Organisation and implementation of training activities on principles and methods of risk assessment in the food chain – Chafea/2018/BTSF/05 - under the "Better Training for safer Food" Initiative

COURSE 1 – CHEMICAL RISK ASSESSMENT

Phase 2

Valid as of 26/07/2023

1. Course objectives....2
2. Training dates and locations....3
3. Selection criteria for participants....4
4. Country allocations....6
5. Face-to-face logistical arrangements....8

Annex 1: Background and main topics covered in training....9
Annex 2: Legislation and guidance....12
Annex 3: Agenda....13
Annex 4: Training material, outcomes and dissemination activities....22
Annex 5: Contractor contact details....23

1. *Course objectives*

General 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.

2. *Training dates and locations*

Two five-day Face-to-face (F2F) training courses will be delivered in October 2023 and May 2024 with approximately 20 people and it will be designed in the following way: overall five full day sessions (from around 9 AM until around 5 PM Central European Time) with opening introductory session in the morning on the first day and a closing morning session on Friday.

Table 1: Training dates and Location

Year	Training sessions	Course title	Locations	Proposed dates	Registration deadline
2023	TS 1	Chemical Risk Assessment	Valencia, Spain	16-20 October 2023	08/09/2023
2024	TS 2	Chemical Risk Assessment	Warsaw, Poland	27-31 May 2024	26/04/2024

3. Selection criteria for participants

Participant must:
1. Fulfil the eligibility criteria
2. Meet the minimum requirements
3. Be selected using the evaluation criteria

1. Eligibility criteria for Course 1 Chemical Risk Assessment
Only **eligible participants** should be further assessed against the minimum requirements below. Trainees must be originated from national authorities and public institutions (e.g. ex art. 36 of EFSA's founding Reg. CE 178/2002), involved in food chain risk assessment.

Participants must meet the minimum requirements below to ensure they can follow and fully participate in this course. Participants who do not meet the minimum requirements should not be proposed for the training.

2. Minimum requirements for Course 1 Chemical Risk Assessment	**Yes/No**
Participant must: • Have worked in functional areas of food chain risk assessment with a minimum of 3 years of professional experience or • Have had experience of setting up and implementation of food chain risk assessment in a Competent Authority (covering areas of food/ feed safety, animal health or animal welfare).	Yes/No

The evaluation criteria should be used as a tool to prioritise participation (higher score indicates higher priority), but there is no minimum score necessary.

3. Evaluation criteria for Course 1 Chemical Risk Assessment		**Enter Score**
a)	Professional experience within a public institution or a competent authority involved in food chain risk assessment <u>Scoring</u> less than 3 years = 1 points; 3 - 5 years = 5 points; 5 - 10 years = 10 points; > 10 years = 12.5 points	
b)	Experience in chemical risk assessment <u>Scoring</u> less than 2 years = 0 points; 2 -5 years = 5 points; 5 - 10 years = 10 points; > 10 years = 12.5 points	
c)	Experience in crisis investigation and management <u>Scoring</u> no experience = 0 points; less than 3 years = 5 points; 3 - 5 years = 10 points; > 5 years = 12.5 points	

d)	During the course, participants will be provided with a training package to be used as support dissemination material. Commitment to disseminate the knowledge received is a prerequisite for course participation. Scoring 1. Commitment to distribute the training material among their colleagues = 5 points; 2. Point 1 plus preparing and giving presentations based on the training material for the staff of national competent authorities/uploading training material to national competent authorities' intranets/websites = 10 points 3. Points 1, 2 plus preparing informative articles in the professional national journals = 12,5 points 4. no commitment = 0 points	
	Maximum total score	**50**

4. Country allocations

A total of 20 seats for each session will be allocated according to the tables below. The course will be offered to officials of the Member States, EEA/EFTA countries and EU candidate countries. It's highlighted that each invited country will be requested to select trainees coming from the risk assessment field. Please note that the number of allocated seats for each country may vary.

