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.

Course 7 – Environmental risk assessment

SYLLABUS

Contents

A. BACKGROUND

Genetically modified (GM) plants submitted within the framework of Regulation (EC) No 1829/2003 on GM food and feed or under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs) should go through the authorization process for placing on the market in the European Union. In this training program we will focus on the environmental risk assessment (ERA) of GM plants according to the relevant EFSA Guidance Document following the 6 steps (1. Problem formulation including hazard identification, 2. Hazard characterisation, 3. Exposure characterisation, 4. Risk characterisation, 5. Risk management strategies, 6. Overall risk

evaluation and conclusions) and the specific areas of concern highlighting selected concerns (e.g. Persistence and invasiveness including plant-to-plant gene flow, Plant to micro-organisms gene transfer, Interactions of the GM plant with target organisms, Interactions of the GM plant with non-target organisms, Impacts of the specific cultivation, management and harvesting techniques) and cross-cutting considerations discussed in this Guidance Document.

We will also cover risk communication, fair communication instead of fake news type ones, socio-economic aspects, innovative solutions (new breeding methods), placing GM plant ERA and subsequent risk management into farming context and considering other relevant regulations such as the “Sustainable Pesticide Use” Directive.

Our training approach will follow the “participatory principles”, be inclusive as much as possible. Accordingly, plenary presentations will introduce and discuss ERA, followed by group activities in breakout sessions taking selected cases for ERA. Results of the discussions will be reported back at the plenary.

We hope that the planned training will demonstrate the joint work, contributions by individuals resulting in harmonized way of thinking and increased capacity in science based ERA of GM plants.

B. KEY ISSUES

Key issues that have been taken in consideration for the preparation of the program and training materials are:

- ✓ Legal Community and international frame of environmental risk assessment of GM plants
- ✓ Structured 6 steps approach in environmental risk assessment for genetically modified plants
- ✓ Principles (science based, step-by step) approach of ERA
- ✓ Specific areas of concern
- ✓ Cross-cutting considerations in ERA
- ✓ Uncertainties in ERA
- ✓ Risk management (mitigation)
- ✓ Post-market environmental monitoring
- ✓ New breeding technics
- ✓ Risk communication
- ✓ Socio-economic aspects
- ✓ Farming system and SUD context of ERA

C. CONTENTS OF THE TRAINING COURSE

TOPIC 1: INTRODUCTION TO ENVIRONMENTAL RISK ASSESSMENT (ERA)

1.1. Legal framework

Module Description

- Regulation No 1107/2009 on the placing of plant protection products on the market;
- Regulation No 1831/2003 on additives for use in animal nutrition;
- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms;
- Regulation No 1829/2003 on genetically modified food and feed;
- Division of competences between risk assessment and risk management.

Key concepts, information and messages for this module

Legislation relating to GMO's and GMP's is substantial not only in the EU Member States but also in the US and Canada. Moreover, in recent times global GMP crop production has increased significantly especially in the US and Canada, followed by Argentina, Brazil Paraguay and Uruguay. Other high populated countries such as India and China are also important GMP crop producers

The development of new genetic modification techniques (nGMs), also referred to as "new (breeding) techniques" in other sources, has raised worldwide discussions regarding their regulation and also in the EU.

As regards EU legislation governing GMO's, different existing regulatory frameworks for genetically modified organisms (GMO's & GMP's) cover nGMs to varying degrees. Coverage of the nGMs depends mostly on what is referred to as the regulatory trigger. In general two different trigger systems can be distinguished, taking into account either the process applied during development, or the characteristics of the resulting product. Such regulatory triggers either refer to specific characteristics of regulated products and the newly developed traits (product-oriented regulatory triggers) or the use of certain technologies in the generation of regulated products (process-oriented regulatory triggers).

Biosafety frameworks for the regulation of GMO use different regulatory triggers, i.e., definitions specifying the products covered by the regulatory frameworks. Such regulatory triggers either refer

to specific characteristics of the regulated products and the newly developed traits (product-oriented regulatory triggers) or the use of particular technologies in the generation of regulated products (process-oriented regulatory triggers).

Legal regulatory frameworks in different countries such as EU Member States, need to provide appropriate and workable procedures for regulation and risk assessment of GM plants.

