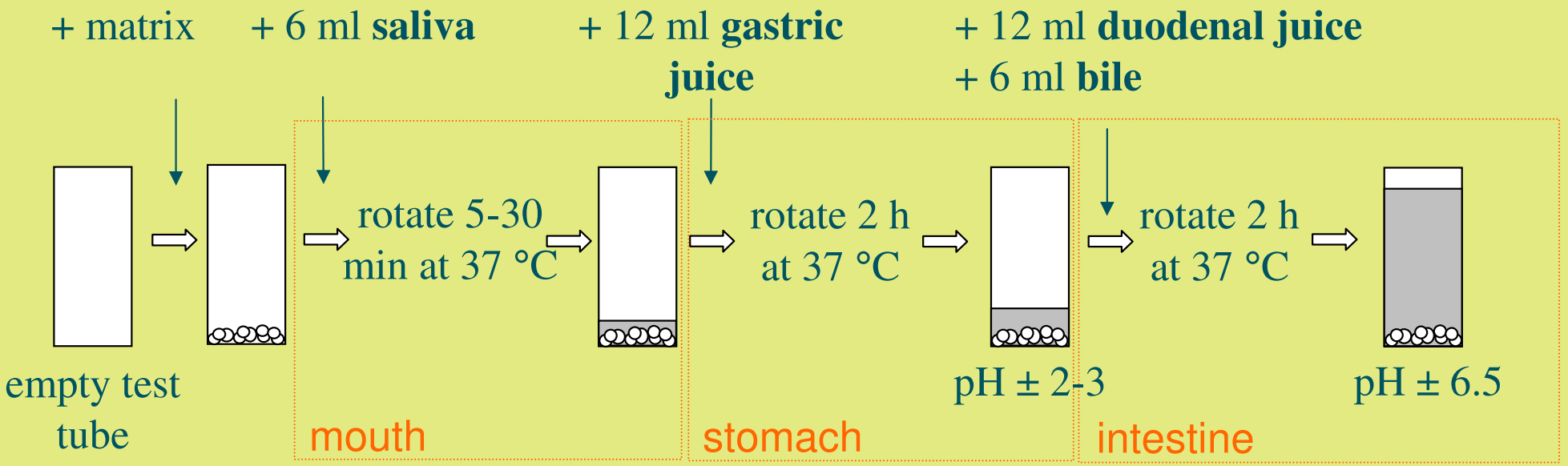
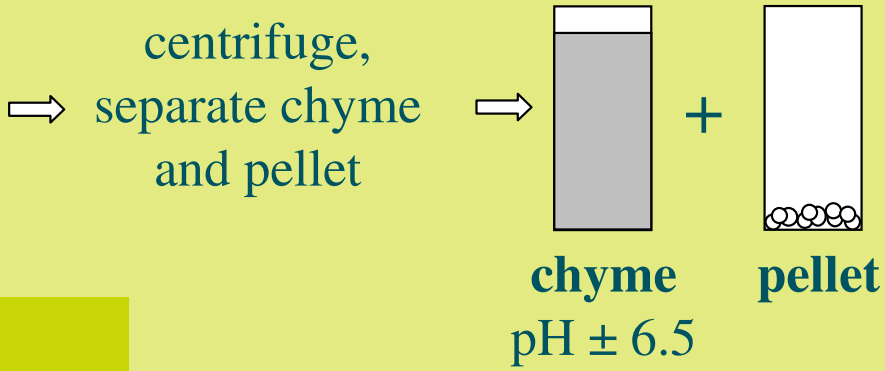
In vitro digestion models

- Principle
  - Various compartments of the human gastrointestinal tract are simulated
  - Digestive juices are prepared artificially
  - Matrix (toy, consumer product) is introduced in mouth compartment, mixed according to physiological transit times, and transferred to next compartment
  - Bioaccessibility: amount of compound released from matrix
    - Mouth: simulating sucking on matrices
    - Intestine: simulating ingestion of matrices