Table 2: Suggested allocation for EU Member States and Candidate Countries

		TS01 - Valencia	TS02 - Warsaw
Country group	**Country**	**16-20 October 2023**	**27-31 May 2024**
Member States	Austria	1	1
	Belgium	1	0
	Bulgaria	0	1
	Croatia	0	1
	Cyprus	1	0
	Czech Republic	0	1
	Denmark	0	1
	Estonia	0	1
	Finland	1	0
	France	1	0
	Germany	1	1
	Greece	1	0
	Hungary	0	1
	Ireland	0	1
	Italy	1	0
	Latvia	0	1
	Lithuania	0	1
	Luxembourg	1	0
	Malta	1	0
	Netherlands	1	0
	Poland	1	1
	Portugal	1	0
	Romania	0	1
	Slovakia	0	1
	Slovenia	0	1
	Spain	1	1
	Sweden	1	0
Candidate Countries	Albania	0	1
	Bosnia and Herzegovina	0	1
	Montenegro	0	1
	North Macedonia	1	0
	Serbia	1	0
	Türkiye	1	0
	Ukraine	0	1

Table 3: Suggested allocation for other non-EU Countries

You are welcome to nominate more participants for the reserve list than indicated in the table above. If seats will become available you will be informed in due time.

Non-EU Countries	Iceland	1	0
	Norway	1	0
	Northern Ireland	0	0

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 15 days from the workshop. A reminder will be sent to NCPs before event.

Should you consider that the number of allocated seats is insufficient to meet your country's training needs, please contact the Project Manager at 20189605riskassessment@btsftraining.com as soon as possible, providing an explanation.

The contractor will evaluate your request and pass it to the Contracting Authority for consideration.

5. Face-to-face logistical arrangements

In the case of face-to face training sessions, the European Commission will fund in full the visa, travel, accommodation, meals for all training participants. No daily allowance will be paid on top of this. Any other costs are to be paid by the participants themselves.

Participants will arrive at the training venues on morning of day 1 (Monday) and training will commence around lunch time (depending on travel connections, participants may be requested to arrive at the training venues on the evening of Sunday). Return travel will be on the afternoon of day 5, upon closure of the session, or on the following morning of Saturday according to flight connections.

The NSF Euro Consultants Team will liaise further with the nominated participants for all logistics and practical aspect.

Annex 1: Background and main topics covered in training

Background

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 programme 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.

* * *

Risk analysis comprises Risk assessment, Risk management and Risk communication. Since the 1990'ies, different regulatory areas have acknowledged the need to assess and manage microbiological risks on the basis of scientific approaches. Internationally, the Risk assessment framework in the area of genetically modified microorganisms was primarily initiated through OECD work in the mid-eighties. These principles were later elaborated and formalised in EC Directives 90/219/EEC and 90/220/EEC. Likewise, the regulation of microbial pesticides in the EC is governed by a Directive 91/414/EEC, where microbial Risk assessment plays a major role.
The international trade agreements: World Trade Organisation WTO SPS agreement (Article 2) establishes that sanitary measures should be based on scientific principles. Risk analysis should be used to enhance protection of human health and minimize the incidence of food-borne disease through establishing realistic and achievable levels of control of food-borne hazards and basing food safety policies on the practical application of the results of Risk assessment and Risk management.

Main topics covered in the training

- 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.

Annex 2: Legislation and guidance

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- Reg. (EC) 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed;
- Reg. (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014;
- Commission Dec. 2008/654/EC of 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Reg. (EC) 882/2004 of the European Parliament and of the Council;
- Reg. (EC)1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
- Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;
- EFSA, 2011, Technical report on technical specifications on training regarding principles and methods of food safety risk assessment;
- EFSA, 2017, Scientific opinion on the requirements for the development of microbiological criteria;
- EFSA, 2017, Guidance on Uncertainty Analysis in Scientific Assessments;
- EFSA Journal - 2021 - coordination and cooperation of risk communication, Mapping the coordination and cooperation mechanisms of risk communication on feed/food safety in the EU
- EFSA Journal - 2021 - Benchmarking current practice in EU
- EFSA, 2021, Engagement-toolkit, Methods, tips and best practices to design effective participatory processes