1.2. Open discussion on ERA

Module Description

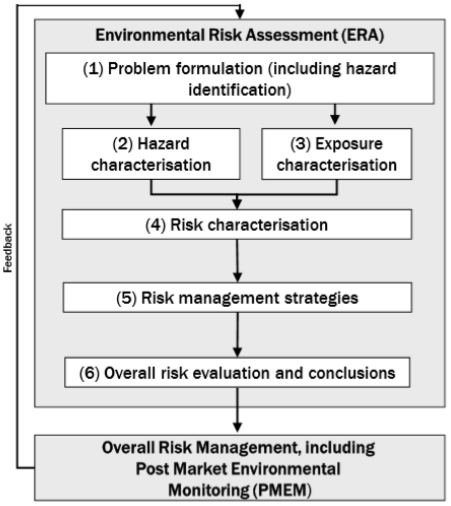
This module aims at involving participants and exploring their experience and view on ERA.

Overview on the steps of ERA. EFSA guidance on ERA. Protection goals and their relevance in ERA. Problem formulation, hazard, risk and harm.

Key concepts, information and messages for this module

The aim of ERA (EFSA Guidance on Environmental Risk Assessment of GM Plants) is to utilise a structured, systematic, predictable, repeatable approach towards risk evaluation – based on the resulting hazard posed and the likelihood of the hazard arising. The objective of ERA is on a case-by-case basis to identify and evaluate potential adverse effects of the GM plant, direct and indirect, immediate or delayed (including cumulative long-term effects) on the receiving environment(s) where the GM plant will be released. The ERA consists of the six steps described in Directive 2001/18/EC as follows:

Problem formulation including hazard identification	**4. Risk characterisation**
Hazard characterisation	**5. Risk management strategies**
Exposure characterisation	**6. Overall risk evaluation and conclusions**



The ERA begins with step 1 and moving towards step 6; steps 2 & 3 can be carried out in parallel. Any uncertainty inherent to the different steps of the ERA must be highlighted and quantified as far as possible.

Understanding that GMO's, GMP's and genetically engineered organisms GEO's are utilised in agricultural practices and with regard to expressing traits of interest such as insect, pesticide or herbicide resistance is fundamental.

Given the extent of monoculture practice as it relates to such GMP crops as soybean, maize, cotton and oilseed rape, the commercial viability of these large scale crops rest in their ability to maximise on crop production. This is based on the key intrinsic characteristics – traits of these crops to resistance to insects and biocides – pesticides & herbicides

The basic premise of environmental risk assessment as it applies to GMO's / GMP's, is the quantification of the risk linked to the production of new organisms – crops, by genetic engineering technology and their introduction into the environment.

Risk assessment is the key method of evaluating hazards in relation to GMO's and requires calculation of two components of risk – magnitude of the potential loss and the probability that the loss will occur.

The role of the EFSA, EU legislation and precautionary principle in providing guidance on the management of the risk associated with the release into the environment of GMO's and GMP's is very important.

1.3. ERA and food chain safety controls

Module Description

ERA within Competent Authorities in relation to food chain safety controls

- Introduction to environmental risk assessment guidance of EFSA;
- ERA at Community, national and international level.

Key concepts, information and messages for this module

EU official control rules are a key element of the governance of the agri-food chain in Europe, which are recognised world-wide as an example of best practice.

Those rules provide national enforcers and the Commission with the necessary powers to ensure effective enforcement of regulatory requirements, and with mechanisms that allow the full cooperation of all parties involved in ensuring the correct application of the law across national borders.

The Official Controls Regulation also provides the Commission with audit and control powers in the EU countries and Third Countries, and with the power to take action at EU level.

Procedures for conducting environmental risk assessment of genetically modified plants is based on the EFSA Guidance Document on the ERA of GM Plants

EU national country competent authorities are responsible for food chain safety controls and also assesses applications for release of GM organisms and prepares a risk assessment and risk management plan.

1.4. Case study on ERA and food chain safety controls

Module Description

Breakout session - Working in small groups

- on use of EFSA guidance;
- exchange of best practices and national experiences in environmental risk assessment using an online tool for such assessment (based on PRIMo).

Plenary discussion.

1.5. Genetically Modified Plants (GMPs) commercial release

Module Description

Specific areas of risks for the commercial (deliberate) release of GMPs

Key concepts, information and messages for this module

The increasing rate of GM crops / plants in agriculture is an indication of the extent within the agri-biotechnology sector of the satisfaction and benefits for the whole production chain.

