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 5 – RISK ASSESSMENT IN BIOTECHNOLOGY

Phase 2

Valid as of 26/07/2023

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 January and November 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
2024	TS 1	Risk Assessment in biotechnology	Rome, Italy	22-26 January 2024	20/12/2023
	TS 2	Risk Assessment in biotechnology	Riga, Latvia	04-08 November 2024	04/10/2024

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 5 Risk assessment in biotechnology
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 5 Risk assessment in biotechnology	**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 5 Risk assessment in biotechnology		**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 Risk Assessment in biotechnology (e.g. GMOs, synthetic biology) <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. <u>Scoring</u> 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 - Riga
Country group	**Country**	**22-26 January 2024**	**04-08 November 2024**
Member States	Austria	1	0
	Belgium	1	0
	Bulgaria	0	1
	Croatia	1	0
	Cyprus	1	0
	Czech Republic	1	0
	Denmark	0	1
	Estonia	0	1
	Finland	0	1
	France	1	0
	Germany	0	1
	Greece	1	0
	Hungary	0	1
	Ireland	1	1
	Italy	1	1
	Latvia	0	1
	Lithuania	0	1
	Luxembourg	0	1
	Malta	1	0
	Netherlands	0	1
	Poland	1	1
	Portugal	1	0
	Romania	1	0
	Slovakia	0	1
	Slovenia	1	0
	Spain	1	1
	Sweden	0	1
Candidate Countries	Albania	1	0
	Bosnia and Herzegovina	1	0
	Montenegro	0	1
	North Macedonia	0	1
	Serbia	1	0
	Türkiye	1	0
	Ukraine	0	1

Table 3: Suggested allocation for other non-EU Countries

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

Genetically modified plants and their products are common constituents of food and feed consumed in Europe and other parts of the world. While only a few countries of the European Union (EU) have adopted the cultivation of GM plants (i.e. currently exclusively maize cultivars with the event MON810), a significant proportion of GM feed is imported from South America, especially Brazil, into the EU. Beyond plants, GM organisms contributing to food and feed supply include microorganisms and possibly, with an increasing trend, also animals and insects. Before such products reach the market, and after their approval, their potential adverse effects on human and animal health as well as on the environment must be assessed and evaluated. EU regulation for pre-marketing risk assessments of GM for food and feed use, for import, processing and cultivation are in place and functional. The legal procedures and risk assessment strategies implemented by the EU differ from those of other countries, like USA or Canada. For many years and until today, the usefulness of the EU procedures is controversially debated between different stakeholders (e.g., GM producers vs. NGOs). Furthermore, increasing international familiarity with some GM plants as well as more precise genetic modification methods on the one side, and increasing molecular complexity of new genetic modifications on the other side, are challenging the currently implemented procedures and ask for updated regulations and guidance for risk assessments.
The overall objective of this course is to provide knowledge about the general and applied risk assessment procedures required for genetically modified organisms and products made by molecular nucleic acid modifying techniques. Legal backgrounds and relevant guidance documents will be presented, addressing the fundamental steps for risk assessment, including data requirements and their statistical treatments. Going through the different key topics for risk assessment step-by-step during the course, the participants will increase their knowledge and gain familiarity with the procedures as they are required for assessing GMO and their products in the EU. Examples of recent opinions of the European Food Safety Authority (EFSA) on the risk assessment of GMO will be analysed. The participants obtain an up-to-date view on the issues related to new molecular plant breeding technologies and new tools for risk assessments.
Five scientific experts with first-hand experience in GMO risk assessment as conducted by the EU will act as tutors in this Course 5. They represent the different topics which are introduced by lectures. Following the experts' presentations, knowledge about the specific topics will be intensified and exercised in interactive sessions and guided discussions, also utilizing a set of four GM case studies. The participants will also gain an understanding about current and future developments of GMO and how those will challenge current regulations and may require adjustments of new regulations. Finally, participants will learn with a lecture and role plays about the principles of risk communication which are an essential part of risk analyses and risk management in the field of food/feed safety.