Annex 3: Agenda

DAY 1 Monday

Time	*Topic*	*Tutor*
11.30-13.00	Registration of participants and lunch	
13.00 - 13.15	Better Training for Safer Food: presentation of a video	
13.15 - 13.30	Preliminary discussion with participants, aimed to enquire about their expectations on the training initiative Welcome addresses, course background, objectives & expected results • Participants present their tasks with regard to food safety risk assessment, giving a short overview of their national food safety risk assessment organization; • An overview of the various national food safety risk assessment structures in the EU and guest-countries will be presented.	Rob THEELEN (TC - Training coordinator)
13.30 – 14.00	Initial test of Knowledge	
14.00 - 14.30	TOPIC 1: INTRODUCTION TO EXPOSURE ASSESSMENT OF CHEMICALS 1.1. Introduction to risk assessment of chemicals in feed and food • Risk analysis principle on food safety according to the Codex Alimentarius and its implementation in the EU legal framework; • Division of competences between risk assessment and risk management; risk analysis in Regulation 178-2002; role of risk assessment in Regulation 178-2002; • 'Risk' according to Regulation 2019/1715, with a focus on RASFF notifications; • Role and responsibilities of EFSA for EU Member States; • How to deal with the outcome of the risk assessment according to the EU legal framework? *Presentation*	TC
14.30 – 15.15	TOPIC 1: INTRODUCTION TO EXPOSURE ASSESSMENT OF CHEMICALS 1.2. Risk and RASFF notifications The participants use the public RASFF database to become familiar with the information described, and with the information in the notifications regarding 'risk'. Next, they discuss about other situations where an exposure assessment is considered useful. For these they need to define what people or organizations have to perform the assessments. Finally, the participants are asked to select a series of RASFF notifications or situations (max. 5) that they would like to be used during the training session as practical examples. *Plenary discussion*	TC
15.15 – 15.45	Coffee break	
15.45 – 16.15	TOPIC 1: INTRODUCTION TO EXPOSURE ASSESSMENT OF CHEMICALS 1.3. Chemical risk assessment in short: overview over the four basic steps; Supporting tools • Introduction into the exposure assessment procedure: 1. Selection of maximal permissible exposure/HBGV/BMDL 2. Defining rate of consumption 3. Intake calculations and 4. Risk characterization; in order to set the scene for the rest of the program in this training. • Introduction to EFSA-RACE and other online tools for exposure calculations. *Presentation*	TC
16.15 – 17.00	TOPIC 1: INTRODUCTION TO EXPOSURE ASSESSMENT OF CHEMICALS 1.4. Exercise on exposure assessment using an calculation tool (with regard to RASFF notifications) In this group exercise (16.15-16.45), the participants use the online EAST tool for rapid exposure assessment of one of the RASFF cases selected in 1.2., to experience what kind of input data is needed in these cases. They are asked to keep track of questions and discussions during the use of the tool. The priority of the questions and discussion are ordered to be presented in the plenary recap of the exercise (16.45 -17.00) *Practical group exercise (4 to 6 participants)*	TC
17.00	End of Day 1	
19.00	Welcome cocktail and dinner	

DAY 2 Tuesday

Time	*Topic*	*Tutor*
09.00 - 09.15	Overview of the topics introduced the previous day	TC
9.15 – 10.00	TOPIC 2: HEALTH BASED GUIDANCE VALUES 2.1. Maximal permissible exposure Introduction in the fundamentals of risk assessment of chemicals: • Hazard versus risk; • Hazard identification and characterization, and ~~various~~ types of HBGVs (e.g. ADI, TDI, RfD,..); How are HBGVs derived? Where can these be found? • BMDLs and Margin of Exposure as an alternative for using HBGVs; how are BMDLs derived? Where can these be found? • Differences between HBGVs and BMDLs with regard to the use in exposure assessment. • How to select a reference value for maximal permissible exposure when series of HBGVs or BMDLs are available. *Presentation*	Ron HOOGENBOON
10.00 - 10.30	TOPIC 2: HEALTH BASED GUIDANCE VALUES 2.2. Exercise on Finding HBGVs In this exercise, the participants explore various well known sources of HBGVs, both from reports available online and from known electronic databases, and select the reference value to be used for the practical examples determined in 1.2. • Exploring common sources of HBGVs, such as WHO and EFSA reports, and US sources; • Exploring common sources of Well known HBGVs databases; • Selection of reference values to be used for the cases studies. *Working group exercise (4 to 6 participants)*	TC + Ron HOOGENBOON
10.30-10.45	TOPIC 2: HEALTH BASED GUIDANCE VALUES 2.3. Debriefing of the exercise on finding HBGVs In a plenary meeting, the results of the various groups are presented and compared between the groups. It is tried to develop a (small) manual on how to find HBGVs from known sources (to keep the results for later) *Plenary exercise*	TC + Ron HOOGENBOON
10.45-11.15	Coffee break	
11.15-12.00	TOPIC 2: HEALTH BASED GUIDANCE VALUES 2.4. Genotoxic carcinogens • What are genotoxic chemicals? Why are they carcinogenic? Which chemicals are to be considered genotoxic? Test-systems and results. How to evaluate series of test results. • How to evaluate exposure to genotoxic carcinogenic chemicals in food; differences between the EU and other countries (e.g. USA); short introduction of the use of VSD and/or slope factors/unit risk to calculate cancer risk of chemicals in food; • EFSAs Margin of Exposure (follow up of 2.1); are there other critical values than 10,000? *Presentation*	Ron HOOGENBOON

