



Scientific technical assistance to RASFF on chemical contaminants

FCM network; Parma; 10 July 2017

Mandate to EFSA

OVERVIEW

- EC mandate to EFSA; November 2016
- EFSA WG established consisting of:
 - EFSA staff from four units/teams (Scientific Committee, contaminants, food contact materials, exposure assessment/data collection)
 - and external experts
- 3 Work Packages (WP); WP1 to be delivered by July 2017

RISK EVALUATION TOOL FOR CONTAMINANTS

Develop a tool to harmonise risk evaluation of RASFF notifications

- Based on science and practical
- Food and feed chemical contaminants
- Risks for human health and animal health
- Both acute and chronic risk
- Reference sources for toxicological parameters and exposure data

APPLICATION AREAS

- Heavy metals
- Industrial and environmental contaminants
- Migration from food contact materials
- Mycotoxins and other biotoxins
- Residues of veterinary medicinal products

PRIMO TOOL

PRIMo – Pesticide Residue Intake Model

- Used to calculate an estimated short term intake, which after simple comparison with the acute reference dose (ARfD)...
- ...leads to a decision on the risk

APPROACH TO BE TAKEN

Work package 1 - Hazards and associated toxicological information

- Food and human health
- A decision tree model
- Consider legal limits, reference points for action, health-based guidance values etc.
- Indicate the respective information sources

APPROACH TO BE TAKEN

Work package 2 - Estimating exposure

- Acute and chronic exposure
- Use of different exposure models
- EFSA Comprehensive European food consumption database
- EFSA's standard terminology (SSD and FoodEx2)

APPROACH TO BE TAKEN

Work package 3 -Evaluating the risk

Association of the developed decision tree with an algorithm:

- Indicating how the different types of toxicological reference levels will have to be considered with the exposure levels
- Conclude on the risk-based decision

IN SUMMARY

Analytical
results

Use of the
tool

OUTCOME



Work Package 1:
Draft decision trees

REFERENCES

- RASFF SOPs
- EU legislation
- Extractions from the RASFF database
- **EFSA Scientific publications***:
 - Risk assessment of contaminants in food and feed
 - A harmonised approach for risk assessment of substances which are both genotoxic and carcinogenic
 - Applicability of the Margin of Exposure (MoE) approach
 - Opinion on Threshold of Toxicological Concern (TTC)
- **Peer-reviewed publications***

*Note: full name of publications in Annex

Decision trees are being developed by the EFSA working group.

The tool have to be “practical”.

Consequently:

- Not a full risk assessment (months to finalise)
- Accept approximations/assumptions

GROUPS OF CHEMICAL SUBSTANCES

Group of chemical substances	Consider legal limits as a trigger	Decision tree
1. Food contaminants	X	X
2. Food contact materials	X	
3. Pharmacologically active substances		X

2. FOOD CONTACT MATERIALS

- Pre-decision tree
- Decision tree

The background of the image is a dense, repeating pattern of sliced oranges. The slices are arranged in a somewhat overlapping, circular pattern, filling the entire frame. The color is a vibrant, warm yellow-orange, with the central pith of each slice appearing as a small, lighter-colored starburst. The lighting is bright and even, highlighting the texture of the fruit segments.

THANK YOU

DISCUSSION



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
- EFSA Scientific Committee; Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal 2012;10(3):2579. [32 pp.]; doi:10.2903/j.efsa.2012.2579.
- 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

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.