Main topics covered in the training

- Introduction to risk assessment in GMOs with a focus on GM plants (scope of GMO applications based on newly expressed proteins and newer biotechnologies such as RNAi, appropriate statistical principles and methods for the comparative analysis of food/feed) and its legal framework;
- Explanation of new breeding techniques such as cisgenesis, intragenesis genome editing, synthetic biology, gene drive;
- The principles and methods of hazard identification and characterization when applied to whole food/feed:

- identification of newly inserted genes and gene products; gene expression / suppression
- toxicity and allergenicity assessment
- feeding studies (with laboratory and target animals) for the safety and nutritional assessment of food/feed derived from GMOs
- intended vs. unintended effects
- scope and interplay between molecular characterization, compositional and agronomic characterisations in the identification of unintended effects of GM plants and products.

- The exposure assessment in the context of the evaluation of food and feed derived from GM plants;
- Risk characterisation, including uncertainty analysis (quantifiable statistical uncertainty, knowledge gaps due to hypothesis formulation, publication bias, etc.);
- Risk mitigation (risk management);
- Post-market monitoring on a case-by-case basis;
- The rationale and methodology of the environmental risk assessment (ERA) of GMOs
  - scopes of application, including or not cultivation in EU
  - problem formulation and assessment endpoints in the ERA
  - data collection and modelling in the development of GMO ERA
  - interplay between EU regulations in the case of herbicide-tolerant GM crops.
- The two approaches of post-market environmental monitoring: case-specific monitoring (of identified risks) and general surveillance (of unidentified risks);
- Synthetic biology;
- Omics in risk assessment;
- 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;
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
- EFSA guidance documents on RA of food and feed from GM plant and on the environmental risk assessment of GM plant
- EFSA guidance document for selection of comparators
- Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 Text with EEA relevance

Annex 3: Agenda

DAY 1 _ Monday

Time	*Topic*	*Tutors*
12.45–13.45	Lunch Registration of participants starting at 13.45	
14.00–14.30	Welcome addresses, course background, objectives & expected results Preliminary discussion with participants, aimed to enquire about their expectations on the training initiative	Training coordinator
14.30–15.00	Initial test of knowledge	
	TOPIC 1: INTRODUCTION TO RISK ASSESSMENT IN GMOs	
15.00–15.30	**1.1 Introduction to risk assessment in GMOs and derived food and feed products** • Risk analysis principle on food safety according to the Codex Alimentarius and its implementation in the EU legal framework [Reg. EC 178/2002, etc.]: division of competences between RA and risk management • How to deal with the outcome of the risk assessment (RA) of GMOs according to the EU and international legal framework? [Directive 2001/18/EC; Reg. (EC) 1829/2003; EFSA guidance documents on RA of food and feed from GM plant and on the environmental risk assessment of GM plant] • Risk analysis of GMOs as an implementation of Precautionary Principle • Overview on GM plants and analysis of recent relevant EFSA opinions on the matter: identifying issues unique to their risk assessment *Presentation*	Tutor
15.30–16.00	Coffee break	
16.00–16.30	**1.2 Overview of techniques for genetically modifying organisms** • Introduction to molecular breeding techniques (trans- and cisgenesis, gene stacking, gene editing and gene drive, synthetic biology) • Genetic transformation methods • Plants genetically modified in their nucleus or in plastids • Controlling the expression of transgenes and the location of transgene products in the plant *Presentation*	Tutor
16.30–16.45	**1.3 Short introduction to the case studies used in this course** Four case studies as a material for participants' exercises *Presentation*	Training Coordinator
16.45–17.15	**1.4 Introduction into the four basic steps of risk assessment** • Risk assessment is the scientific evaluation of known or potential adverse health effects in consequence of human exposure to foodborne hazards. The process consists of the following steps: (1) Hazard identification: identification of known or potential health effects connected with an agent (2) Hazard characterization: qualitative and/or quantitative evaluation of the adverse effects associated with agents, which may be present in food and a dose-response assessment if the data is obtainable	Tutor

