

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 4 – RISK ASSESSMENT IN NUTRITION

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 | 10 |
| Annex 3: Agenda..... | 11 |
| Annex 4: Training material, outcomes and dissemination activities..... | 18 |
| Annex 5: Contractor contact details..... | 20 |

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 December 2023 and October 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 | Risk Assessment in nutrition | Rome, Italy | 4-8 December 2023 | 03/11/2023 |
| 2024 | TS 2 | Risk Assessment in nutrition | Vienna, Austria | 21-25 October 2024 | 20/09/2024 |

For organisational purposes, names of participants should be communicated at the latest 30 days before the workshop. A reminder will be sent to NCPs before the event.

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 4 - Risk assessment in nutrition

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 4 - Risk assessment in nutrition

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 4 - Risk assessment in nutrition

Enter Score

a) Professional experience within a public institution or a competent authority involved in food chain risk assessment

Scoring

less than 3 years = 1 points; 3 - 5 years = 5 points; 5 - 10 years = 10 points; > 10 years = 12.5 points

b) Experience in Risk Assessment in nutrition

Scoring

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

Scoring

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

| | | |
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| | <p>received is a prerequisite for course participation.</p> <p><u>Scoring</u></p> <ol style="list-style-type: none"> 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 - Rome | TS02 - Vienna |
|---------------------|------------------------|-------------------|--------------------|
| Country group | Country | 4-8 December 2023 | 21-25 October 2024 |
| Member States | Austria | 0 | 1 |
| | Belgium | 1 | 0 |
| | Bulgaria | 0 | 1 |
| | Croatia | 0 | 1 |
| | Cyprus | 1 | 0 |
| | Czech Republic | 0 | 1 |
| | Denmark | 0 | 1 |
| | Estonia | 0 | 1 |
| | Finland | 0 | 1 |
| | France | 1 | 0 |
| | Germany | 1 | 1 |
| | Greece | 1 | 0 |
| | Hungary | 0 | 1 |
| | Ireland | 1 | 1 |
| | Italy | 1 | 1 |
| | Latvia | 0 | 1 |
| | Lithuania | 0 | 1 |
| | Luxembourg | 1 | 0 |
| | Malta | 1 | 0 |
| | Netherlands | 1 | 0 |
| | Poland | 0 | 1 |
| | Portugal | 1 | 1 |
| | Romania | 1 | 0 |
| | Slovakia | 1 | 0 |
| Slovenia | 1 | 0 | |
| Spain | 1 | 0 | |
| Sweden | 0 | 1 | |
| Candidate Countries | Albania | 1 | 0 |
| | Bosnia and Herzegovina | 0 | 1 |
| | Montenegro | 0 | 1 |
| | North Macedonia | 0 | 1 |
| | Serbia | 1 | 0 |
| | Türkiye | 1 | 0 |
| | Ukraine | 0 | 0 |

Table 3: Suggested allocation for other non-EU Countries

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

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.

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 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.

OPERA 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 recognised 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 differently at the 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.

Main topics covered in the training

- The specificities of risk assessment in nutrition, i.e. assessed and managed either at the level of nutrients and/or at the level of foods, and its legal framework;
- The risk assessment model in nutrition: concepts, terminologies and methods
 - defining Dietary Reference Values (DRV);
 - Tolerable Upper Intake Levels
 - nutrient based goals and objectives;
 - food based dietary guidelines (FBDG);
- The specificities and challenges of nutrient risk assessment
 - essential and non-essential nutrients, i.e. assessment of insufficiency and excess (absolute and/or relative) vs. assessment of excess only;
 - risk assessment of macronutrients;
 - risk assessment of micronutrients;
- Dietary intake assessment
 - advantages and limits of different methods for dietary surveys: 24-hr recall, food diaries, food frequency questionnaires;
 - food data sheets, household budget surveys, use of anthropometric data
 - human biomonitoring;
 - translation into nutrient intakes: correction of raw data for usual intakes, use and limits of food composition tables, statistical treatment (single endpoints vs. distribution).