12.00 – 12.30	TOPIC 2: HEALTH BASED GUIDANCE VALUES 2.5. Exercise to define the risk of genotoxic carcinogens • Which chemicals in food or feed are to be considered genotoxic? How about the chemicals in the case studies? • The participants use of Margin of Exposure approach with regard to permissible cancer risk levels; What critical values are to be used for the cases studies? *Practical group exercise (4 to 6 participants)*	TC + Ron HOOGENBOON
12.30 – 12.45	TOPIC 2: HEALTH BASED GUIDANCE VALUES 2.6. Results of the exercise on genotoxic carcinogens In a plenary meeting, the results of the various groups are presented and compared. It is tried to develop a (small) manual on how to evaluate cancer risk (to keep the results for later) *Plenary discussion*	TC + Ron HOOGENBOON
12.45 – 13.45	Lunch break	
13.45 – 14.30	TOPIC 3: FOOD SAMPLING AND ANALYSIS 3.1. Sampling of food stuffs • Residues and contaminants in relevant commodities; • Consequences of different types of sampling design (e.g., monitoring, survey, risk-based programs) in relation to use of the known data sources for exposure assessment *Presentation*	Ana SERRALLER
14.30 – 15.15	TOPIC 3: FOOD SAMPLING AND ANALYSIS 3.2. Group exercise on National and international sources of data • National sources of data on contaminated food; • International sources of data; • Use of unified food commodities descriptors e.g. EFSAs SSD2 and FoodEx_2, GEMS FOOD. *Practical group exercise (4 to 6 participants)*	TC + Ana SERRALLER
15.15 – 15.45	Coffee break	
15.45 – 16.30	TOPIC 4: CHEMICAL ANALYSIS 4.1. Analysis of food stuffs • Interpretation of the results of chemical analysis; • How to read reports of laboratories? • Statistics of series of numbers; • Impact of non-detectable concentrations; • Reporting mixtures of toxicologically related chemicals (dioxins-TEQ) • Differences between samples analysed, and foods as consumed. Correction of reported values of concentrations for composition or processing. Sources of composition and processing factors. *Presentation*	Ana SERRALLER

16.30 – 17.15	TOPIC 4: CHEMICAL ANALYSIS 4.2. Exercise on setting concentrations (as consumed) using the results of chemical analysis of samples. • Simple Statistics of series of numbers; • How to deal with non-detectable concentrations; • How to deal with mixtures of related chemicals; • How to correct the numbers for composition and processing. In the exercise, a series of data is received, to be interpreted by the participants. Special attention is given to the non-detectable results; understanding TEQ; setting numbers for the concentration to be used in the case studies. *Practical group exercise (4 to 6 participants)*	TC + Ana SERRALLER
17.15	End of Day 2	
18.30	Guided tour	
20.00	Social dinner	

DAY 3 – Wednesday

Time	*Topic*	*Tutor*
09.00 - 09.15	Overview of the topics introduced the previous day	TC
09.15- 10.00	TOPC 5: FOOD CONSUMPTION 5.1. Finding food consumption data in existing data sources; units to describe consumption; variation of consumption within the population • Food consumption data sources (surveys) and exploring such national and international databases; • EFSAs Comprehensive European food consumption database • variation between individual consumers; • how to deal with variation? Basic statistics (e.g. max, median, average, min), worst case versus realistic case consumption quantities • rare foods, how to collect such data. *Presentation*	Dimitra PAPADIMITRIOU
10.00 - 10.45	TOPC 5: FOOD CONSUMPTION 5.2. Exercise on databases of consumption data • Using existing databases of food consumption; • Collection of consumption quantities for the case studies • Selection of the relevant number(s) to be used in exposure calculations from these sources • Consumption of food commodities that can not be found in the EU databases In this exercise, the focus is on sources/databases/tables of consumption data. The participants try to find these (and eventually download data from it) and to select a dataset that is to be used for a given case study. *Practical group exercise (4 to 6 participants) and plenary discussion*	TC + Dimitra PAPADIMITIROU
10.45 - 11.15	Coffee break	
11.15 - 12.00	TOPC 5: FOOD CONSUMPTION 5.3. Presentations of the results of the exercise between the different groups; comparing the numbers with available data in international sources; impact of regional differences. *Plenary discussion*	TC + Dimitra PAPADIMITIROU