Indications from North America – US & Canada and also in the EU, it is predicted that the demand for the commercial release and growth of GM will continue to increase in the future

In the EU, Canada, North America, where GM crops are grown, there are strict regulatory systems in place by way of legislation and which are regularly updated by the competent authorities

The key component of applications for the commercial release of GM crops / plants is the requirement that a detailed environmental risk assessment - ERA be undertaken and which considers potential harm to human health, other organisms and the environment.

The ERA evaluates possible options that any risks arising from the commercial release of GM crops / plants, can be mitigated, minimised, avoided. Particular emphasis has to be placed in the risk assessment and any procedures for risk management

References

Pirondini, A. and Marmiroli, N (2008), Environmental Risk Assessment in GMO Analysis. Rivista di biologia 103(2-3):371-402 · December 2008

Guidance on the Environmental Risk Assessment of Genetically Modified Plants. EFSA Panel on Genetically Modified Organisms (GMO); EFSA Journal 2010;8(11):1879

TOPIC 2: SPECIFIC COMPONENTS OF ERA

2.1. Receiving environment (part 1): presentation and discussion

Module Description

Different aspects, components and interpretation in ERA

Key concepts, information and messages for this module

The way the applicants should consider the role of the receiving environment during their ERA of genetically modified plants (GMPs) is described in the EFSA “Guidance on the environmental risk assessment of genetically modified plants” (2010).

Attributes pertinent to biogeographic (e.g. climate, soil, fauna, etc.) and agronomic characteristics

(e.g. land use, pest management programs, tilling, etc.) need to be considered for better focusing ERA.

Environmental protection goals (e.g. protecting biodiversity and ecosystems) establish the context for ERAs by describing the components of the specific ecosystem that needs be protected, and thus considered during ERA. To make ERA effective, generally stated protection goals need to be translated into specific, operational goals.

A sequential analysis of the current and expected range of the geographical distribution of the crop shall provide evidence that data generated are representative of the range of receiving environment(s) where the crop will be grown in the European Union. Similarly, a selection matrix can be used to select relevant assessment endpoints that reflect the specific protection goals for representative receiving environments.

The role of risk managers is very important in ensuring that ERA has duly considered the characteristics of specific receiving environments.

2.2. Non-Target Organisms (NTOs): presentation and discussion

Module Description

- definition, selection of NTOs;
- test levels (Tiered approach), measurement and assessment endpoints.

Key concepts, information and messages for this module

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. The document requires that, in the context of the ERA, potential interactions between a genetically modified (GM) plant and non-target organisms (NTOs) are considered, including direct and indirect, as well as immediate and delayed effects.

For the ERA there is the necessity of clear and objective protection goals, for which assessment and measurement endpoints shall be developed. Setting testable hypotheses, defining criteria for appropriate selection of test species and ecological functional groups and developing appropriate laboratory and field studies to collect relevant NTO data are an integral part of experimental designs.

2.3. Receiving environment (part 2): presentation and discussion

Module Description

Crop x trait interactions in Receiving Environments as per EFSA GD

Key concepts, information and messages for this module

Please make reference to 2.1.

2.4. – 2.5. Case study on ERA of selected GMPs

Module Description

Life cycle, exposure, developmental stages of NTOs.
Working groups and plenary discussion.

Key concepts, information and messages for this module

In order to formulate a judgement on the safety of the GM event under discussion, the ERA of GMPs involves generating, collecting and assessing information in order to determine its impact on human/animal health and the environment relative to their near-isogenic control (i.e. non-GMPs), and thus assessing its relative safety.

The EFSA guidance document provides guidance to risk assessors for assessing potential effects of GMPs into the environment and the rationale for data requirements in order to complete a comprehensive ERA.

The analysis of specific case studies will enable to familiarize with steps for the ERA of GMPs, as indicated in Directive 2001/18/EC: problem formulation including hazard identification, hazard characterization, exposure characterization, risk characterization and management strategies; overall risk evaluation.

On a case by case basis, information relevant to the receiving environment and to the specific GM event need to be used for each definite area of concern have to be analysed.

2.6. – 2.7. Learning from diversity: group exercise

Module Description

Environments, cases, regions, perceptions: good examples for ERA.
Working groups and plenary discussion.

Key concepts, information and messages for this module

ERA concepts can be used broadly, however local differences may trigger different solutions. Local peculiarities need to be considered, with special reference to existing protection goals, exposure analysis and selection of assessment endpoints.