In vitro digestion model RIVM





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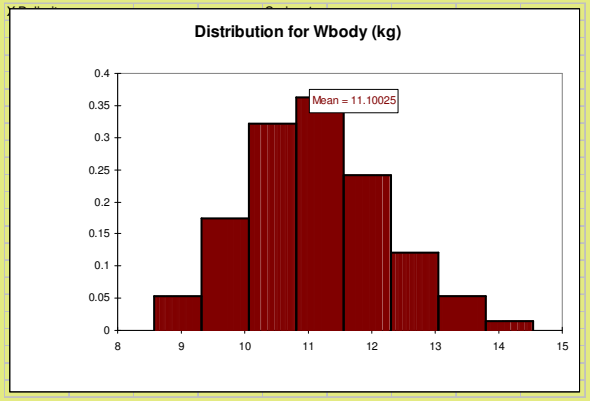
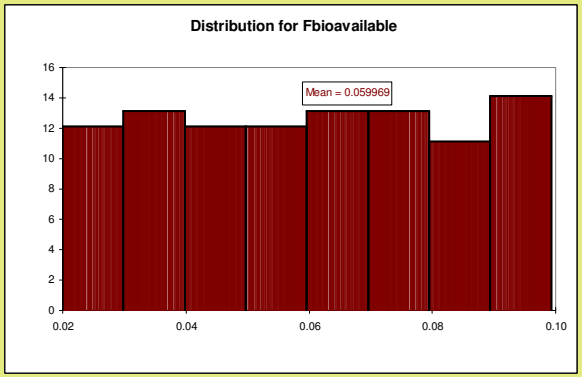
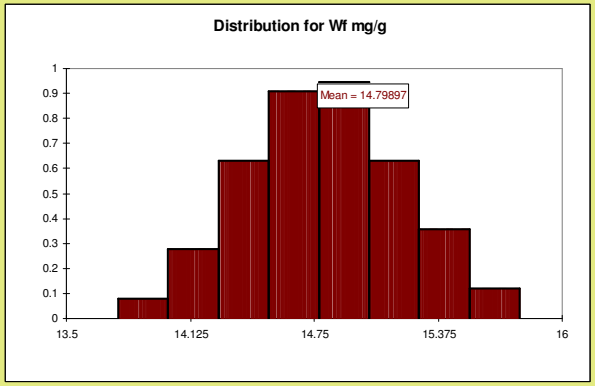
Probabilistic assessment: distributions

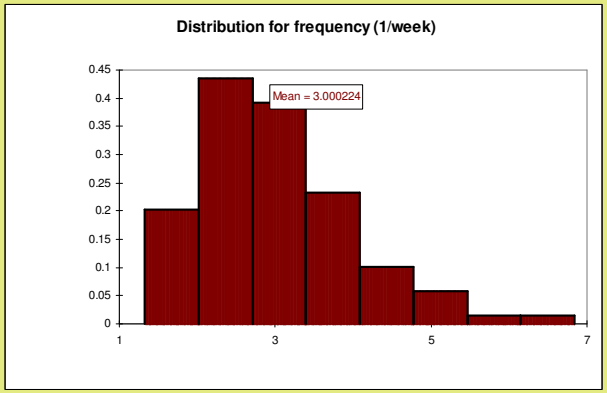
- distributions for exposure parameters
  - frequency : log normal : mean 3 - s.d. 1 (times/week)
  - paint migration fraction: uniform: 0.001- 0.1 g
  - bio-accessibility: uniform 2-10 %
  - body weight log normal: mean 11.1 – s.d. 1.1 kg
  - lead fraction paint log normal: mean 14.8 – sd 0.4 mg/g