- Risk assessment of novel foods (Regulation 2015/2283);
- Integrated risk-benefit assessment of food and nutrition;
- 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;
- European Council Directive 90/496/EC of 1990 on nutrition labelling for foodstuffs lays down the rules for nutrition labelling in the European Community. The Directive is amended by Regulation (EU) 1169/2011 ... on the provision of food information to consumers in force from 12 December 2011 except for the provisions on nutrition labelling, which must be fully implemented by 31 December 2016;
- Regulation (EU) 2015/2283 on Novel Foods. Lays down rules for the placing of NFs on the market within the Union; ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers interests;
- Commission Implementing Regulation (EU) 2017/2468: Commission Implementing Regulation (EU) 2017/246 concerning traditional foods from third countries;
- Commission Implementing Regulation (EU) 2017/2469: lays down administrative and scientific requirements for applications for authorising the placing on the market within the Union of a NF and updating the Union list;
- Commission Implementing Regulation (EU) 2017/2470: establishing a Union list of all authorised NFs to be placed on the market within the Union.
- Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the foodchain;
- EFSA, 2011, Technical report on technical specifications on training regarding principles and methods of food safety risk assessment.
- EFSA, 2011, Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources
- EFSA, 2018, Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources

Annex 3: Agenda

DAY 1 Monday

| <i>Time</i> | <i>Topic</i> | <i>Tutor</i> |
|--|--|-----------------------|
| 13.00– 14.00 | Lunch Registration of participants starting at 14.00 | |
| 14.00– 14.30 | Welcome addresses, course background, objectives & expected results, presentation of tutors and participants | Training Coordinator) |
| 14.30– 14.35 | Better Training for Safer Food: presentation of a video | |
| 14.35– 14.50 | Initial test of Knowledge | |
| TOPIC 1 – INTRODUCTION TO RISK ASSESSMENT AT THE LEVEL OF NUTRIENTS | | |
| 14.50– 15.05 | Interactive session on TOPIC 1 What is a “serious” risk perception? PART 1: Food safety vs. food quality <i>In a plenary discussion, the participants try to define similarities and dissimilarities between food safety and food quality.</i> <i>Plenary discussion</i> | Plenary session |
| 15.05– 15.35 | TOPIC 1: INTRODUCTION TO RISK ASSESSMENT AT THE LEVEL OF NUTRIENTS 1.1 Risk assessment applied to nutrients: Overview of the four basic steps <ul style="list-style-type: none"> • From foods to nutrients: definition of the subject matter • Food safety vs. food quality • Conceptual differences between “hazard” and “risk” • Introduction to Risk Assessment in Nutrition: 1. Identification of adverse health effects associated with the (high or low) intake of a given nutrient 2. Evaluation of the adverse effects (e.g. toxicity/deficiency associated with an increased/low intake) 3. Exposure assessment 4. Risk characterization; in order to set the scene for the rest of the program in this training, <ul style="list-style-type: none"> • EFSA Scientific Opinions on principles deriving and applying Dietary Reference Values and Tolerable Upper Intake levels for vitamins and minerals A general overview. <i>Presentation</i> | Tutor |
| 15.35– 16.00 | Coffee break | |
| 16.00– 16.30 | Interactive session on TOPIC 1 What is a “serious” risk perception? PART 2 Practical definition of “serious” risk in nutrition <i>In a plenary discussion, the participants try to define what is to be considered a serious risk, focusing on the views of European consumers in food-related health risks and trying to understand their perceptions on food safety and quality so as to formulate fit-for-purpose communication strategies.</i> <i>Plenary discussion</i> | Plenary session |
| 16.30– 17.00 | 1.2 Risk assessment in Europe and beyond | Tutor |

