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Risk evaluation tool for chemical contaminants in the context of RASFF

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40th EFSA Focal Points meeting

Trusted science for safe food

efsa
European Food Safety Authority

Mandate to EFSA

- Develop a tool to harmonise risk evaluation
- Propose methodology for a risk-based classification of RASFF notifications on contaminants
- Based on science
- Practical
- Application areas (examples):
  - Industrial and environmental contaminants
  - Heavy metals
  - Mycotoxins and other biotoxins
  - Migration from food contact materials
  - Residues of pharmacologically active substances

In summary

Analytical results

Use of the tool

OUTCOME

- Not risk assessment (time /data requirements)
- Transparent evaluation
- Accept uncertainty

EFSA working group

- EFSA staff and external experts
- 3 Work Packages (WP):
  - WP1 Toxicological parameters
  - WP2 Estimating exposure
  - WP3 IT tool

- Consultation with RASFF network

TECHNICAL REPORT

https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1625

Risk evaluation description

Insert new analysis | print excel analysis | delete analysis

Population group	Mean	95th percentile
Infants	21.0	
Toddlers	130.7	
Other children	220.5	
Adolescents	130.5	41.0
Adults	80.6	92.6
Elderly	78.5	
Very elderly	138.7	
Pregnant women	42.5	

Reference

Reference po

1.3

mg/kg bw/day

matic

m/kilogram

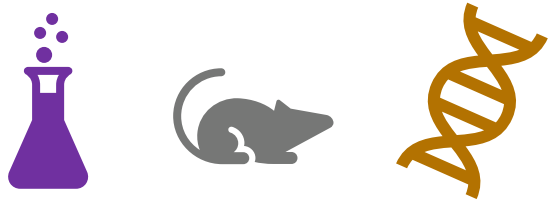
Survey's country	Mean	95th percentile
Czech Republic	232,605	287,994
Germany	5,279	449,541
Denmark	34,415	50,721
Estonia	15,247	
Spain	25,307	
Finland	17,882	13,510
France	20,677	7,974
United Kingdom	115,838	
Ireland	81,313	
Italy	51,105	
Netherlands	1,141	
Portugal	17	
Romania	269,303	85,779
Sweden	27,705	

Reference value type chronic: Benchmark Dose Lower (Genotoxic)

reference value: 340 µg/kg bw/day

reference value reference: EFSA, 2008. BMDL 10 for PAH4

WP1 Toxicological parameters

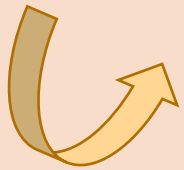


Methodology

- EU legislation
- Past notifications - RASFF database
- **EFSA Scientific publications*:**
  - Contaminants in food and feed
  - Substances which are both genotoxic and carcinogenic
  - Margin of Exposure (MoE) approach
  - Threshold of Toxicological Concern (TTC)
  - Reference Points for Action (RPAs)
  - etc.
- **Peer-reviewed publications***

*Note: full name of publications in Annex

Groups of chemical substances

Group	Decision tree
1. Food contaminants	Next slides 
2. Food contact materials	
3. Pharmacologically active substances	In the Technical report 

Decision tree principles

- TOX – hazard characterization
  - Identification of potential genotoxic and carcinogenic properties of the contaminant
  - Available HBGV (ARfD, TDI, TWI, TMI, etc)
  - Available Reference Point (NOAEL, BMDL)
  - Use of the Threshold of Toxicological Concern (TTC) approach
- Exposure assessment (acute and/or chronic)
- Output