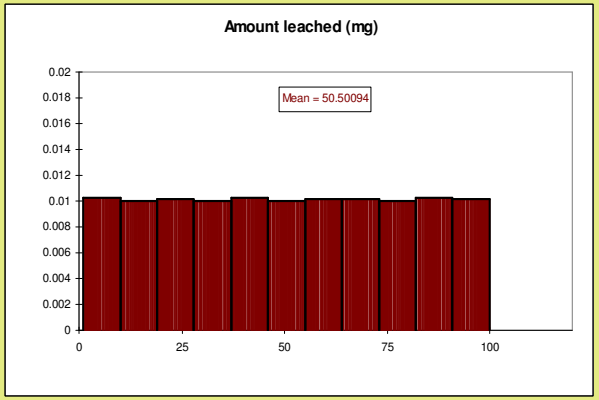
Probabilistic assessment: distributions



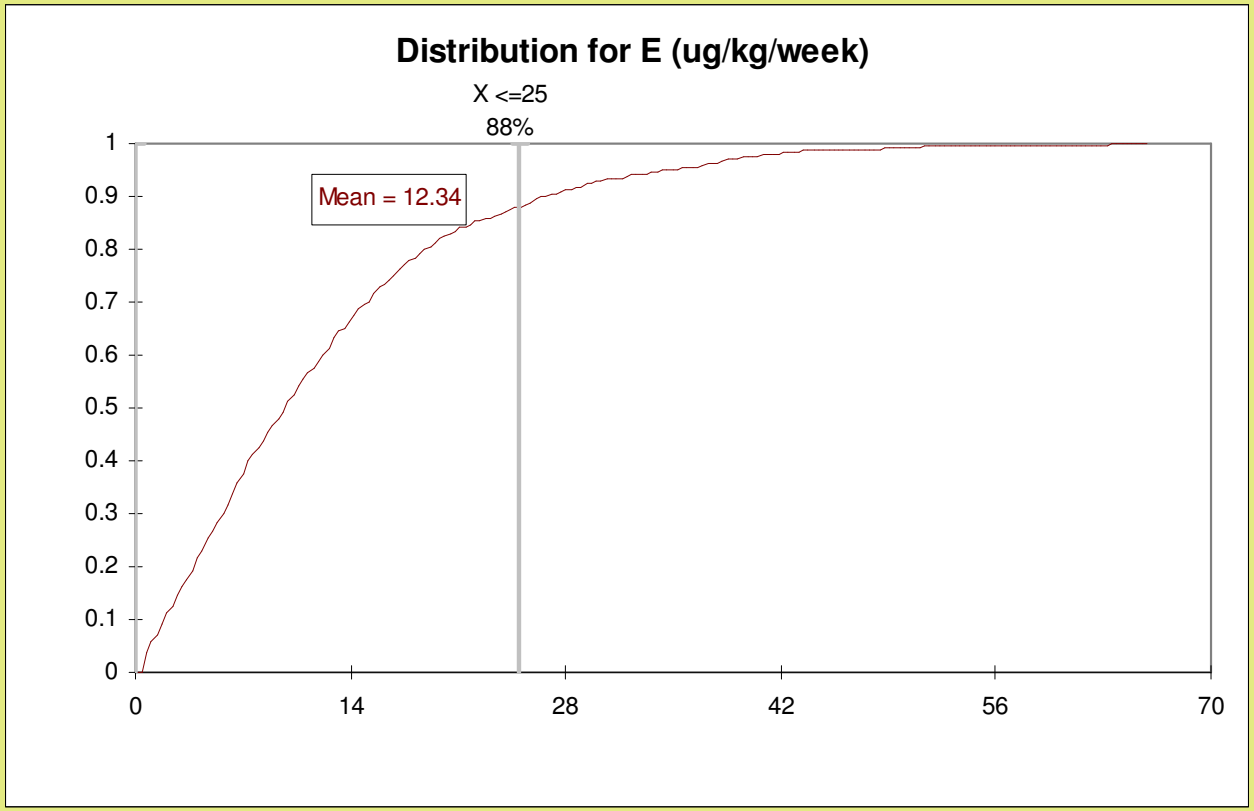








Probabilistic assessment: results



Conclusions

- Screening assessment gives insight in order of magnitude
- More refined methods (like in vitro digestion method) give more realistic values
- Probabilistic assessment takes uncertainty (and variability) into account and provides insight in (sub)-population exposure

Thank you for your attention !

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