	(3) Exposure assessment: qualitative and/or quantitative evaluation of the degree of intake likely to occur (4) Risk characterization: integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population. • The risk assessment of GM food/feed is characterized by an assessment of a whole food or of a component thereof relative to the appropriate conventional counterpart taking into account both intended and unintended effects, identifying new or altered hazards, identifying changes in key nutrients relevant to human health. *Presentation*	
17.15–17.45	**1.5 Interactive session on Topic 1 (Introduction to risk assessment)** *Issues raised during the presentations will be discussed, participants may ask questions or tutors fuel the discussion with challenging the knowledge of the participants*	Plenary discussion
	TOPIC 2: HAZARD IDENTIFICATION	
17.45–18.15	**2.1 Molecular characterization and comparative approach** **2.1.1 Molecular characterization: genetic elements and their biological functions** • Providing data on the structure and expression of the insert(s) and on the stability of the intended trait(s) in order to assess whether genetic modification raises any issues regarding the potential for producing new toxins or allergens *Presentation*	Tutor
18.15–18.30	Overview and Conclusions of Day 1 – incl. involvement of participants	Training Coordinator
18.30	End of Day 1	
19.30	Welcome cocktail and welcome dinner	

DAY 2 – Tuesday

Time	*Topic*	*Tutor*
	TOPIC 2: HAZARD IDENTIFICATION	
09.00–09.30–	**2.1.2 Performing comparative analysis** • Rationale of the comparative risk assessment strategy • Overview of the biology of the plant (compositional, agronomic and phenotypic characteristics) • The tests of difference and equivalence between a GM plant and a non-GM reference variety (comparator) • Their practical implementation through field trials in appropriate receiving environments *Presentation*	Tutor
09.30–10.00–	**2.1.3 EFSA guidance for selection of comparators** • Criteria for the selection of receiving environments and of comparator(s): Introducing the relevant EFSA guidance *Presentation*	Tutor
10.00–10.30	**2.2 Toxicity and allergenicity assessments** • Introduction to methodology of toxicity and potential allergenicity assessment • Assessing potential toxicity/allergenicity of gene products and/or of the whole GM plant and derived food/feed	Tutor

	• Introduction to OECD principle for a toxicology study and to EFSA guidance updating and complementing an allergenicity assessment: • Experiments to support the toxicity assessment should consider the newly expressed proteins, new constituents other than proteins, altered levels of food and feed constituents, assessment of the whole food and/or feed derived from GM plants, • Experiments to support the allergenicity assessment should consider allergenicity of the newly expressed protein, allergenicity of the whole GM plant, possible adjuvant activity, Non-IgE-mediated adverse immune reactions to foods *Presentation*	
10.30-11.00	Coffee break	
11.00-11.30	**2.3 Animal Feeding studies** • According to the EU legislation the potential impact of any changes resulting from the expression of introduced genes or any other type of genetic modification shall be assessed; • Relevant toxicity data may be obtained from in vivo, in vitro and/or in silico studies. • The purpose of animal feeding studies is: (1) To demonstrate that the intended effect(s) of the genetic modification of the GM animal and derived food or feed has no adverse effects on human and animal health upon consumption; (2) To demonstrate the absence of unintended effect(s) of the genetic modification(s) on human and animal health upon consumption. • Experiments to support the assessment should consider: (1) The presence of newly expressed proteins; (2) The potential presence of other new constituents; (3) The possible changes in the levels of natural constituents; (4) The impact of changes in composition due to the genetic modification. *Presentation*	Tutor
11.30-12.00	**2.4 Interactive session on Topic 2 (Hazard identification)** *Issues raised during the presentations will be discussed, participants may ask questions or tutors fuel the discussion with challenging the knowledge of the participants.* *Tutors: Roberta Onori, Salvatore Arpaia*	Plenary discussion
	TOPIC 3: HAZARD CHARACTERIZATION	
12.00-12.30	**3.1 Intended modifications vs. unintended effects** The module further describes the tests of difference/equivalence introduced above and how lack of equivalence and/or differences between a GM plant and its comparator is analysed so as to assess potential impact on human and animal health: • Intended alterations fulfilling the objective of the modification vs unintended effects; • Concepts of biological relevance, uncertainty analysis and weight-of-evidence to support the identification of unintended effects *Presentation*	Tutor
12.30-13.30	Lunch	
13.30-14.00	**3.2 Implementing nutritional assessments of food/feed products derived from GM plants** • Evaluating potential alterations in the total diet for the consumers/animals due to the introduction of food/feed derived from GM plants. The nutritional assessment should consider: (1) The composition of the food with regard to the levels of nutrients and anti-nutrients; (2) The bioavailability and biological efficacy of nutrients in the food taking into account the potential influences of transport, storage and expected treatment of the foods; (3) The anticipated dietary intake of the food and resulting nutritional impact.	Tutor