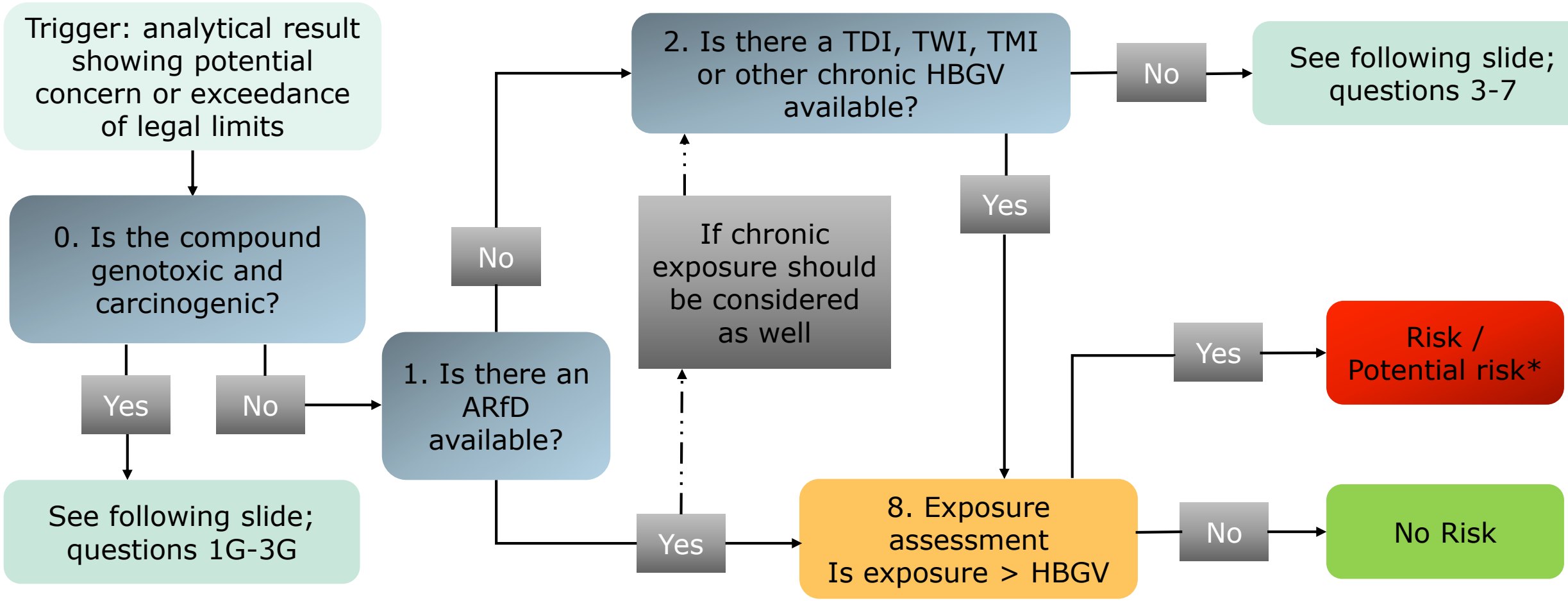
No risk;

Low probability of adverse health effects;

