BTSF *Initiative*

BTSF – RISK ASSESSMENT IN THE FOOD CHAIN

Course 5 - Risk assessment in biotechnology

Notification to NCPs

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

Objectives of the proposed training and goals to be reached

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

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

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

The present training 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. **To facilitate this, invited countries will be requested to select on the specific training sessions officials coming from the risk assessment field.**

General training objective

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

OPERA NSF

Specific objectives:

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

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

Main topics that will be addressed:

- Introduction to 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.

Training agenda

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

Courses, locations and allocations of seats

Due to current COVID-19 epidemics, it has been just scheduled one session out of two, waiting for further development in 2022.

The date and location of the training sessions are the following:

Training sessions: dates and locations

Year	Training session	Tentative dates	City
2021	1	13 - 17 December 2021	Valencia (Spain)
2022	2	To be announced	To be announced

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

It is also clarified that in case COVID-19 epidemiological situation will make the face-to-face organisation of the training session unsafe and dangerous for participants, session will be organised in virtual mode. In such case, NCPs will be timely informed.

Quota of allocated seats for the **training session 1** will be according to table below (allocated seats for training session 2 will be made available in due time:

Table 1: Suggested allocation for EU Member States and Candidate Countries

	country / suggested allocation					
Member States	Austria	1	Germany	2	Poland	1
	Belgium	1	Greece		Portugal	1
	Bulgaria		Hungary	1	Romania	
	Croatia	1	Ireland		Slovakia	1
	Cyprus		Italy	2	Slovenia	1
	Czech Republic	1	Latvia		Spain	2
	Denmark	1	Lithuania		Sweden	1
	Estonia		Luxembourg		United Kingdom (NI)	
	Finland	1	Malta			
	France	1	Netherlands	1		
	Total Member States					***20***
Candidate Countries	Albania		North Macedonia		Turkey	
	Montenegro		Serbia			
	Total Candidate Countries					***0***
Global participation EU Member States and Candidate Countries						***20***

Table 2: Suggested allocation for other non-EU Countries

	country / suggested allocation		
EFTA/ EEA countries	Iceland	Norway	Switzerland
	Lichtenstein		
	Total EFTA/EEA Countries		***0***

Global participation other non-EU Countries	***0***

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

For logistic organisational reasons, it is kindly requested that names of participants shall be communicated at the latest within 30 days from each workshop (**deadline is Monday 15 November 2021).** A reminder will be sent to NCPs before the event. **In case event is turned into Virtual class, a new allocation of seats will be timely circulated to NCPs with a relevant new deadline for sending registration forms.**

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

Participants' profile

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

Selection criteria for regular participants

Minimum requirements *(participants who do not meet the minimum requirements should not be proposed for the training and should not be evaluated according to the selection criteria listed below)*		
Minimum 3 years of professional experience in the food chain risk assessment		Yes/No
Competent national authority responsible for the food chain risk assessment		Yes/No
Evaluation criteria		**Max. score**
1)	Professional experience in public institutions and national authorities involved in food chain risk assessment *Scoring* *less than 3 years = 1 point; 3-5 years = 5 points; 5-10 years = 7 points; > 10 years = 10 points*	10
2)	Experience in risk assessment in biotechnology (e.g. GMOs, synthetic biology) *Scoring* *less than 3 years = 1 point; 3-5 years = 5 points; 5-10 years = 7 points; > 10 years = 10 points*	10
3)	Experience in crisis investigation and management *Scoring* *no experience = 0 points; less than 3 years = 1 point; 3-5 years = 5 points; 5-10 years = 7 points; > 10 years = 10 points*	10
	Maximum total score	**30**

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

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, preparing informative articles in the professional national journals or preparing presentations based on the training materials for the staff of national Competent Authorities or other disseminating methods which could be appropriate to share the information received via the BTSF training. During the course participants will be provided with a training package to be used as supporting dissemination material.

Dissemination questionnaire

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

Initial and final tests of knowledge

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

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

Data protection

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

Project Management

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

Project Manager is Claudio BOMPARD. Training Coordinator is Christoph TEBBE.

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

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

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

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

Agenda of the training follows:

Course 5 – Risk assessment in biotechnology (e.g. GMO, synthetic biology)

DAY 1 Monday

Time	*Topic*	*Tutors*
11.30–13.15	Registration of participants and lunch	
13.15–13.30	Welcome addresses, course background, objectives & expected results	TC
13.30–13.45	Better Training for Safer Food: presentation of a video	
13.45–14.00	Preliminary discussion with participants, aimed to enquire about their expectations on the training initiative • Participants present their job-related tasks with regard to food safety risk assessment, giving a short overview of their national organization; • An overview of the various national food safety risk assessment (RA) structures in the EU and guest-countries will be presented (BY PARTICIPANTS).	TC
14.00–14.30	Initial test of knowledge	
14.30–15.15	**TOPIC 1: INTRODUCTION TO RISK ASSESSMENT IN GMOs** **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
15.15–15.45	Coffee break	
15.45–16.15	**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
16.15–16.30	**1.3 Short introduction to the case studies used in this course** • Five case studies as a material for participants' exercises *Presentation*	Tutor
16.30–17.15	**1.4 Introduction into the four basic steps of risk assessment**	Tutor