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| | <ul style="list-style-type: none"> • Core principles of Risk Analysis at international (Codex Alimentarius) and EU level • Division of competences between risk assessment and risk management; risk analysis in Regulation (EC) No.178/2002; risk assessment in Regulation (EC) No.178/2002. • Framework for nutritional risk assessment • How to deal with the outcome of the risk assessment according to the EU legal framework and international (WHO, EFSA) guidance? • EFSA guidance for the conduct of risk assessment at the level of nutrients. <p><i>Presentation</i></p> | |
| TOPIC 2: DIETARY INTAKE ASSESSMENT | | |
| 17.00– 17.30 | <p><u>2.1 Individual dietary surveys: assessing exposure to nutrients according to the most common methods (advantages and disadvantages)</u></p> <ul style="list-style-type: none"> • i) 24-hour dietary recalls; ii) Food records; iii) Food frequency questionnaires; • short overview of dietary assessment tools available in Europe and worldwide (<i>e.g. different software, procedures and connected databases</i>). <p><i>Presentation</i></p> | Tutor |
| 17.30– 18.30 | <p>Interactive session on TOPIC 2 <u>(Limitations and challenges of methods commonly used in individual dietary surveys)</u></p> <p><i>In this exercise, participants will discuss limitations and challenges of each method and how survey designs can address these limitations.</i></p> <p><i>Working group exercise</i></p> | All tutors |
| 18.30 – 18.45 | Overview/Conclusions of Day 1, Questions & Answers | TC |
| 18.45 | End of Day 1 | |
| 19.30 | Welcome cocktail and welcome dinner | |

DAY 2 Tuesday

| <i>Time</i> | <i>Topic</i> | <i>Tutor</i> |
|--|---|----------------------|
| TOPIC 2: DIETARY INTAKE ASSESSMENT | | |
| 09.00– 09.30 | 2.2 Presentation of the EFSA EU–MENU guidance document to collect harmonised data on dietary exposure in all EU Member States <i>Presentation</i> | Tutor |
| 09.30– 10.00 | 2.3 Food Balance Sheets and Household Budget Surveys: assessing dietary exposure at national level <ul style="list-style-type: none"> • Estimation of food availability at household level (household budget surveys, HBS) or approximated through food supply data derived from food balance sheets (FBS); • Evaluating advantages and limitations of FBS and HBS. <i>Presentation</i> | Training coordinator |
| 10.00– 10.30 | 2.4 Collection of non–dietary information <ul style="list-style-type: none"> • Socio–demographic and other personal characteristics; • Anthropometric measurement and data collection methods (“self–reporting” vs “measurement by interviewer”); • Physical activity (retrospective and real–time data collection). <i>Presentation</i> | Tutor |
| 10.30– 10.45 | <i>Questions & Answers</i> | |
| 10.45– 11.15 | Coffee break | |
| 11.15– 13.00 | Interactive session on TOPIC 2 (Exercise on assessing dietary exposure) <i>In this exercise, participants will be challenged with scenarios on food safety problems and will be asked to propose methods to assess dietary exposure to initiate the risk assessment process. In a plenary meeting, the results of the various groups are presented and discussed.</i> <i>Working group exercise, followed by plenary discussion</i> | All tutors |
| 13.00– 14.00 | Lunch break | |
| TOPIC 3: NUTRIENT INTAKE ASSESSMENT | | |
| 14.00– 15.00 | 3.1 Translation of exposure data into nutrient intake <ul style="list-style-type: none"> • Application of food composition tables and other databases (related to e.g. recipe, edible portion, raw to cook calculations) (analysis of the use and limitations of the food composition tables/databases) • Procedures to correct the measurement error associated with short–term measurements of dietary intake in order to estimate intake distributions and “usual” intake (g/person/day), Introduction to models for usual intake estimation (“single endpoints” vs “multiple endpoints” treatment); <i>Presentation</i> | Tutor |
| 15.00– 16.00 | Interactive session on TOPIC 3 (Case study – part 1) <i>In this case study, participants will be provided with specific exposure data to be translated into nutrient intake, discussing possible limitation of intake data as well as the supporting databases provided and possible need for other/additional intake data or supporting databases.</i> <i>Working group exercise</i> | All tutors |