Low concern for public health

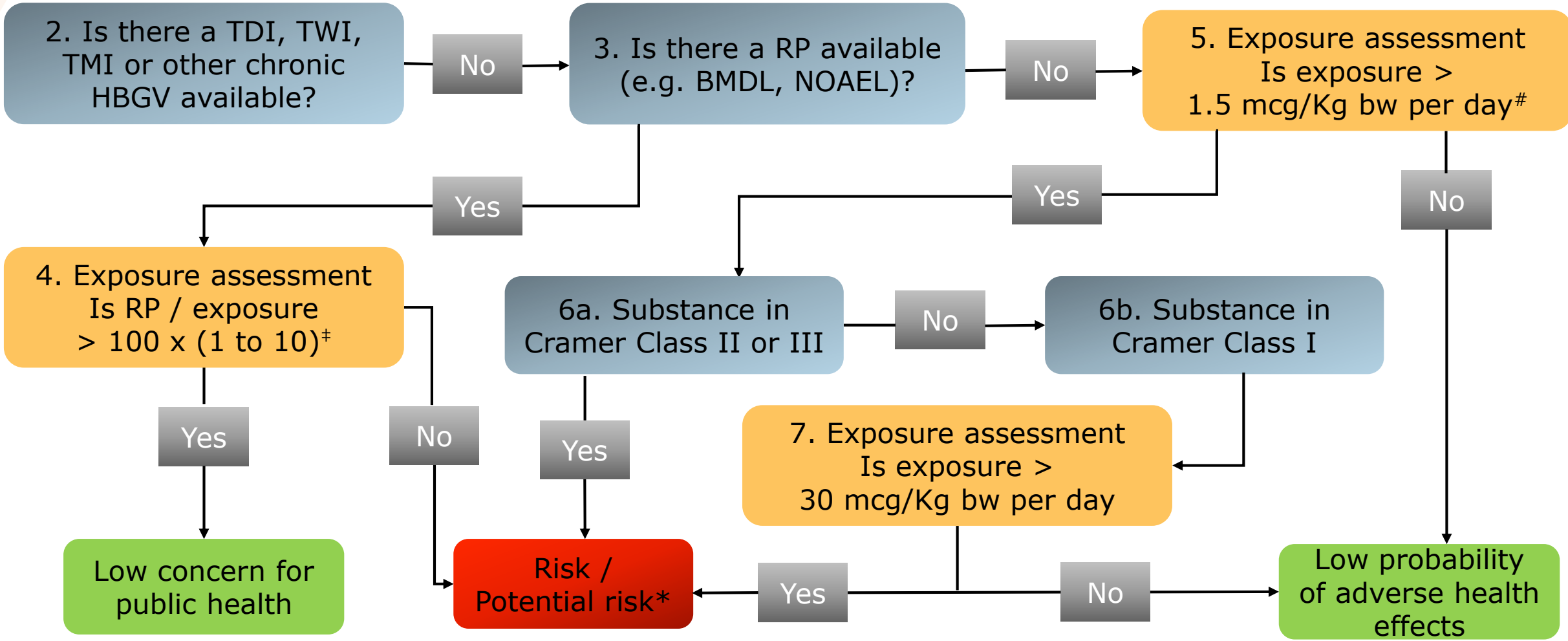
Risk / Potential risk

Non-genotoxic/carcinogenic substances 1/2



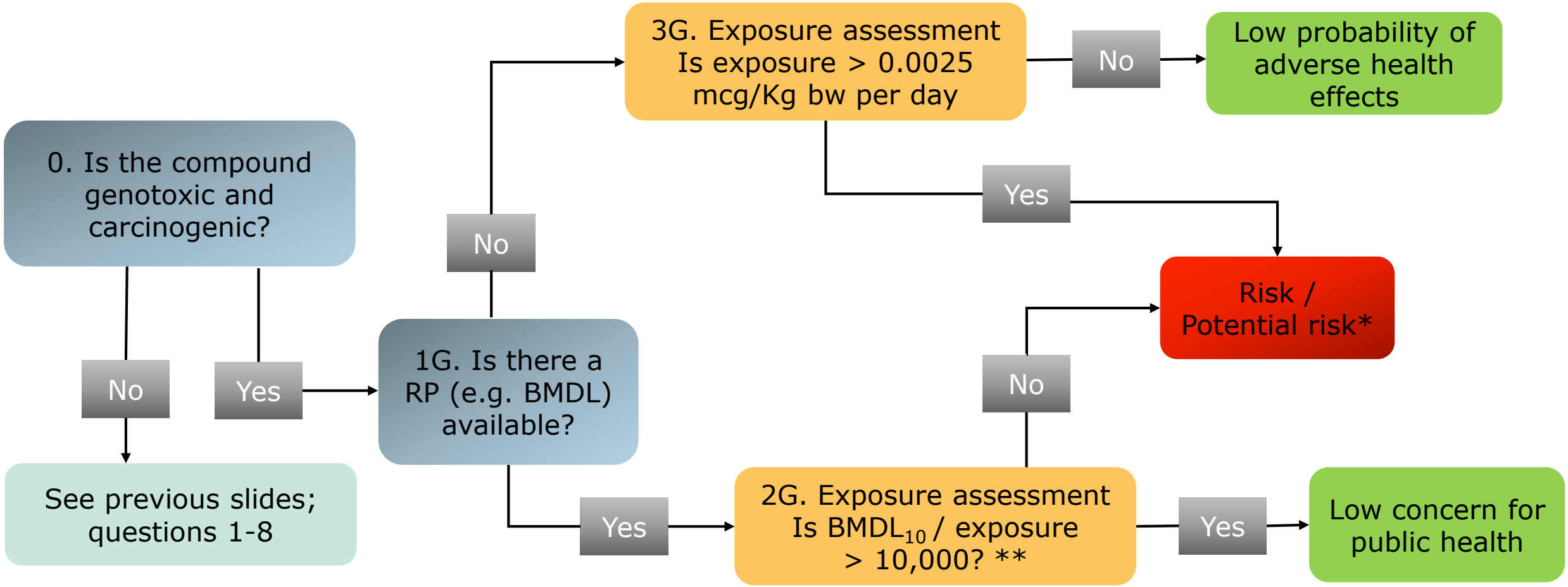
*depending also on rate of exceedance, food, population category/ies exposed etc.
Note: draft decision tree for food contaminants and food contact materials

