

3 October 2019

Risk evaluation tool for chemical contaminants in the context of RASFF

Ana Afonso
Tilemachos Goumperis

Joint meeting RASFF /AAC contact
points and stakeholders



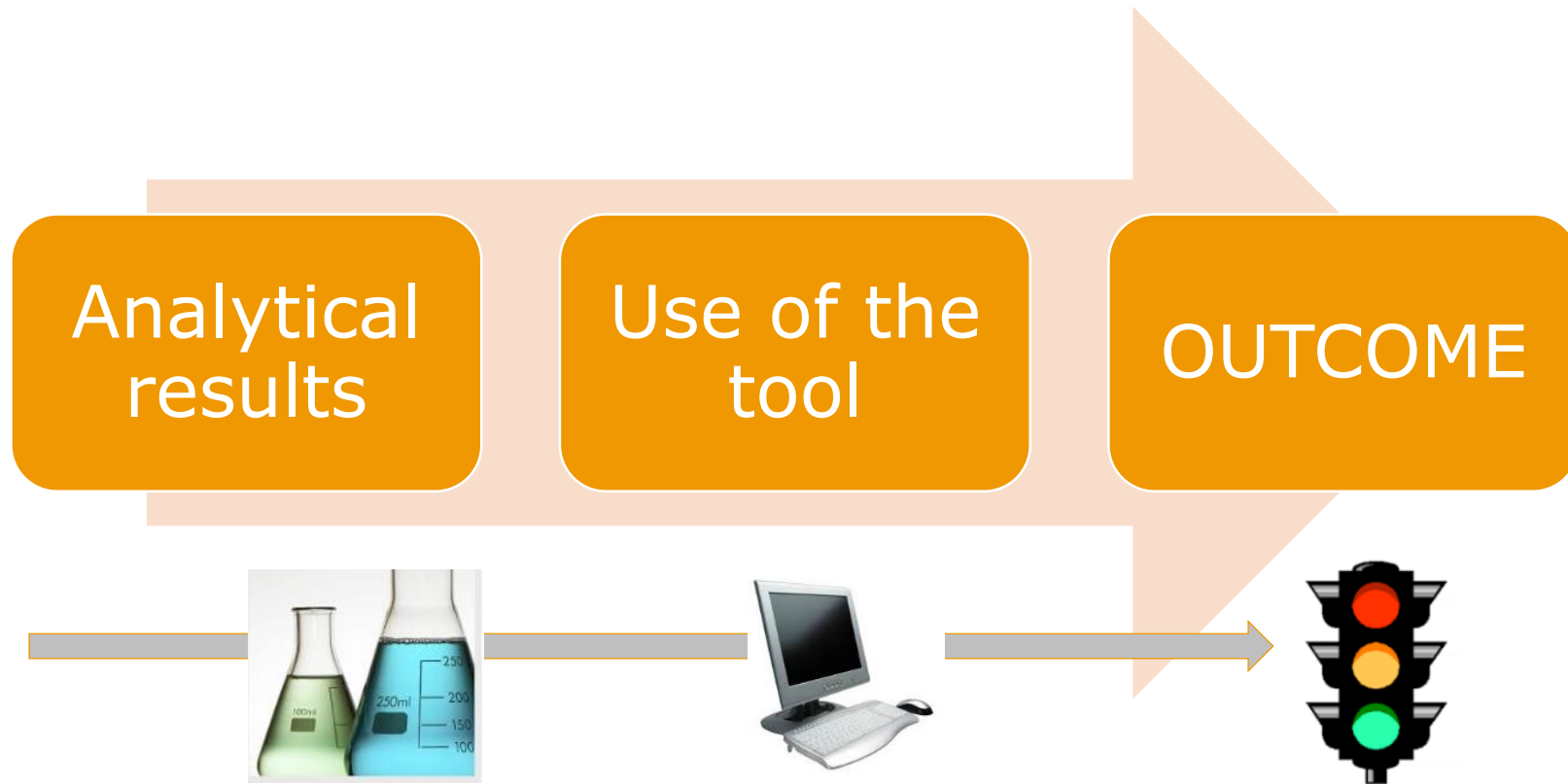
Trusted science for safe food

- Assessment calculation tools
 - Feed Additive Consumer Exposure (**FACE**)
 - Feed Additives Maximum Safe Concentration in Feed for Target Species calculator (**FACTS**)
 - Food Enzyme Intake Model (**FEIM**)
 - Food Additives Intake Model 2.0 (**FAIM**)
 - Pesticide residues intake model (**PRIMo**)
 - Rapid Assessment of Contaminant Exposure (**RACE**)
- Repositories and platforms