12.00 - 12.45	TOPIC 6: EXPOSURE CALCULATIONS 6.1. Calculating exposure of a single consumer (e.g. point estimate); • Point estimates; • Terms being used (e.g. IESTI); • realistic and worst case calculations; • how to deal with non-consumers; • how to deal with n.d. concentrations • how to define the partial contribution of one foodstuff in a series of foods • basic statistics *Presentation*	TC
12.45 – 13.45	Lunch break	
13.45 - 14.30	TOPIC 6: EXPOSURE CALCULATIONS 6.2. Exercise on exposure calculation of a single contaminant or residue in a single foodstuff for a single/default consumer The calculation of a single contaminant or residue in a single foodstuff for an average/default/single consumer; In this exercise the participantst use the numbers on concentration in food and consumption rate for an exposure calculation of the case studies that were defined in 4.2 and 5.2 . They are asked to evaluate the intake in relation to the default body weight. The calculations are to be done using a calculator or spreadsheet. Then the same scenarios are to be calculated using a rapid exposure assessment tool (EAST). *Practical group exercise (4 to 6 participants)*	TC
14.30-15.15	TOPIC 6: EXPOSURE CALCULATIONS 6.3. Calculating exposure of a single consumer to one chemical compound from various different food items simultaneously or to a mixture of chemicals. • Terms being used (e.g. cumulative exposure) • Exposure to a series of toxicologically related compounds (e.g. PAHS, dioxins) simultaneously. • How to deal with series of results of chemical analysis, and how to deal with variation in food consumption. • Impact of different sources of a chemical, relative contribution of food or a foodstuff *Presentation*	TC
15.15 – 15.45	Coffee break	
15.45 - 16.30	TOPIC 6: EXPOSURE CALCULATIONS 6.4. Exercise on exposure calculation of a single contaminant or residue in a series of foodstuffs The calculation of a single contaminant or residue in a series of foodstuffs for a single consumer; calculation of the relative contribution; exposure to a group of related chemicals (PAH and dioxins); calculation for a series of consumers In this exercise. The participants are asked to select of the appropriate numbers on concentration in food and consumption rate for an exposure calculation, taken into account the impact of the different choices that can be made. They need to use the results for some descriptive statistic, e.g. relative contribution, ranges of intake, differences for subpopulations. *Practical group exercise (4 to 6 participants)*	TC

16.30-17.15	TOPIC 6: EXPOSURE CALCULATIONS 6.5. Presentation of results from the exercise on exposure calculation Comparing the results of the exercise between the different groups; discussion on the consequences of the different choices with regard to concentration, food stuff, type of consumer and consumption rate. *Plenary discussion*	TC
17.15	End of Day 3	
19.00	Dinner	

DAY 4 – Thursday

Time	*Topic*	*Tutor*
09.00 - 09.15	Overview of the topics introduced the previous day	TC
09.15 – 10.00	TOPIC 6: EXPOSURE CALCULATIONS 6.6. Limit of rejection and Monte Carlo Techniques Use of Article 14 of the General food Law, calculation of a Limit of Rejection for a chemical in food stuff. Maximal consumption quantity, for semi-quantitative evaluations. The use of Monte Carlo techniques to find the normal variation of intake; existing (online) Monte Carlo computer applications; what can you do with the results of a Monte Carlo type of calculation; critical notes on Monte Carlo techniques (e.g. statistics). *Presentation*	TC
10.00 – 10.45	TOPIC 6: EXPOSURE CALCULATIONS 6.7. Exercise on limit of rejection and Monte Carlo Techniques In a practical exercise the participants will calculate a Limit of Rejection for a chemical in a foodstuff; next they will make a Monte Carlo type of calculation using EAST; Discussion on the relevance of Monte Carlo calculations c.q. exposure calculations for individual consumers with regard to RASFF notifications and for the health impact on the national/regional population. *Practical group exercise (4 to 6 participants) followed by a short plenary debrief*	TC
10.45 – 11.15	Coffee break	
11.15 - 12.00	TOPIC 7 RISK CHARACTERIZATION 7.1. Exposure assessment using HBGVs or BMDLs; sources of uncertainty in the HBGV; impact of these uncertainties on the risk • Fundamental uncertainties (e.g. scaling by body weight, and use of safety factors), versus uncertainties resp. variability in data; consequences for the risk characterization outcome. Comparison of the exposure with HBGVs; *Presentation*	Alberto MANTOVANI