Comparing different case studies favors the identification of key factors determining the outcome of ERA. Science should keep supplying ecological information (and ideas) to give risk assessors always the best chances for making a correct informed judgement for ERA

TOPIC 3: ERA AT FARM LEVEL

3.1. – 3.2. – 3.3. ERA for GMPs in Integrated Pest Management (IPM): presentation and case study

Module Description

Risk assessment in farming:

- System approach;
- Multiple stressor in the system;
- Resistance management
- Good agricultural practices;
- Practical examples.

How risk management and farming practices are in harmony: presentation and teamwork.
Introduction by the Tutor followed by group activity and plenary discussion.

Key concepts, information and messages for these modules

In any ecosystem, including agro-ecosystems, hundreds of species are sustained in food webs, above and below ground, based on cultivated plants as the main primary producers and only a minority of them may become economically relevant pests. Reliance on a wide diversity of solutions is needed to ensure the long-term sustainability of control measures. Integrated pest management (IPM) principles apply to cropping systems over an extended spatial and temporal scale, rather than to individual crops. Many of the levers that are key to achieving robust agroecosystems are to be found at the cropping system level and at larger scales.

Monitoring of insect pests and natural enemies (a necessary activity in any IPM program) is not hampered by the cultivation of GMPs.

Insect resistant GM crops, as well as traditionally bred insect resistant plants, work independently of any action threshold established for target pests, since they produce a preventive defense even before insects attack cropped plants.

Insect-plant relationships need to be investigated and the role of this germplasm in combination with other means of pest control in the agro-ecosystem, included the use of biocontrol agents and chemical pesticides, needs to be assessed in each GM agroecosystem.

3.4. – 3.5. – 3.6. New breeding techniques for GMPs: presentation and case study

Module Description

- CRISPR; gene editing, gene silencing;
- RNAi based plants;
- GMPs of improved agronomic performance.

Presentation, working group and plenary discussion.

Key concepts, information and messages for this module

The existing regulatory framework in the European Union allows the assessment of the safety of GMPs (and their derived food/feed) obtained with new breeding techniques. The applicability of the existing regulatory framework needs to be guaranteed also for future applications.

While some of the requirements for ERA could be relaxed for specific products, the problem formulation phase is always necessary to frame the safety assessment.

Experimental protocols for ERA may need adjustments to ensure their efficiency.

TOPIC 4: ENVIRONMENTAL RISK ASSESSMENT: selected aspects

4.1. ERA for GMPs: specific exposures

Module Description

- food and feed purposes;
- non-food and non-feed purposes.

Key concepts, information and messages for this module

Introduction into basic biological and technical implications of GMP's as living organisms with respect to their release into the environment and respective exposure according to different purposes (deliberate release and placing on the market) should consider:

- Information requirements for the ERA with respect to Exposure:
- Information relating to the GMP;
- Information relating to the conditions of release and the potential receiving environment;
- Information on the interactions between the GMP and the environment;
- Knowledge derived through the step-by-step principle of Directive 2001/18/EC, provision 24:

The introduction of GMPs into the environment should be carried out according to the step by step principle. This means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken.

The exposure characterisation step within the (step-by-step) ERA approach as performed for different areas of risk, should consider:

- Persistence and invasiveness including plant-to-plant gene flow;
- Plant to micro-organisms gene transfer;
- Interactions of the GMP with target organisms;
- Interactions of the GM plant with non-target organisms.

4.2. – 4.3. Case study on ERA for GMPs: specific exposures

Module Description

Group exercise introduced by Tutor.

Case studies are supported by respective sets of relevant information.

- Task 1:work out relevant exposure characteristics of selected GMP for the intended uses: import or cultivation
- Task 2: work out how the relevant areas of risk can be informed by the identified technical/biological elements of the exposure pattern
- Task 3: describe the role of identified exposure characteristics in the formula quantifying the Environmental risk given as: Risk = Hazard x Likelihood of hazard arising

How ERA for food feed, non-food non-feed is conducted focused on specific exposures.

Group work and plenary discussion.

Key concepts, information and messages for this module

ERA of GMPs for food and feed purposes: Import and processing in spatial and temporal context:

- Transport and storage

- Retailment
- Excretions/animal manure
- Vertical and horizontal gene flow

ERA of GMPs for non-food and non-feed purposes: Import and processing in spatial and temporal context:

- Transport and storage
- Retailment
- vertical gene flow

Understanding the implications of the handling of GMP's during import and processing and how these shape the risks and the selection of management measures coming into use.