Non-genotoxic/carcinogenic substances 2/2



*depending also on rate of exceedance, food, population category/ies exposed etc. ‡margin to be defined; # for organophosphates and carbamates the threshold is 0.3 mcg/kg b.w. per day

Genotoxic/carcinogenic substances



*depending also on rate of exceedance, food, population category/ies exposed etc.
**In the absence of BMDL, if T25 is available then a margin of 25,000 shall be considered.
Note: draft decision tree for food contaminants and food contact materials

WP2 Estimating exposure

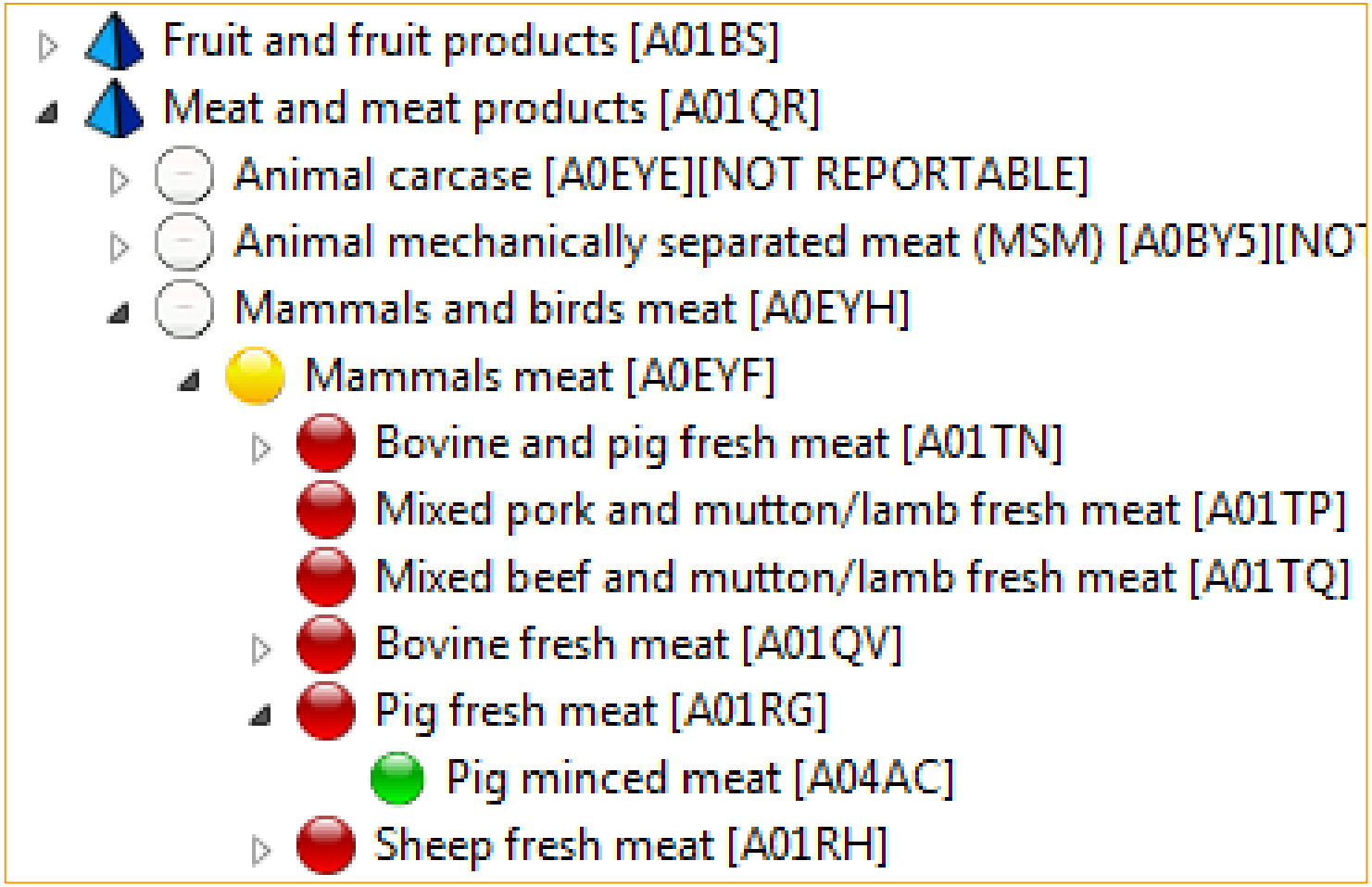
Food consumption data

- Collected from EU Member States
- Stored in the EFSA Comprehensive European Food Consumption Database