12.00 - 12.45	TOPIC 7 RISK CHARACTERIZATION 7.2. Exercise on Comparison of exposure – part 1 Comparison of the exposure as defined in previous practical activities) with appropriate HBGVs; Identification and evaluation of uncertainties for the practical case; Conclusion for the case with regard to "serious risk". In the exercise results of exposure calculations from case studies in this training are to be compared with the appropriate HBGVs, to conclude on the presence of a serious risk. *Working group exercise (4 to 6 participants)*	TC + Alberto MANTOVANI
12.45 – 13.45	Lunch break	
13.45 - 14:30	TOPIC 7 RISK CHARACTERIZATION 7.3. Sources of uncertainty in the calculation of exposure; impact of these uncertainties on the risk Demonstrating the impact of sources of uncertainties in the selection of numbers for the exposure assessment, e.g. median, worst case or maximum, non-consumers versus normal and high consumers, special groups. Impact of study design and consequences of detection limits of the chemical analysis "Serious" risk, i.e. when can we expect adverse effects actually to occur in consumers? *Presentation*	TC + Alberto MANTOVANI
14.30 - 15.00	TOPIC 7 RISK CHARACTERIZATION 7.4. Exercise on Comparison of exposure – part 2 Comparison of exposure (as defined in previous practical activities) with appropriate HBGVs or BMDLs and the Margin of Exposure Identification and evaluation of uncertainties for the practical case; Conclusion for the case with regard to "serious risk" The result of the previous exercise on risk characterization (7.2) is to be reassessed, taken into account the uncertainties in this case. The conclusion is to be adapted accordingly. *Practical group exercise (4 to 6 participants)*	TC + Alberto MANTOVANI
15.00 - 15.15	TOPIC 7 RISK CHARACTERIZATION 7.5. Presentation of results from the exercises Final result of the risk characterization; based on the comparison of the results of the different groups. In the plenary exercise, the results of the different groups are presented and to be compared between each other. Based on the discussion the participants must conclude on a final evaluation. *Plenary discussion*	TC + Alberto MANTOVANI
15.15 - 15.45	Coffee break	
15.45 - 16.30	TOPIC 8: STAKEHOLDERS AND REPORTING 8.1. Reporting c.q. communicating the outcome of the assessment to relevant stakeholders. Follow up activities for the official control organization to be considered on the basis of the exposure assessment and Risk Communication Different stakeholders and their risk perception; Follow up activities (support of official control activities such as calculation of action values, consumer advice...) • Impact of the outcome of the risk assessment on different follow up activities Stakeholders can be involved in specific situations of food and feed safety, and how this might affect risk perception (e.g. farmers, consumers, policy makers, legal officers, ...) with a special focus on communication strategies to be adopted in case of crisis situations; *Presentation*	TC

16.30 - 17.15	TOPIC 8: STAKEHOLDERS AND REPORTING 8.2. Exercise on report preparation Preparation of a report of the outcome of the risk assessment of a chemical in food Some advice for the competent authority on how to proceed after the risk assessment is to be added to the report; it should include the arguments on which the advice is based A small report is to be written, describing the exposure assessment and uncertainties, and the final conclusion with regard to the impact on the health of the consumers. *Practical group exercise (4 to 6 participants)*	TC
17.15	End of Day 4	
19.00	Dinner	

