



BTSF – RISK ASSESSMENT IN THE FOOD CHAIN

COURSE 5 – Risk assessment in biotechnology

Fact-sheet

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. 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.

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.

OBJECTIVES

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 are:

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

TOPICS

The following topics will be covered during the training sessions, both from a theoretical and practical standpoint.

1. Introduction to risk assessment in GMOs with a focus on GM plants
2. Explanation of new breeding techniques such as cisgenesis, intragenesis genome editing, synthetic biology, gene drive
3. 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

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- scope and interplay between molecular characterization, compositional and agronomic characterisations in the identification of unintended effects of GM plants and products.
4. The exposure assessment in the context of the evaluation of food and feed derived from GM plants
 5. Risk characterisation, including uncertainty analysis
 6. Risk mitigation (risk management)
 7. Post-market monitoring on a case-by-case basis
 8. 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
 9. The two approaches of post-market environmental monitoring: case-specific monitoring (of identified risks) and general surveillance (of unidentified risks)
 10. Synthetic biology
 11. Omics in risk assessment
 12. Short introduction to Risk Communication.

Besides, group works, exercises and case studies will be included. A test of knowledge will be carried out by all participants at the beginning and at the end of each workshop.

FACTS AND FIGURES

During the second phase, 2 five-day training sessions will be organised and implemented, and approximately 20 people will attend each training session.

TRAINING LOCATIONS AND CALENDAR

Training sessions will be implemented according to the following calendar.

Year	Training sessions	Locations	Proposed dates
2024	TS 1	Rome, Italy	22-26 January 2024
	TS 2	Riga, Latvia	04-08 November 2024

PARTICIPANT SELECTION CRITERIA

The training will be addressed to official from Competent Authorities and scientists from public institutions and national authorities involved in food chain risk assessment (with a focus on biotechnology risk assessment). They 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).

PROJECT MANAGEMENT AND TUTORS' TEAM

The project will be implemented by the company OPERA srl in consortium with NSF Euro Consultants SA. The project's staff includes Mr. Claudio Bompard (CEO of OPERA) as Project Manager, Mr. Christoph Tebbe as training coordinator, Mr. Luigi Pisanello and Ms. Guendalina Mamma as Event Managers and a pool of 4 highly qualified tutors from 4 MS: Mr. Antoine Messéan, Mr. Patrick Du Jardin, Ms. Roberta Onori, Mr. Salvatore Arpaia.

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