FoodEx2

- A common language
- Developed and maintained by EFSA
- Clearly defined groups
- Parent-child structure



Webinar: The FoodEx2 classification system

Overview

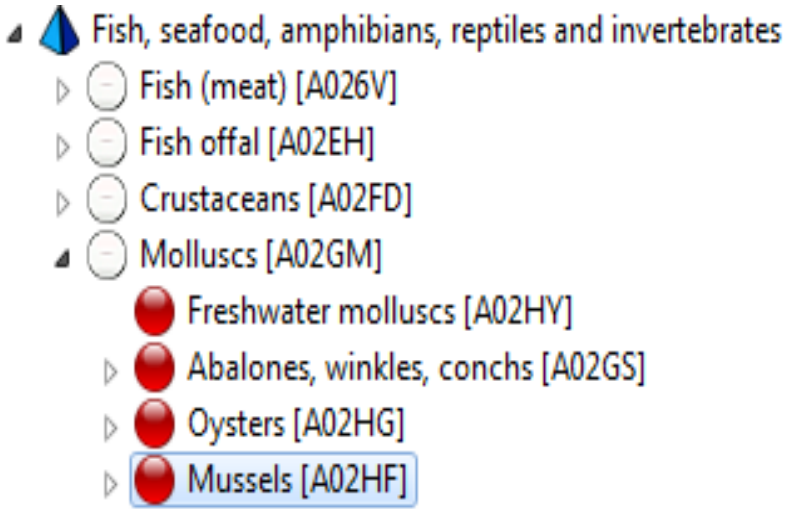
WP3 IT tool

Example: 100 µg/kg TTX (tetrodotoxin) in mussels

Trigger: analytical result showing potential concern or exceedance of legal limits → 0. Is the compound genotoxic and carcinogenic? → No → 1. Is there an ARfD available? → Yes → 8. Exposure assessment Is exposure > HBGV

EFSA, 2017: ARfD 0.25 µg/kg bw

FoodEx2:



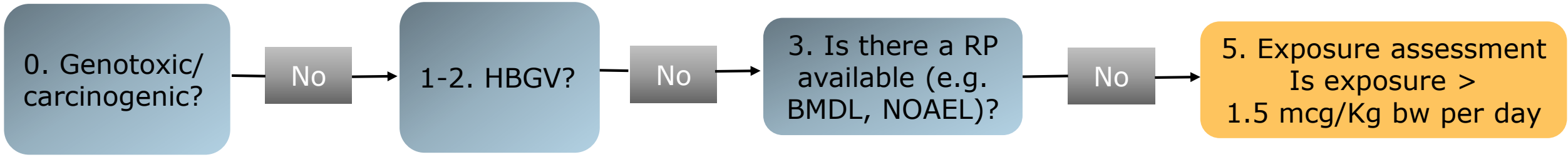
IT tool: summary outcome*

Population group	Mean	95th percentile
Infants	21.0	
Toddlers	**130.7**	
Other children	**220.5**	
Adolescents	**130.5**	41.0
Adults	80.6	92.6
Elderly	78.5	
Very elderly	**138.7**	
Pregnant women	42.5	

Survey's country	Mean	95th percentile
Austria	66.5	
Belgium	**158.5**	
Bulgaria	**102.6**	
Czech Republic	19.0	
Germany	**100.0**	
Denmark	2.5	3.0
Spain	44.3	41.0
Finland	19.1	
France	**130.7**	71.4

*values are example only

Example:50 µg/kg beauvericin (BEA) in dried pasta



No HBGV or RP are available

FoodEx2:

- Grains and grain-based products [A000J]
  - Cereals and cereal primary derivatives [A000K]
  - Bread and similar products [A004V]
  - Pasta, doughs and similar products [A04QT]
    - Pasta and similar products [A007D]
      - Pasta, plain (not stuffed), uncooked [A(
        - Pasta wholemeal [A04LC]
        - Fresh pasta [A007F]
        - Dried pasta [A007L]
          - Dried egg pasta [A007M]
          - Dried durum pasta [A007P]

