

BTSF – RISK ASSESSMENT IN THE FOOD CHAIN Course 1 - Chemical risk assessment in food Notification to NCPs

Organisation and implementation of training activities on principles and methods of risk assessment in the food chain under the "Better Training for Safer Food" initiative

Objectives of the proposed training and goals to be reached

The EFSA Advisory Forum has on several occasions expressed a need to develop a long-term training programme on risk assessment for experts working in different fields of the food chain, wishing also more recently to extend these training programmes to additional areas of risk assessment.".

The harmonisation of risk assessment methodologies has been identified as a priority area of the Strategy for Cooperation and Networking between the EU Member States and EFSA, since harmonisation would help in the development of high quality scientific opinions that are recognise as truly authoritative. This harmonisation does not aim at standardising risk assessment methodology, but merely at identifying possible discrepancies between the approaches used by different Member States in order to increase transparency and trust amongst Member States' authorities in each other's risk assessments.

2008 EFSA Working Group Report on "Fostering harmonised risk assessment approaches in Member States" pointed out how countries organised risk assessment different at time. Many of the procedures in the countries appeared to be in line, or at least not in conflict, with procedural aspects within EFSA, however highlighting discrepancies in procedural aspects of risk assessment, mostly regarding declarations of interest, public register of risk assessment requests, procedures concerning the selection of experts, the interaction with stakeholders and between risk assessors and risk managers during the risk assessment process. Harmonisation of risk assessments is thus considered fundamental to avoid divergences by different national agencies and strengthen collaboration within Europe and beyond.

The present training proposal will address issues listed above through the adoption of a practical approach, aimed to increase knowledge of Competent Authorities and scientists from public institutions and national authorities involved in food chain risk assessment in order to increase the level of expertise and harmonisation. To facilitate this, invited countries will be requested to select on the specific training sessions officials coming from the risk assessment field.





General training objective

The main goal of the training programme is to disseminate best practices for the implementation of principles and methods of food chain risk assessment, improving knowledge of this complex area of work and ensuring consistent and high implementation standards across the European Union.

Specific objectives:

- Promoting reduction of discrepancies in procedural aspects of risk assessment
- Contribute to the harmonisation of risk assessment approaches
- Contribute to increasing transparency and building trust amongst Member States' authorities in each other's risk assessments.
- Disseminate best practices for risk management and communication
- Promote exchange of experience in order to increase the level of expertise and harmonisation of approaches.

The training will be addressed to officials from the Member States, EEA/EFTA countries and EU candidate countries involved in the risk assessment field

Main topics that will be addressed:

- Introduction to chemical risk assessment (different steps, chemical risk assessment at national and at international level, approaches in different areas of food and feed safety, problem formulation, routes of exposure, differences between types of chemicals in food and feed, fate and behaviour of chemical contaminants) and its legal framework.
- Hazard Identification and Characterization
- Basic concepts in toxicology
 - Concepts of hazard versus risk;
 - Dose response relationships, threshold values, stochastic and non-stochastic dose response;
 - Risk assessment paradigm: hazard identification and characterisation, exposure assessment, risk characterisation;
 - Threshold approach: LOAEL, NOAEL, ADI/TDI, ARfD, Benchmark dose;
 - Uncertainty assessment safety factors;
 - Relevance of a Mode of Action for Humans species differences and intra-species /human variability;
 - Non-threshold approaches: extrapolation, Margin of Exposure; ALARA principle;
 - Threshold of Toxicological Concern;
 - Acute vs. chronic toxicity;
 - OECD test guidelines;
 - Main sources and quality of toxicological data.
- Basic knowledge of different endpoints in toxicity studies
 - Toxicokinetics and toxicodynamics (ADME);
 - Histopathology;
 - Genotoxicity / carcinogenicity;
 - Reproductive and developmental toxicity;
 - Neurotoxicity;





- Immunotoxicity;
- Endocrine effects;
- QSAR, In silico" toxicity, read-across.

Chemicals in foods:

- Nutrients;
- Non-nutrients;
- Contaminants (man-made, natural);
- Food additives.
- Exposure Assessment (focused on intake from consumption of food)

• Collection of consumption data:

- Methods for food consumption surveys (pro et contra);
- Food composition databases;
- SSD2/FoodEx2;
- EFSA and WHO databases.

Collection of chemical occurrence data

- Random or targeted sampling
- Monitoring, control and/or scientific data;
- EFSA and WHO database;
- Quality of collected data (Accreditation);
- Handling of left-censored data.

Exposure estimations

- Point estimates probabilistic estimates;
- Acute and chronic exposure;
- Human) biomonitoring;
- Combined exposure to multiple chemicals and/or from multiple sources (e.g. cumulative/aggregate exposure, mixtures);
- Uncertainties sensitivity analyses.

Challenge of connecting consumption data with chemical occurrence data

- Data source, availability and gaps;
- Technical factors;
- Uncertainties.
- Short introduction to Risk Communication.

Training agenda

The training will be organised over 5 days and it will be designed in the following way: opening introductory session in the afternoon on the day of arrival, three full day sessions and a session in the morning on the final day.

Courses, locations and allocations of seats

Two four-day training courses will be delivered in February 2020 and November 2020.