<https://www.efsa.europa.eu/en/science/tools-and-resources>

- Published 15/5/19
 - RASFF network training 23/5/19
 - Crisis simulation exercise 28/8/19
 - Enquires and technical support
- **229** registered users
 - **93** of them run at least one analysis
 - **452** analysis are now stored in the accounts of the users

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



- 3 Work Packages (WP):

- WP1 Toxicological parameters



- WP2 Estimating exposure



- WP3 IT tool



- Consultation with RASFF network




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Risk evaluation of chemical contaminants in food in the context of RASFF notifications

Rapid Assessment of Contaminant Exposure tool (RACE)

Peter Furst, Maria Rosaria Milana, Karla Pfaff, Christina Tlustos, Christiane Vleminckx, Davide Arcella, Eric Barthélémy, Paolo Colombo, Tilemachos Goumperis, Luca Pasinato, Ruth Roldán Torres, Ana Afonso ... [See fewer authors](#) ▾

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Requestor: European Commission

Question number: EFSA-Q-2019-00005

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

WP1 Toxicological parameters



- 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***

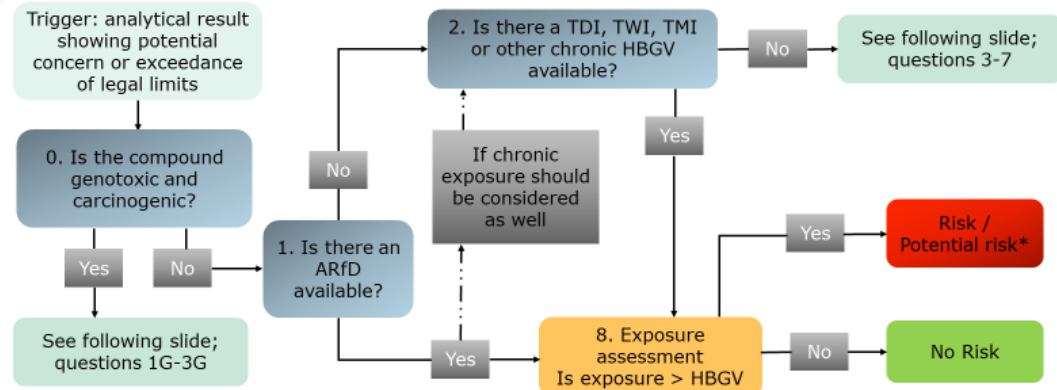
*Note: full name of publications in Annex

Group	Exceedance of legal limit/ concern	Decision tree
1. Food contaminants	Yes/ Pre-decision tree 1	Decision tree 1
2. Food contact materials	Yes/Pre-decision tree 2	
3. Pharmacologically active substances	Yes	Decision tree 2

Decision tree 1

- Is the compound Genotoxic and Carcinogenic?
- Is there an ARfD available?
- Is there a Chronic HBGV available?
- Is there a Reference Point available

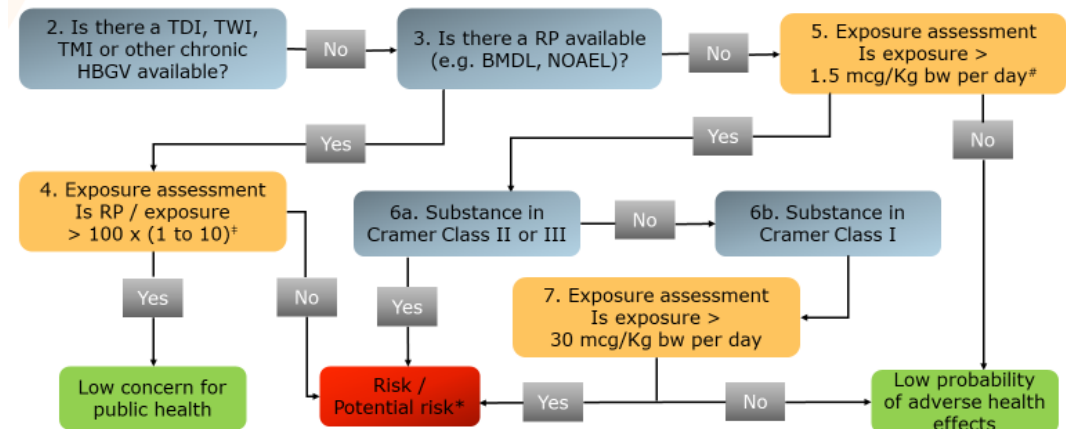
Non-genotoxic/carcinogenic substances 1/2