DAY 5 – Friday

Time	*Topic*	*Tutor*
09.00-09.15	Overview of the topics introduced the previous day	TC
09.15-10.00	TOPIC 9: RISK COMMUNICATION 9.1. Exercise on preparation of a presentation of the outcome of the risk assessment for all stakeholders involved, and formulating advice for follow up activities e.g. how the report is to be used by the society. The participants use the overarching report to evaluate what topics are relevant for various stakeholders and how risk perception might have an impact on the conclusions and advice for follow up, and what relevant information is missing in the report (e.g. financial consequences of a crisis situation?) *Practical group exercise (4 to 6 participants)*	TC
10.00 - 10.45	TOPIC 9: RISK COMMUNICATION 9.2. Role play on a public hearing (preparation) The different groups are assigned the role of a stakeholder group. Then they are told that a public hearing will take place, where they have to play the role of the stakeholder; they have to prepare themselves for that role. *Practical group exercise (4 to 6 participants)*	TC
10:30 - 10.45	Coffee break	
10.45 – 11.30	TOPIC 9: RISK COMMUNICATION 9.3. Role play on a public hearing (public hearing) The public hearing is performed; all groups play their role as assigned. *Role play*	TC

11.30 - 11.45	TOPIC 9: RISK COMMUNICATION 9.4. Evaluation of the public hearing and comments on the training session In the evaluation it is noted how different risk perceptions of the stakeholders and various social aspects (e.g. economic impact) can influence the general opinion of a case and of the follow up activities. A short discussion with the participants about their comments on the training course session. Proposals for adaptations of the program, or other topics to be included, or other comments. *Plenary discussion*	TC
11.45 - 11.50	Dissemination of the contents of the training *Presentation*	TC
11.50 - 12.15	Final Test of knowledge	
12.15 - 12.35	On-line evaluation of training	
12.35 – 12.45	Training certificates and training conclusions	
12.45	End of the training session	
12.45	Lunch	

Annex 4: Training material, outcomes and dissemination activities

Training material

All participants will receive the training material well in advance of the training. The material will include additional pre-recorded material for offline studies. Preparatory videos will introduce the specific topic and provide background information to participants.

All participants will receive a Dissemination Kit electronically to enable them to actively disseminate course knowledge upon their return from BTSF training. Participants attending face-to-face courses will receive the information on the USB key.

Dissemination Kit

This contains the following training materials:

- All course presentations
- Study notes on field trips and group activities/discussions and conclusions thereof
- The course syllabus
- The training information sheet
- Glossary of terms and abbreviations used in the course
- Additional references for further study
- Written guidance on how to actively disseminate course knowledge to colleagues upon participants' return to their home countries, different methodologies/examples/best practice
- Other information and material delivered at the course such as quizzes, FAQs etc.

Dissemination questionnaire

Participants will be requested to commit themselves to disseminate the knowledge received via different dissemination methods, i.e. informing colleagues about the information received at the training, distributing (photocopying or sending via electronic way) the training materials among their colleagues. Two to three months after the respective training session, participants will receive a standard questionnaire requesting information on the dissemination activities of the participant after the training, and details on differences in the approach adopted in day-to-day work following the training.

Test of knowledge

Furthermore, the programme 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 participants of the subjects taught.

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

Participants agree to be registered in the BTSF Academy and to participate in a group photo of the participants and tutors at the end of the training.

Please find more information regarding data protection here:

https://better-training-for-safer-food.ec.europa.eu/training/mod/page/view.php?id=417

Annex 5: Contractor contact details

The project is managed by OPERA Srl, in consortium with NSF Euro Consultants SA.

Project manager: **Claudio BOMPARD**

Training coordinator for Course 1: **Rob THEELEN**

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

All official communication between National Contact Points and the project will be maintained through the functional e-mail address 20189605riskassessment@btsftraining.com or by phone to +39 06 80773315 telephone number.

All information on BTSF training can be found at the BTSF Academy website and at www.btsftraining.com/btsf-risk-assessment. The website will be regularly updated with details of forthcoming courses.

Data Protection Notice for the BTSF online Trainings

This processing operation concerns the participation in BTSF online training activities which are held within the context of the Better Training for Safer Food Initiative (BTSF) and hosted in the BTSF ACADEMY to provide wider accessibility to training in the areas of food law, feed law, animal health and animal welfare rules, as well as plant health rules by using a state-of-the-art and interactive e- learning system. The BTSF is a Commission DG Health and Food safety (DG SANTE) Initiative managed by the European Health and Digital Executive Agency (HaDEA) and aimed at organising a EU training strategy in the areas mentioned above.

This data protection notice explains the reason for the processing of all personal data provided and how HaDEA collects and handles them and ensures their protection. It also details how that information is used and what rights the data subject may exercise in relation to the data. Your personal data is processed in accordance with Regulation (EU) No 2018/1725. Please find more details on the following link https://better-training-for-safer-food.ec.europa.eu/training/mod/page/view.php?id=417.