Exemplify the structured, systematic, predictable, repeatable approach towards risk evaluation of import and processing of gm– based on the resulting hazard posed and the likelihood of the hazard arising.

4.4. Farmers and innovative solutions

Module Description

ERA of GMPs in spatial context:

- single field(s)
- complexity of multiple field

ERA of GMPs in broader temporal context

- in a single growing season of the crop plants
- broader temporal scale (multiple years, crop rotation, rotation of events, traits)

How the ERA of GMPs informs the risk managers with respect to IPM principles

- preventive measures
- pest regulation, informed decision based on pest level, subsequent management tool decision

- economic and action threshold levels as part of ERA complex,
- biodiversity, protection of natural regulating mechanism
- monitoring and success feed back
- resistance risk management
- economic and social sustainability of the farming system and ERA

Key concepts, information and messages for this module

Adoption of GM plants (specifically new traits, outputs of new breeding techniques) requires broad functional (farm) approach by risk assessors and risk managers as well. Therefore it's important to address some aspect of ERA that relates already risk management and provides feed-back to risk assessors including those that are executing the risk management (farmers).

ERA and risk management at farm level for GMP's is very important.

GMPs are released for cultivation purposes in a broad spatial and temporal "receiving environment", in this case on the key functional and operational unit called farm. Therefore, GMPs related ERA should be placed into this context. Most of present GMPs and likely increasing innovative GMPs will serve different (sometimes multiple) protection goals under the sustainable agricultural production (thus pest regulation, better use of natural resources such as water, higher specific quality production, etc.). Accordingly, on a hypothetical farm, several crops of different GM events, traits will be cultivated over years in mosaic type spatial arrangements. In addition to the cultivated crops, non-cropped habitats and related NTOs are also present.

SUD IPM and overall ERA and environmental risk management (ERM) under farming context for innovative practices needs to be considered as well.

The Directive "Sustainable use of Pesticides" aims at reducing the risk by pesticides on human health and the environment. The eight principles of this Directive guides risk managers including farmers on the implementation and execution of IPM according these principles. It should be understood how the ERA of GMPs can inform the risk manager in order to consider these principles.

4.5. ERA around the world: presentation and discussion

Module Description

Experiences of ERA in various regions in the World: learning from each other

Key concepts, information and messages for this module

Different Regulatory standards around the world (CBD, OECD, EU …)

Countries follow different Standards. The regulatory status changes and differs from country to country.

Experience practical implementation of regulatory requirements in different countries => e.g. Database on GMP's, risk assessments and Country's Decisions: https://bch.cbd.int/

References

Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment; CBD Conference of the Parties to the Convention of Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety 2016, UNEP/CBD/BS/CPO-MOP/8/8/Add.1

Safety Assessment of Transgenic Organisms in the Environment; OECD Consensus Documents 2017, Volume 7

Guidance on the Environmental Risk Assessment of Genetically Modified Plants. EFSA Panel on Genetically Modified Organisms (GMO); EFSA Journal 2010;8(11):1879

TOPIC 5: RISK MANAGEMENT AN RISK COMMUNICATION

5.1. Introduction to risk management and risk communication

Module Description

- general intro to risk management
- Engagement Toolkit, Catalogue of Communication Tools and Dissemination Guidelines: benchmarking current practice in EU and Member State bodies
- Risk Communication Plan
- Problems and Challenges in Risk Communication how to adjust communication according to the special target (eg. scientists vs general public);

Key concepts, information and messages for this module

The basics of risk management processes and why and how it is carried out consider different steps.

First, it is necessary to establish a context. The audience will understand the circumstances in which

the process is taking place.