	• 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 (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*	
17.15–17.40	**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* *All tutors*	Plenary
17.40–18.00	Overview and Conclusions of Day 1 – incl. involvement of participants	TC
18.00	End of Day 1	
19.00	Welcome cocktail and welcome dinner	

DAY 2 Tuesday

Time	*Topic*	*Tutor*
9.00–9.30	**TOPIC 2: HAZARD IDENTIFICATION** **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
9.30–10.00	**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
10.00–10.15	**2.1.3 EFSA guidance for selection of comparators**	Tutor

	• Criteria for the selection of receiving environments and of comparator(s): Introducing the relevant EFSA guidance *Presentation*	
10.15–10.45	**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 • 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*	Tutor
10.45–11.15	Coffee break	
11.15–11:45	**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
11.45–12.00	**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.* *All tutors*	Plenary
12.00–12.30	**TOPIC 3: HAZARD CHARACTERIZATION** **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
12.30–13.00	**3.2 Implementing nutritional assessments of food/feed products derived from GM plants**	Roberta ONORI

	• 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. *Presentation*	
13.00–14.00	Lunch break	
14.00–14.15	**Introduction to Exercises A and B on Topic 3 (Hazard characterization)** *for participants to be used in group work*	Tutor
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 (3 groups of 6 to 7 participants)* *All tutors*	Plenary
15.15–15.45	**Coffee break**	
15:45–16.45	**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 (3 groups of 6 to 7 participants)* *All tutors*	Plenary
16.45–17.30	**3.5 Interactive session on Topic 3 (Hazard characterization) – Joint discussions** *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.* *All tutors*	Plenary
17.30–17.35	Overview and Conclusions of Day 2	TC
17.35	End of Day 2	
18.00	Guided tour	
20.00	Social dinner	

DAY 3 – Wednesday

Time	*Topic*	*Tutor*
09.00–10.00	**TOPIC 4: ASSESSMENT OF EXPOSURE TO CONSUMERS** **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	Tutor

	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*	
10.00–10.30	**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 (3 groups of 6 to 7 participants)* *All tutors*	Plenary
10.30–11.00	Coffee break	
11.00–11.40	**TOPIC 5: RISK CHARACTERIZATION** **5.1 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
11.40–12.20	**5.2 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
12.20–13.00	**5.3 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 (3 groups of 6 to 7 participants)* *Tutors: Patrick Du Jardin, Antoine Messéan*	Plenary
13.00–14.00	Lunch break	
14.00–14.45	**TOPIC 6: POST-MARKETING MONITORING** **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	Tutor

	Presentation	
14.45–15.45	**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. Case study* *Working group exercise (3 groups of 6 to 7 participants)* *Tutors: Roberta Onori, Antoine Messéan*	Plenary
15.45–16.15	Coffee break	
16.15–17.00	**TOPIC 7: BEYOND PLANTS: GM FOOD AND FEED FROM MICROORGANISMS AND INSECTS** **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) *Presentation*	Tutor
17.00–17.30	**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.* *Tutor: Christoph Tebbe*	Plenary
17.30–17.50	Overview and Conclusions of Day 3 – with involvement of participants	TC
17.20	End of Day 3	
19.00	Dinner	

DAY 4 – Thursday

Time	*Topic*	*Tutor*
09.00–09.45	**TOPIC 8 ENVIRONMENTAL RISK ASSESSMENT (ERA) OF GMOs** **8.1 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

09.45–10.45	**8.2 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*	Tutor
10.45–11.15	Coffee break	
11.15–12.15	**8.3 Interactive session on Topic 8 (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 (3 groups of 6 to 7 participants)* *All tutors*	Plenary
12.15–13.00	**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; • Change in management practices may have indirect negative or positive environmental effects. *Presentation*	Tutor
13.00–14.00	Lunch break	
14.00–14.45	**TOPIC 9 POST-MARKETING ENVIRONMENTAL MONITORING (PMEM)** **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
14.45–15.30	**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
14.30–15.30	**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*	Plenary

	study. *Working group exercise (3 groups of 6 to 7 participants)* *All tutors*	
15.30–16.00	Coffee break	
16.00–17.00	**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.* *All tutors*	Plenary
17.00–17.20	Overview and conclusions on the day	TC
17.20	End of Day 4	
19.00	Dinner	

DAY 5 – Friday

Time	*Topic*	*Tutor*
09.00–09.30	**TOPIC 10 GMOs MADE BY NEW TECHNOLOGIES – CHALLENGES FOR REGULATIONS** **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 *Presentation with discussion*	Tutor
09.30–10.00	**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
10.00–10.30	**TOPIC 11 RISK COMMUNICATION** **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*	Tutor
10.30–11.00	Coffee break	
11.00–12.00	**11.2 Interactive session on Topic 11 (Risk communication):- Role plays**	Plenary

	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* *All tutors*	
11.45–12.00	Dissemination of the contents of the training *Presentation*	TC
12.00–12.15	Conclusions and Lessons learned on the topics covered. Questions & Answers	TC
12.15–12.30	Final Test of knowledge	
12.30–12.45	On-line evaluation of training	
12.45–13.00	Training certificates	
13.00	End of the training session	
13.00	Lunch	
14.00	Departure to the airport	