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

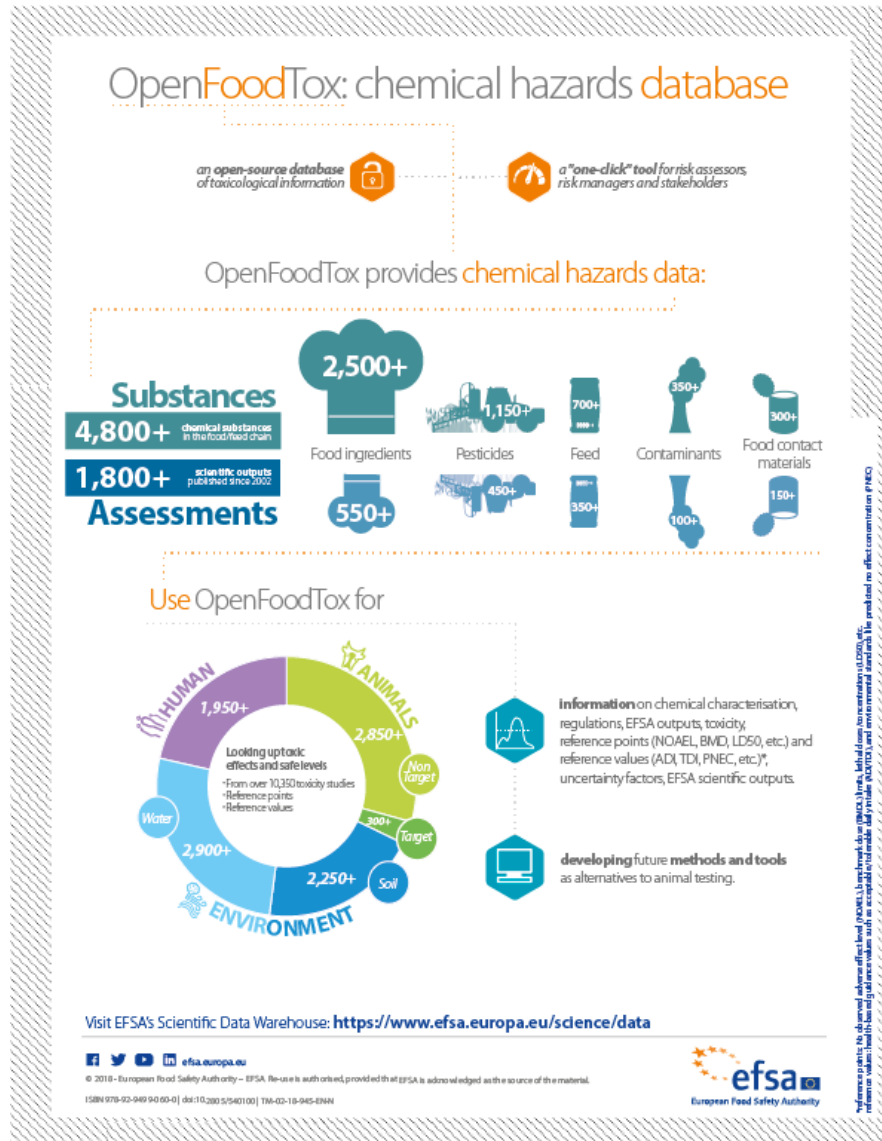
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Non-genotoxic/carcinogenic substances 2/2



*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

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- OpenFoodTox - open source data for the substance characterisation, the links to EFSA's related output, background European legislation, and a **summary of the critical toxicological endpoints and reference values.**