	Presentation	
14.00–14.15	**Introduction to Exercises A and B on Topic 3 (Hazard characterization)** *for participants to be used in group work*	Training Coordinator
14.15–15.15	**3.3 Interactive session on Topic 3 (Hazard characterization): A. Implementing a toxicological study** *Under the guidance of tutors, the participants will design a toxicological study for testing a new GM plant* *Working group exercise (groups of 5 participants)*	
15.15–15.30	Coffee break	
15:30–16.15	**3.4 Interactive session on Topic 3 (Hazard characterization): B. Beyond 90-d-feeding studies** *Participant will identify issues for hazard characterization, not covered by 90-d feeding studies* *Working group exercise (groups of 5 participants)*	
16.15–17.00	**3.5 Interactive session on Topic 3 (Hazard characterization) – Joint discussion** *Issues which were raised during the presentations and exercises 3.3 and 3.4 will be discussed, participants may ask questions or tutors fuel the discussion with challenging the knowledge of the participants.*	
17.00–17.15	Overview and Conclusions of Day 2	Training Coordinator
17.15	End of Day 2	
18.00	City guided tour, followed by the social dinner	

DAY 3 – Wednesday

Time	*Topic*	*Tutor*
	TOPIC 4: ASSESSMENT OF EXPOSURE TO CONSUMERS	
09.00–09.30	**4.1 Methodologies for assessing the exposure of GM food/feed products to consumers** The estimation of dietary exposure requires two types of data: occurrence or concentration data that provides information on the amount of a compound/s present in different food commodities, and consumption data that informs on the intake of these food commodities. By combining these two types of data and considering the body weight of the subjects, dietary exposure is estimated. In the frame of the authorisation of GM crops, the focus is put on how both the available concentration and consumption data should be used to estimate dietary exposure by: • Estimating the average and maximum dietary intake level (use of international Food consumptions databases and EFSA Comprehensive European food consumption database); • Anticipating influences by processing the food and feed; • Identifying particular groups of population with an expected high exposure; • Evaluating intended function and level of use (e.g. raw, cooked, etc.). *Presentation*	Tutor
09.30–10.30	**4.2 Interactive session on Topic 4 (Exposure assessment)** *Participants will be challenged by simulating an exposure assessment (e.g. starting from realistic and "worst-intake" scenarios)* *Working group exercise (groups of 5 participants) followed by plenary discussion*	
10.30–11.00	Coffee break	
	TOPIC 5 ENVIRONMENTAL RISK ASSESSMENT (ERA) OF GMOs	