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| 16.00– 16.20 | Coffee break | |
| 16.20– 16.50 | Interactive session on TOPIC 3 (Case study – part 2) <i>In a plenary meeting, the results of the various groups are presented and discussed.</i> <i>Plenary discussion</i> | Plenary session |
| 16.50– 17.00 | Overview and Conclusions of Day 2 | TC |
| 17.00 | End of Day 2 | |
| 17.45 | Guided tour of city center, followed by the social dinner | |

DAY 3 Wednesday

| <i>Time</i> | <i>Topic</i> | <i>Tutor</i> |
|--|---|----------------------|
| TOPIC 4: SPECIFICITIES AND CHALLENGES OF RISK ASSESSMENT IN NUTRITION | | |
| 08.45– 09.30 | 4.1 Introduction to research methods such as: – balance studies, depletion-repletion studies, observational epidemiological studies (cohort and case-control) and experimental epidemiological studies (randomised interventions and clinical trials). <i>Presentation</i> | Training coordinator |
| 09.30– 10.00 | 4.2 Specificities and challenges in the risk assessment of different macro- and micronutrients <i>Presentation</i> | Tutor |
| 10.00– 10.45 | Interactive session on TOPIC 4 (Working group on risks associated with macro- and micronutrients intakes – part 1) <i>In this exercise, participants will be asked to interpret a series of data related to risks associated with macro- and micronutrient intakes. On the basis of the concepts, terminologies and methods learned in the theoretical studies, participants will be requested to estimate the risk of inadequate/excessive intakes of macro/micronutrients.</i> <i>Working group exercise</i> | All tutors |
| 10.45– 11.15 | Coffee break | |
| 11.15– 11.45 | Interactive session on TOPIC 4 (Working group on risks associated with macro- and micronutrient intakes – part 2) <i>In a plenary meeting, the results of the various groups are presented and discussed</i> <i>Plenary discussion</i> | Plenary session |
| TOPIC 5: DIETARY REFERENCE VALUES (DRVs) | | |
| 11.45– 12.15 | 5.1 Concepts, terminologies and methods used in risk assessment in nutrition Presentation of an EFSA video: https://www.youtube.com/watch?v=WfcmanEi5gQ <ul style="list-style-type: none"> • Conceptual basis for derivation of DRVs; • How are DRVs derived? • General principles for deriving dietary recommendations: <ul style="list-style-type: none"> ✓ Establishing nutrient goals and objectives (difference between DRVs and nutrient goals) – Practices of EU–MS (e.g. the Netherlands) ✓ Establishing food based dietary guidelines (FBDG) ✓ How these values are used in the EC ✓ How these values are used in Codex Alimentarius <i>Presentation</i> | Tutor |