WP2 Estimating exposure



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



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

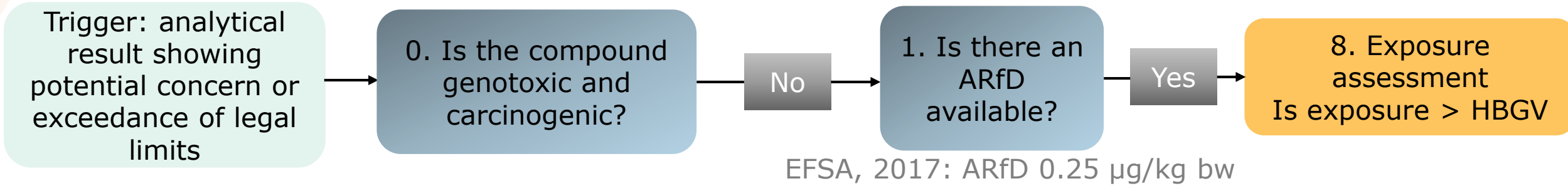
- ▷ ▲ Fruit and fruit products [A01BS]
- ▲ ▲ Meat and meat products [A01QR]
 - ▷ ○ Animal carcase [A0EYE][NOT REPORTABLE]
 - ▷ ○ Animal mechanically separated meat (MSM) [A0BY5][NO]
 - ▲ ○ Mammals and birds meat [A0EYH]
 - ▲ ● Mammals meat [A0EYF]
 - ▷ ● Bovine and pig fresh meat [A01TN]
 - Mixed pork and mutton/lamb fresh meat [A01TP]
 - Mixed beef and mutton/lamb fresh meat [A01TQ]
 - ▷ ● Bovine fresh meat [A01QV]
 - ▲ ● Pig fresh meat [A01RG]
 - Pig minced meat [A04AC]
 - ▷ ● Sheep fresh meat [A01RH]

[Webinar: The FoodEx2 classification system](#)

WP3 IT tool



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



FoodEx2:

- ▲ Fish, seafood, amphibians, reptiles and invertebrates
 - ▷ Fish (meat) [A026V]
 - ▷ Fish offal [A02EH]
 - ▷ Crustaceans [A02FD]
 - ▲ Molluscs [A02GM]
 - Freshwater molluscs [A02HY]
 - ▷ Abalones, winkles, conchs [A02GS]
 - ▷ Oysters [A02HG]
 - ▷ **Mussels [A02HF]**

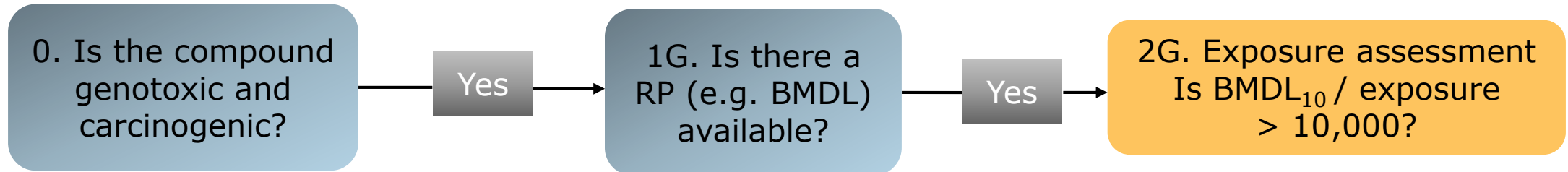
IT tool: summary outcome*

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: 127.63 µg/kg PAH4 in dried garlic



EFSA, 2008: BMDL₁₀ 340 µg/kg bw/day

FoodEx2:

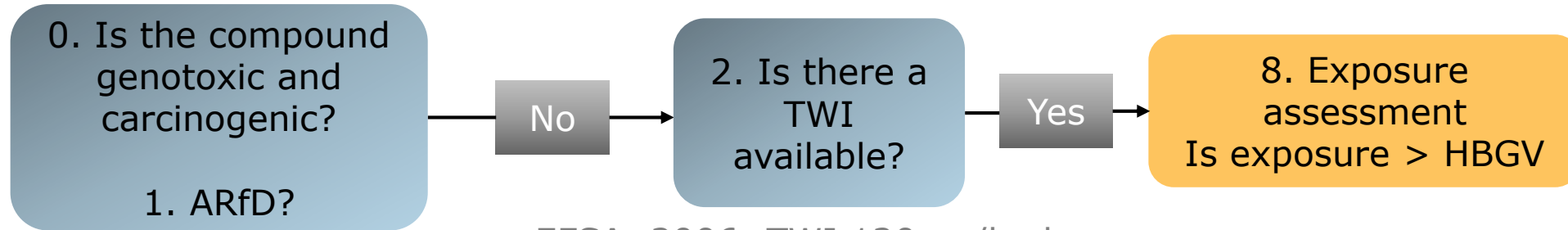
- ▶  Vegetables and vegetable products [A00FJ]
 - ▶  Leafy vegetables [A00KR]
- ▶  Processed or preserved vegetables and similar [A00ZA]
 - ▶  Processed tomato products [A04MB]
 - ▶  Fermented or pickled vegetables [A00ZH]
 - ▶  Vegetable puree or paste [A0F3F]
 - ▶  Salted vegetables [A0ETR]
 - ▶  Candied or sugar preserved vegetables [A0ETS]
 - ▶  Dried vegetables [A00ZQ]