11.00–11.45	**5.1 Purpose of environmental risk assessments** • According to Directive 2001/18/EC that regulates the deliberate release into the environment of GMOs, they shall only be authorised for placing on the market after a scientific assessment of any risks, which they might present for human and animal health and for the environment. • Environmental risk assessment is a science-based evaluation of complex data sets selected according to defined protection goals; • Criteria for conducting ERA: problem formulation, hazard characterization, exposure analysis, risk assessment, risk management; • Cross-cutting considerations: choice of comparators, receiving environment, long-term effects. *Presentation*	Tutor
11.45–12.45	**5.2 The seven areas of concern** • (1) Persistence and invasiveness, (2) Plant to micro-organisms gene transfer, (3) Interactions with target organisms, (4) Interactions with non-target organisms, (5) Cultivation practices, (6) Biogeochemical processes, (7) Human and animal health • Horizontal gene transfer – Rational and data requirements *Presentations*	Training Coordinator + Tutor
12.45–13.45	Lunch break	
13.45–14.45	**5.3 Interactive session on Topic 5 (ERA of GMOs). Collecting and assessing data for environmental risk assessments of GMO plants** *Cases studies will be evaluated for data requirements and their quality* *Working group exercise (groups of 5 participants) followed by plenary discussion*	
TOPIC 6: POST-MARKETING MONITORING		
14.45–15.15	**6.1 Evaluating predictions made in risk assessments** • Unintended side effects of the product and the need for their detection • The need of a case-by-case post-marketing monitoring (e.g. foods with altered nutritional composition and modified nutritional value and/or with specific health claims) to analyse whether known-effects and side-effects are as predicted or not *Presentation*	Tutor
15.15–16.15	**6.2 Interactive session on Topic 6 (PMM)** *In this exercise, participants will be presented different GMO-issues and will be challenged by designing a post-marketing programme, complementing a pre-marketing toxicological testing programme to confirm the pre-market risk assessment.* *Working group exercise (groups of 5 participants) followed by plenary discussion*	
16.15–16.30	Coffee break	
TOPIC 7: BEYOND PLANTS: GM FOOD AND FEED FROM MICROORGANISMS AND INSECTS		
16.30–17.15	**7.1 GM microorganisms, animals and insects for food/feed purposes** • Importance of GM microorganisms and their products for food/feed processing and as supplements • Short introduction to the current possible future importance of GM animals, including farm animals, insects and fish • Introduction to EFSA guidance documents dealing with GM microorganism and animals (including fish and insects)	Training Coordinator

	Presentation	
17.15–17.45	**7.2 Interactive session on Topic 7 (Beyond GM plants)** *Issues raised in context of assessing the risk of GM other than plants will be discussed, participants may ask questions to the tutor, or he will fuel the discussion with challenging the knowledge of the participants.*	Plenary discussion
17.45–18.00	Overview and Conclusions of Day 3 – with involvement of participants	Training Coordinator
18.00	End of Day 3	
20.30	Dinner	

DAY 4 – Thursday

Time	*Topic*	*Tutor*
	TOPIC 8: RISK CHARACTERIZATION	
09.00–09.40	**8.1 Implementing risk characterization** • Integrative manner vs case-by-case basis, considering also other factors (e.g. receiving environments and cultivation practices affecting food and feed quality) • Key concepts and approaches of uncertainty analyses • Overview on the uncertainty analysis framework as proposed by EFSA • How to move from a qualitative to a more quantitative risk characterization: role of modelling *Presentation*	Tutor
09.40–10.20	**8.2 Risk management** • The concept of risk management measures • Acceptable and inacceptable risk levels • How to upscale effects (long-term, landscape) observed of small scale (field trails) and role of modelling • Mitigation of risk using specific risk management strategies (e.g. containment, monitoring) and precautionary approach *Presentation*	Tutor
10.20–10.50	Coffee break	
10.50–11.50	**8.3 Interactive session on Topic 5 (Risk characterization and management)** *Issues raised during the two lectures will be discussed, participants may ask questions to the tutors, or they will fuel the discussion with challenging the knowledge of the participants.* *Working group exercise (groups of 5 participants) followed by plenary discussion*	
11.50–12.30	**8.4 The interplay between EU regulations on GMO and on pesticides** • Directive 2001/18/EC requires the assessment of possible immediate and/or delayed direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for GMP. For GM herbicide tolerant (GMHT) plants this means assessing also the possible environmental impacts of the post-emergence use of the complementary herbicides. • While GMO legislation includes the assessment of indirect effects linked to the change of herbicide regime, these are not part of ERA for pesticides, however the post-emergence use of the complementary herbicide in a GMHT crop requires a new authorisation according to the EU pesticide Regulation, because it is a new application of the herbicide;	Tutor