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| 12.15– 13.00 | <p>Interactive session on TOPIC 5 (Working groups on deriving DRVs – part 1)</p> <ul style="list-style-type: none"> • Study of EFSA DRV Opinions to identify criteria and how they were used <i>Participants will be given specific EFSA DRV opinions in which various different criteria (e.g. nutrient requirements, average intakes of relatively healthy populations or epidemiological data) have been used. They will be requested to prepare presentations summarising the rationale to DRVs in each occasion.</i> <p><i>Working group exercise</i></p> | All tutors |
| 13.00– 14.00 | Lunch break | |
| 14.00– 14.45 | <p>Interactive session on TOPIC 5 (Working groups on deriving DRVs – part 2)</p> | Plenary session |
| | <i>In a plenary meeting, the results of the various groups are presented and discussed.</i> <i>Plenary discussion</i> | |
| 14.45– 15.15 | <p>Interactive session on TOPIC 5 (Working group exercise with the “DRV Finder” tool to practice in using the values)</p> <p><i>In this exercise, the participants will familiarize with the “DRV Finder” tool and practice in using the tool and its operations.</i></p> <p><i>Plenary exercise based on problem solving</i></p> | Plenary session |
| TOPIC 6: TOLERABLE UPPER INTAKE LEVEL (UL) | | |
| 15.15– 15.45 | <p>6.1 Steps in the development of the UL</p> <ul style="list-style-type: none"> • Hazard identification: evidence of adverse effects on humans; causality; relevance of experimental data; quality of and completeness of the database; identification of vulnerable subgroups); • Hazard characterisation: data selection; identification of the critical endpoint and Reference Point (e.g. NOAEL or LOAEL); uncertainty assessment; derivation of an UL; • Benchmark dose. <p><i>Presentation</i></p> | Tutor |
| 15.45– 16.00 | Coffee break | |
| 16.00– 17.45 | <p>Interactive session on TOPIC 6 (Practical calculations of UL)</p> <p><i>In this case study, the participants will be challenged to simulate the derivation of an UL for a given nutrient, according to a specific data set and its related uncertainty factors. In a plenary meeting, the results of the various groups are presented and compared.</i></p> <p><i>Working group exercise, followed by plenary discussion</i></p> | All tutors |
| 17.45– 18.00 | Overview and Conclusions of Day 3 | TC |
| 18.00 | End of day 3 | |
| 20.00 | Dinner | |

Day 4 Thursday

| <i>Time</i> | <i>Topic</i> | <i>Tutor</i> |
|---|---|-----------------|
| TOPIC 7: RISK CHARACTERIZATION | | |
| 09.00– 09.30 | <p>7.1 Impact of the uncertainties</p> <ul style="list-style-type: none"> Demonstrating the impact of uncertainties in the selection of numbers for the exposure assessment, e.g. limitations and opportunities in different target populations. Translating the exposure into health effects. <p><i>Presentation</i></p> | Tutor |
| 09.30– 10.30 | <p>Interactive session on TOPIC 7 – Risk characterisation (Comparison of exposure – as defined in previous practical activities –with appropriate ULs; Identification and evaluation of uncertainties for the practical case – part 1). Conclusion for the case with regard to “serious risk”</p> <p><i>In the exercise results of exposure calculations from exercises and case studies in this training are to be compared with the appropriate ULs, to conclude on the presence of a serious risk.</i></p> <p><i>Working group exercise</i></p> | All tutors |
| 10.30– 11.00 | Coffee break | |
| 11.00– 11.30 | <p>Interactive session on TOPIC 7 – Risk characterisation (Comparison of exposure with appropriate ULs; Identification and evaluation of uncertainties for the practical case – part 2).</p> <p><i>In the plenary meeting, the results of the different groups are presented and discussed. Based on the discussion, the participants must conclude on a final evaluation.</i></p> <p><i>Plenary discussion</i></p> | Plenary session |
| TOPIC 8: REPORTING | | |
| 11.30– 12.00 | <p>8.1 Reporting the outcome of the assessment to relevant stakeholders</p> <ul style="list-style-type: none"> Different stakeholders and their risk perception; Impact of the outcome of the risk assessment on different follow-up activities (e.g. risk communication and management options). <p><i>Presentation</i></p> | Tutor |
| 12.00– 12.45 | <p>Interactive session on TOPIC 8 (Preparation of a report of the outcome of the risk assessment)</p> <p><i>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.</i></p> <p><i>Working group exercise</i></p> | All tutors |
| 12.45– 13.45 | Lunch break | |
| TOPIC 9: ADVANCED METHODS OF INTAKE ASSESSMENT | | |
| 13.45– 14.15 | <p>Total Diet Studies</p> <ul style="list-style-type: none"> Definition; Methods; Strengths/Limitations Assessing intake and the contribution of foods to nutrient intake <p>Human biomonitoring (HBM)</p> <ul style="list-style-type: none"> Definition and description of HBM techniques and requirements; Biomarkers of status and biomarkers of intake; Possible application of HBM to the different steps of risk assessment; Strengths/Limitations; Usefulness incl. complementarity with other dietary | Tutor |