The dates and locations of the training sessions are the following:





Training sessions: dates and locations

Year	Training session	Tentative dates	City	
	1	10 - 14 February 2020	Valencia	(Spain)
2020	2	09 - 13 November 2020	Riga	(Latvia)

The attendance will be approximately 20 people for each session. As specified, the courses will be offered to officials of the Member States, EEA/EFTA countries and EU candidate countries. It's again highlighted that each invited country on the different training sessions will be requested to select trainees coming from the risk assessment field

Quotas of allocated seats for the first training session is provided as per below table. Quotas of allocated seats for the second training session will be provided in due time.

		Course 1 – Chemical risk assessment in food	
country group	Country	TS 01 10-14/02/2020 Valencia	
	Austria	1	
	Belgium	1	
	Bulgaria	0	
	Croatia	0	
	Cyprus	1	
	Czech Republic	0	
	Denmark	0	
es	Estonia	0	
Stat	Finland	0	
ber	France	1	
Member States	Germany	1	
Σ	Greece	1	
	Hungary	1	
	Ireland	1	
	Italy	1	
	Latvia	0	
	Lithuania	0	
	Luxembourg	0	







	Malta	1
	Netherlands	1
	Poland	1
	Portugal	1
	Romania	0
	Slovakia	0
	Slovenia	1
	Spain	2
	Sweden	0
	United Kingdom	0
	Albania	1
ate ies	North Macedonia	1
<u> </u>	Montenegro	0
	Serbia	1
	Turkey	1
EA es	Iceland	0
EFTA/EEA Countries	Norway	0
EF]	Switzerland	0
		20

In addition to the numbers indicated above, each country will be requested to indicate additional participants for a reserve list to be used should one or more countries not meet the proposed quota.

For logistic organisational reasons, it is kindly requested that names of participants shall be communicated at the latest within 30 days from each workshop. A reminder will be sent to NCPs before each event.

Participants will arrive at the training venues on Monday morning and training will commence on Monday afternoon (depending on travel connections, participants may be requested to arrive at the training venues on Sunday evening). Return travel will be on Friday afternoon or Saturday morning according to flight connections.

Participants' profile

The proposal of OPERA will aim at disseminating best practices for the implementation of principles and methods of food chain risk assessment, improving knowledge of this complex area of work and ensuring consistent and high implementation standards across the European Union. To ensure a properly targeted selection of participants in the field of risk assessment, relevant selection criteria are enclosed here below.

Selection criteria for regular participants

Minimum requirements (participants who do not meet the minimum requirements should not be proposed







for the training and should not be evaluated according to the selection criteria listed below)				
Minimum 3 years of professional experience in the food cha	Yes/No			
Competent national authority responsible for the food chai	Yes/No			
Evaluation criteria	Max. score			
1) Professional experience in public institutions and nation food chain risk assessment Scoring less than 3 years = 1 point; 3-5 years = 5 points; 5-10 years = 7 points		10		
2) Experience in chemical risk assessment Scoring less than 3 years = 1 point; 3-5 years = 5 points; 5-10 years = 7 points	ots; > 10 years = points	10		
3) Experience in crisis investigation and management Scoring no experience = 0 points; less than 3 years = 1 point; 3-5 years = 5 p > 10 years = points	points; 5-10 years = 7 points;	10		
	30			

As concerns the Evaluation Criteria, these should be used as a tool to rank participants according to priority (where higher scoring indicates higher priority) but there is no expected minimum scoring to be met with.

<u>Participants will be requested to commit themselves to disseminate the knowledge received via different dissemination methods</u>, i.e. informing colleagues about the information received at the training, distributing (photocopying or sending via electronic way) the training materials among their colleagues, preparing informative articles in the professional national journals or preparing presentations based on the training materials for the staff of national Competent Authorities or other disseminating methods which could be appropriate to share the information received via the BTSF training. During the course participants will be provided with a training package to be used as supporting dissemination material.

Dissemination questionnaire

Between two to three months after the respective training session, participants will receive a standard questionnaire requesting information of dissemination activities performed by the participant after the workshop and details on differences in the approach adopted in day-to-day work after having undergone the training.

<u>Initial and final tests of knowledge</u>

Furthermore, selected participants should be informed that the program will include an anonymous knowledge test to be carried out at the beginning and at the end of each training session in order to measure the impact of the training on the understanding of the taught subjects by participants.

Participants are expected to agree to carry out the above tests and to reply to the questionnaire.

Data protection







For the the purpose of selection, enrolment and participation in the training activities under the BTSF, as well as for statistical purposes, personal data of participants will be processed in accordance with Regulation (EU) No 2018/1725 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data. As the organisation of BTSF training courses implies the collection of individuals' personal data, its processing falls within the provisions of the above mentioned Regulation. Further details can be found at the following link: https://btsfacademy.eu/training/mod/page/view.php?id=417

Project Management

The project is managed by OPERA Srl, in consortium with NSF Euroconsultants.

Project Manager is Claudio BOMPARD.

Training Coordinator is Rob THEELEN.

Separate notifications will be sent to NCPs for each course and will contain the names and contact details of the Event Manager and Assistant Event Manager as also logistical details on the event.

All official communication between NCPs and the project will be maintained through the functional e-mail 20189605riskassessment@btsftraining.com or phone to + 39 06 96042652.

Booking of flights and other logistical arrangements will be handled by OPERA and NSF Euroconsultants staff. Contacts of relevant staff members involved will be supplied to the participants.

The project website is <u>www.btsftraining.com/btsf-risk-assessment</u> and will be regularly updated with details of forthcoming courses.