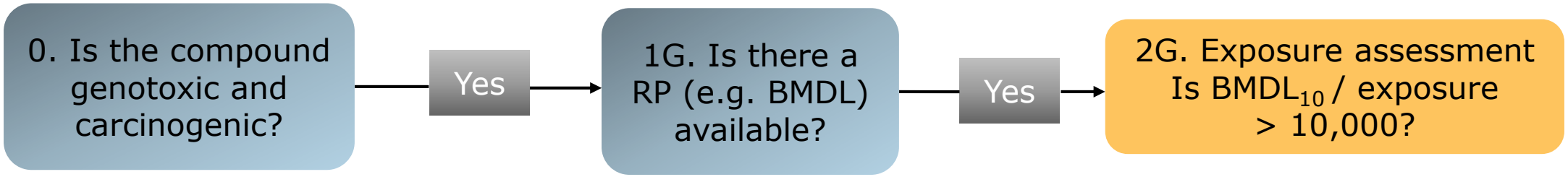
IT tool: summary outcome*

Population group	Mean	95th percentile
Infants	0.292	
Toddlers	0.167	0.211
Other children	0.118	0.240
Adolescents	0.078	0.172
Adults	0.041	0.081
Elderly	0.039	0.078
Very elderly	0.041	0.084
Pregnant women	0.070	0.127

Survey's country	Mean	95th percentile
Bulgaria	0.090	0.138
Germany	0.099	0.222
Estonia	0.109	
Spain	0.078	0.211
Finland	0.051	0.105
France	0.040	0.116
United Kingdom	0.063	
Greece	0.083	0.182
Hungary	0.018	

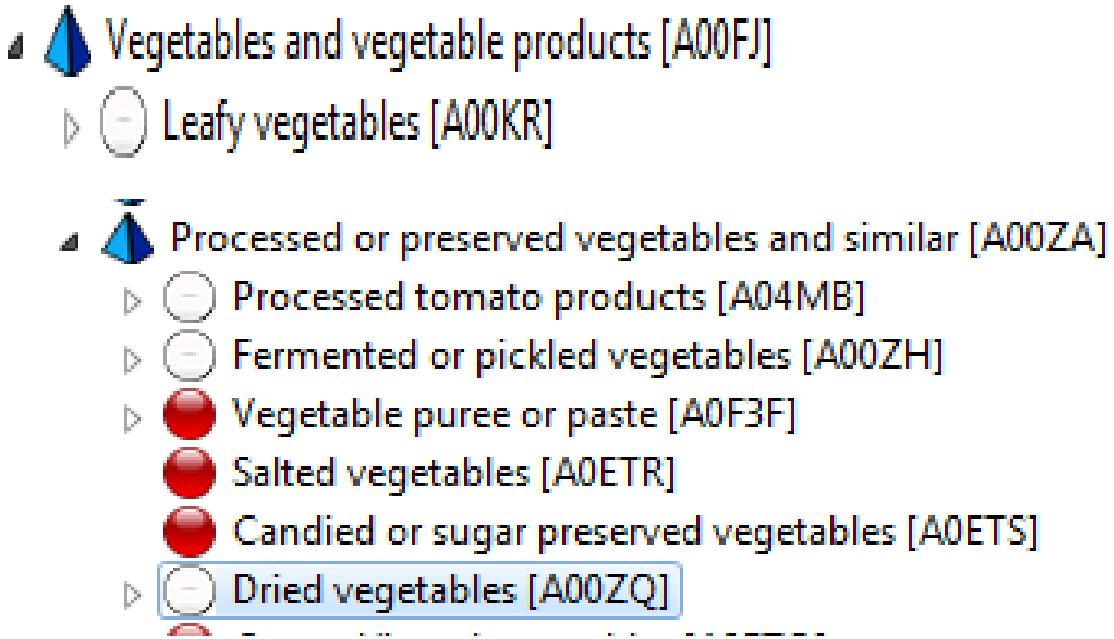
*values are example only

Example: 127.63 µg/kg PAH4 in dried garlic



EFSA, 2008: $BMDL_{10}$ 340 µg/kg bw/day

FoodEx2:

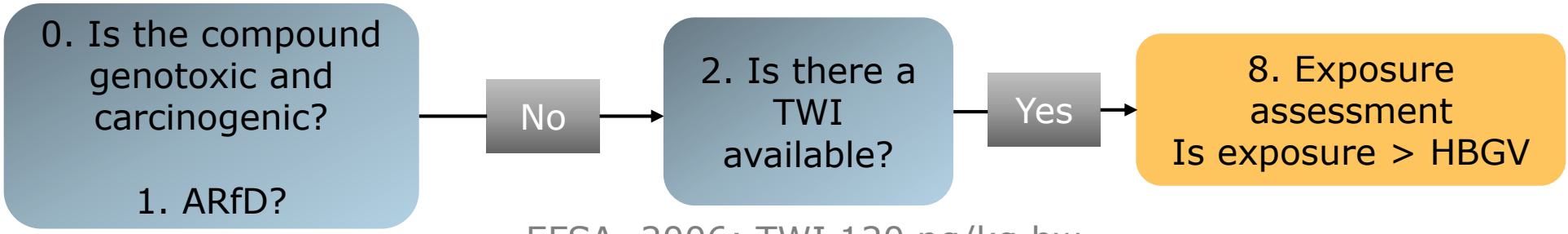


IT tool: summary outcome*

Population group	Mean	95th percentile
Toddlers	**1,141**	
Other children	**2,163**	
Adolescents	22,792	
Adults	10,435	7,974
Elderly	**5,279**	
Very elderly	66,643	
Pregnant women	112,441	
Lactating women	121,598	

*values are example only

Example: 47 µg/kg ochratoxin (OTA) in dried mulberries



EFSA, 2006: TWI 120 ng/kg bw

FoodEx2:

- Grains and grain-based products [A000J]
- Vegetables and vegetable products [A00FJ]
- Starchy roots or tubers and products thereof, sugar plants [A00ZR]
- Legumes, nuts, oilseeds and spices [A011X]
- Fruit and fruit products [A01BS]
  - Fruit used as fruit [A04RK]
  - Processed fruit products [A01ML]
    - Dried fruit [A01MA]

IT tool: summary outcome*

Population group	Mean	95th percentile
Infants	608	723
Toddlers	758	764
Other children	165	524
Adolescents	169	258
Adults	142	472
Elderly	138	540
Very elderly	119	
Pregnant women	156	399
Lactating women	152	

*values are example only

Considerations in characterising the risk

Outcome of the Decision Tree

RASFF terminology

No risk;
Low probability of adverse health effects;
Low concern for public health

Risk / Potential risk

Rate of exceedance;
Population categories exposed;
Severity of the effect;
Duration of exposure;
Characteristics of the food