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| | assessment methods <i>Presentation</i> | |
| TOPIC 10: RISK ASSESSMENT OF NOVEL FOODS | | |
| 14.15– 14.45 | <ul style="list-style-type: none"> Principles of risk assessment applied to Novel Food according to Reg. 2015/2283. Assessing safety in use and evaluating the nutritional impact of novel foods for the consumer <i>Presentation</i> | Tutor |
| TOPIC 11: RISK–BENEFIT ASSESSMENT IN FOOD AND NUTRITION | | |
| 14.45– 15.15 | 11.1 The need of an integrated approach <ul style="list-style-type: none"> Presentation of the risk–benefit assessment paradigm; Risk–benefit assessment at different levels: examples of situations for which a risk–benefit assessment might be appropriate in nutrition only or including also toxicological and microbiological impacts; Current approach to perform a risk–benefit assessment; Integrating risks and benefits: different metrics used; Current developments of this emerging area and challenges identified. <i>Presentation</i> | Tutor |
| 15.15– 15.30 | Question & Answers | |
| 15.30– 16.00 | Coffee break | |
| 16.00– 17.30 | Interactive session on TOPIC 11 (Working group on conducting a risk–benefit assessment) <i>In this exercise, participants will be provided examples to illustrate types of issues that need to be considered in conducting a risk–benefit assessment, starting with a specific problem formulation, working on identification of benefits, risks and endpoints of relevance.</i> <i>Working group exercise</i> | All tutors |
| 17.30– 17.45 | Conclusions of Day 4 (summary of main topics) | TC |
| 17.45 | End of Day 4 | |
| 20.00 | Dinner | |

DAY 5 Friday

| <i>Time</i> | <i>Topic</i> | <i>Tutor</i> |
|-------------------------------------|--|----------------------|
| TOPIC 12: RISK COMMUNICATION | | |
| 08.30– 09.00 | 12.1 Development of risk communication strategies In a short introduction, different communication strategies are presented, according to stakeholders involved in specific situations and according to their risk perception, with a special focus on communication strategies to be adopted in case of crisis situations. It is underlined that different types of communication “styles” need to be used according to the target audience (e.g. scientists vs general public). <i>Presentation</i> | Training coordinator |

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| 09.00– 09.30 | <p>Interactive session on TOPIC 12 (Presentation of the outcome report 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 and risk managers)</p> <p><i>The participants will use the outcome report from previous day 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.</i></p> <p><i>Plenary discussion</i></p> | Plenary session |
| 09.30– 10.15 | <p>Interactive session on TOPIC 12 (Role Play on a public hearing – part 1)</p> <p><i>The different groups are assigned the role of a stakeholder group: a public hearing, to which they will take part to, will be simulated. Preparation for the role play.</i></p> <p><i>Working group exercise</i></p> | All tutors |
| 10.15– 10.30 | Coffee break | |
| 10.30– 11.15 | <p>Interactive session on TOPIC 12 (Role Play on a public hearing – part 2)</p> <p>The public hearing is performed; all groups play their role as assigned</p> <p><i>Role play – plenary discussion</i></p> | Plenary session Role play |
| 11.15– 11.30 | Dissemination of the contents of the training <i>Presentation</i> | Event Manager |
| 11.30– 11.45 | Conclusions and Lessons learned on the topics covered. Questions & Answers | TC |
| 11.45– 12.00 | Final Test of knowledge | |
| 12.00– 12.15 | <ul style="list-style-type: none"> • Evaluation of training • Training certificates | |
| 12.15 | End of the training session | |
| 12.15 | Lunch, followed by departure to the airport | |

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 4:

Androniki NASKA

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>.