IT tool: summary outcome*

Population group	Mean	95 th 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

IT tool: summary outcome*

Population group	Mean	95 th 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

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]

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

No risk

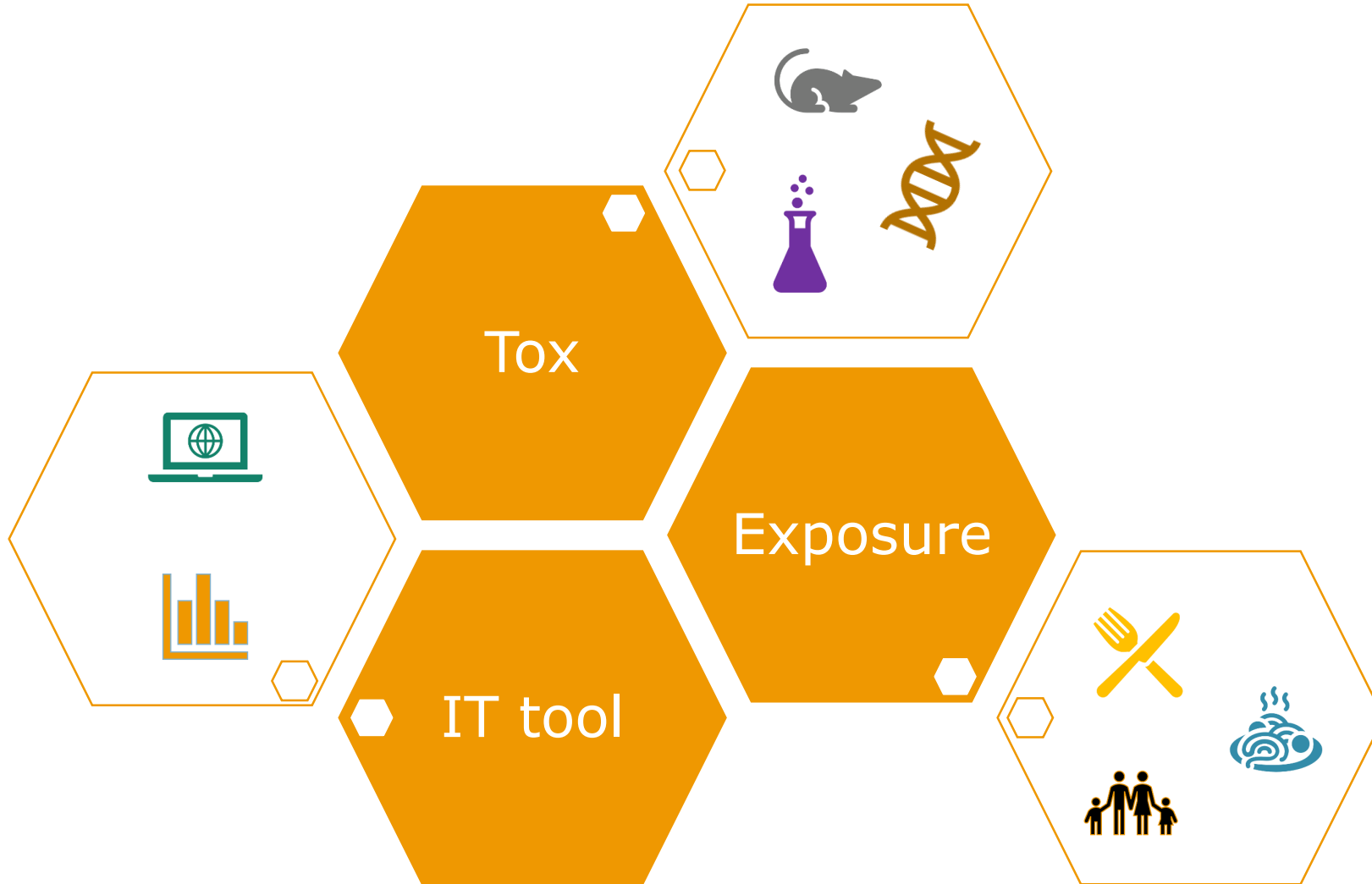
Risk / Potential risk

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

Not serious risk

Serious risk

- 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?

ana.afonso@efsa.europa.eu
tilemachos.goumperis@efsa.europa.eu



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Annex

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.