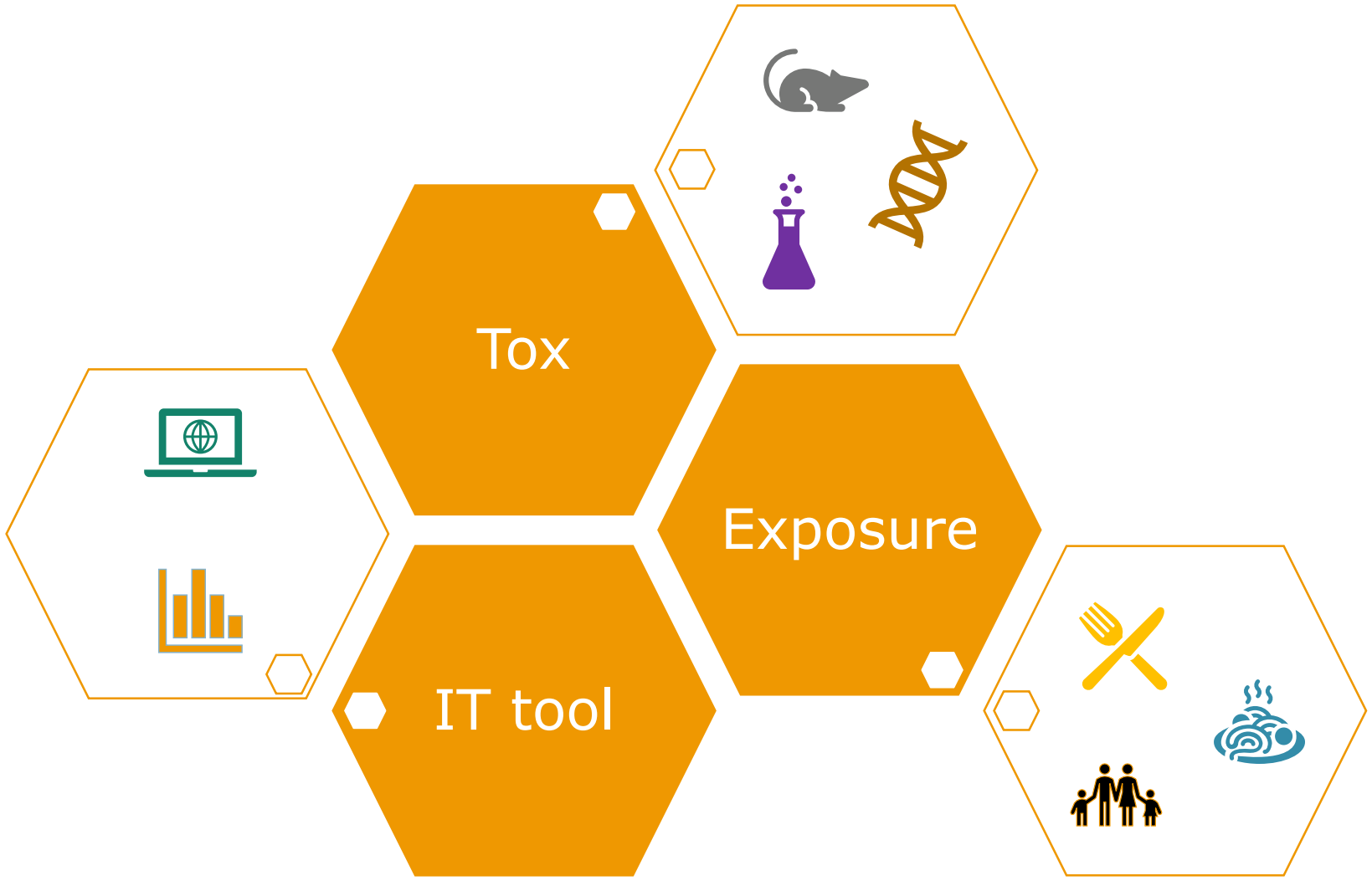
No risk

Not serious risk

Serious risk

Final Notes

- Tool access https://www.efsa.europa.eu/en/microstrategy/race
- Tool manual => **Appendix J**
- Tool registration sc.secretariat@efsa.europa.eu
- Technical support by EFSA
- Feedback from RASFF network sc.secretariat@efsa.europa.eu
- Future developments



Thank you!

Any questions?

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Annex

MAIN REFERENCES

EFSA Scientific outputs

- Opinion of the Scientific Committee on a request from EFSA related to a harmonised approach for risk assessment of substances which are both Genotoxic and Carcinogenic. EFSA Scientific Committee, 2005 ; DOI: 10.2903/j.efsa.2005.282
- Statement on the applicability of the Margin of Exposure approach for the safety assessment of impurities which are both genotoxic and carcinogenic in substances added to food/feed- EFSA Scientific Committee, 2012; DOI: 10.2903/j.efsa.2012.2578
- EFSA Scientific Committee, 2012. Scientific opinion on exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC) - DOI: 10.2903/j.efsa.2012.2750
- Alexander J, Benford D, Boobis A, Eskola M, Fink-Gremmels J, Fürst P, Heppner C, Schlatter J, van Leeuwen R; Special Issue: Risk assessment of contaminants in food and feed. EFSA Journal 2012;10(10):s1004. [12 pp.]. doi:10.2903/j.efsa.2012.s1004.
- Risk assessment of contaminants in food and feed, EFSA CONTAM, 2012 ; DOI:10.2903/j.efsa.2012.s1004
- EFSA CONTAM Panel, 2013. Guidance on methodological principles and scientific methods to be taken into account when establishing Reference Points for Action (RPAs) for non-allowed pharmacologically active substances present in food of animal origin. EFSA Journal 2013;11(4):3195, 24 pp.

Peer-reviewed publications

- Benford D. et al. Application of the Margin of Exposure (MOE) approach to substances in food that are genotoxic and carcinogenic, Food and Chemical Toxicology 48(2-24), 2010.
- Kroes R. et al. Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet, Food and Chemical Toxicology 42(65-83), 2004.