	• Change in management practices may have indirect negative or positive environmental effects. *Presentation*	
12.30–13.30	Lunch break	
	TOPIC 9 POST-MARKETING ENVIRONMENTAL MONITORING (PMEM)	
13.30–14.15	**9.1 Ensuring continued safety – Monitoring the impact of GM plants in agroecosystems** • Methodology for Case-Specific Monitoring (CSM): Choice of comparator, Spatial and temporal scale of CSM • General Surveillance, Approach and principles, Protection goals, assessment endpoints and indicators • Tools for General Surveillance: On-site monitoring, Existing monitoring networks, Review of scientific literature *Presentation*	Tutor
14.15–15.00	**9.2 Reporting PMEM results** • Potential use of existing monitoring networks, conceptual framework articulating CSM and GS • Description of methods, frequency and timing for applicants' reporting in their monitoring plan; • Procedures to be adopted if unanticipated adverse effects have been detected *Presentation*	Tutor
15.00–15.30	Coffee break	
15.30–16.30	**9.3 Interactive session on Topic 9 (PMEM). Implementing and evaluating post-marketing environmental monitoring plans and results (Part 1)** *In this exercise, based on GMO-cases of previous days, participants will be asked to adopt the different approaches and asked for their proposals to solve the issue. Case study.* *Working group exercise (groups of 5 participants)*	
16.30–17.30	**9.3 Interactive session on Topic 9 (PMEM). Implementing and evaluating post-marketing environmental monitoring plans and results (Part 2)** *Results of the first part of this exercise as elaborated for each group will be presented in this exercise, and discussed among the participants and tutors.*	Plenary discussion
17.30–17.40	Overview and conclusions on the day	Training Coordinator
17.40	End of Day 4	
20.30	Dinner	

DAY 5 – Friday

Time	*Topic*	*Tutor*
	TOPIC 10 GMOs MADE BY NEW TECHNOLOGIES – CHALLENGES FOR REGULATIONS	
08.15–08.45	**10.1 Implications of Synthetic biology for environmental risk assessments** • What is Synthetic Biology? • ERA of microorganisms made by Synthetic biology • Xenobiology • ERA of plants made by Synthetic biology	Training Coordinator

	Presentation with discussion	
08.45–09.15	**10.2 "Omics"-technologies and molecular techniques to deal with unintended effects** • Application of 'Omics' and high-throughput sequencing technologies in support of risk assessment • Tackling unintended effects due to the insertion of new pieces of DNA • Tackling the need of selection markers during the genetic transformation *Presentation with discussion*	Tutor
	TOPIC 11 RISK COMMUNICATION	
09.15–09.45	**11.1 An introduction to risk communication strategies** • Definition of risk communication • Purpose of risk communication • Principles of good risk communication • Communication strategies in case of crisis situations • Best practice to communicate uncertainties • The importance of the risk perception in handling hazards • Different types of communication "styles" adjusted to target audience • Stakeholders, their core business and their language • Communication levels – written, discussions, interviews *Presentation*	Training Coordinator
09.45–10.05	Coffee break	
10.05–11.05	**11.2 Interactive session on Topic 11 (Risk communication):- Role plays** *The participants will exercise risk communication from sides of the communicator and recipients, the first representing scientists and risk assessors or public authorities, the latter stakeholders* *Following the role plays, the participants will discuss with the tutors the best strategies and approaches to communicate risks*	Plenary
11.05–11.15	Dissemination of the contents of the training *Presentation*	Event Manager
11.15–11.25	Conclusions and Lessons learned on the topics covered. Questions & Answers	Training Coordinator
11.25–12.00	Final Test of knowledge, Evaluation of training and training certificates	
12.00	End of the training session	
12.15	Lunch and following departure to 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 5: **Christoph TEBBE**

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.