Secondly, the criteria that will be used to evaluate risks should also be established and the structure of the analysis should be defined. Key points are the following:

- Risk identification - identifies and defines potential risks/factors/events that may negatively influence a specific process or project (there are also the so called positive risks – inaction leading to missed opportunities…).
- Risk analysis. Once specific types of risk are identified, the odds of it occurring as well as its consequences determine "probability" and "impact".
- The goal of risk analysis is to further understand each specific instance of risk, and how it could influence the objectives.
- Risk assessment and evaluation. The risk is then further evaluated after determining the risk's overall likelihood of occurrence combined with its overall consequence. Risk assessment = "probability" and "impact", Risk evaluation = "probability" x "impact" (Risk value represented as multiplication of probability and impact).
- A decision on whether the risk is acceptable or not is included. Not only accepted, there is scale of possible decisions, a standard one is:
    AC: accepting
    AV: avoiding
    EL: eliminating
    RE: reducing
    SH: sharing

- Risk mitigation. During this step, the highest-ranked risks are assessed (the assessment phase is a previous one, here is only the action plan) and a plan is developed to alleviate/address them using specific risk controls. These plans include risk mitigation processes, risk prevention tactics, and contingency plans in the event the risk comes to fruition.
- Risk monitoring. Part of the mitigation plan includes following up on both the risks and the overall plan to continuously monitor and track new and existing risks. (Monitoring the action plan for the implementation of the risk control measures, the resulting dynamics and the newly involved risks…).
- The overall risk management process should also be reviewed and updated accordingly.
- Communicate and consult. Internal and external shareholders should be included in communication and consultation at each appropriate step of the risk management process and with regard to the process as a whole.
- Risk Communication – background in the context of General Food law
- Tools used in Risk Communication
- Challenges and Problems in Risk Communication

Finally, assigning the risk to an ‘owner’ is crucially important in terms of response so the risk is managed and monitored.

Further reference is made to recent documents/guidelines issued by EFSA:

- *Communication inside Risk Assessment and Risk Management (COMRISK): Final report (2020). An external scientific report.*
- *Technical assistance in the field of risk communication (2021)".*

5.2. – 5.3. Case study on risk measures and record-keeping

Module Description

Presentation, teamwork and plenary discussion.

Key concepts, information and messages for this module

The risk management framework comprises 6 main steps: identification of the risks, analysis of the risks through risk assessment meetings, prioritizing exercise and ranking together with probability (ranking and prioritizing exercise), assigning ownership and responsibility to a 'risk owner', responding to the risk with some contingency plans, and monitoring of the risk.

The objective of this exercise is to apply the concepts of risk measures and to understand the importance of record-keeping in the risk management process.

During the group case study activity, the following key topics will be discussed:

- Measure: The extent to which uncertainties in data and analyses can be measured and expressed in highly quantitative terms depends upon the types of investigations used to develop scientific knowledge.
- Uncertainties in data and analyses can enter the risk assessment process at every step; the sources of the largest uncertainties include the use of observational studies, extrapolation from studies in animals to humans, extrapolation from high- to low-dose exposures.

Risk measures and record keeping go hand in hand. Risk measures and record-keeping are fundamental activities in the ERA process. Consideration for the following questions to be discussed:

1. What can go wrong?

2. How will it affect the objectives / the project? Consider the probability of the event and whether it will have a large or small/limited impact.

3. What can be done? What steps can be taken to prevent the loss? What can be done to recover and /or compensate if a loss does occur?

4. If something happens, how will stakeholders pay for it?

5.4. Socio-economic and co-innovation aspects

Module Description

Implications of ERA GMPs Non-technical aspects of ERA of GM plants

Key concepts, information and messages for this module

It's important to take into account national, regional and local policy frame of GM plants ERA.

Economic aspects (field, farm, commodity chain) of GM plant adoption for cultivation should also be considered.

Understanding what are the key stakeholders in GM plants ERA is of paramount importance as well, taking into account possible conflicts of interest and protection goals.

Understanding the role of co-innovation and participatory solutions is crucial for future actions.

TOPIC 6: ERA AND OFFICIAL CONTROLS

6.1. Participants contribution on official controls

Module Description

Debate on official controls best practices at the primary production level in the Member States

6.2. Official controls and management of environmental risk of GMPs

Module Description

- Best practices for official controls on primary production;
- Use of guides to good practice and implications for official controls;
- Sampling methods and other specialised inspection procedures;
- Analytical results.

Key concepts, information and messages for this module

Controls may consist of audits, inspections, sampling, and testing. GMO testing for the purpose of official controls is carried out using validated methods of detection.

Commission Recommendation 2004/787/EC provides guidance for sampling and detection of GMOs and materials produced from GMOs. For sampling of feed, Regulation (EC) 152/2009 applies. In a report from 2013, the conclusion of the Overview report states the following:

"Most GMO controls are adequately planned and prioritised in line with the EU legislation. However,

in some cases regarding food and feed, the controls did not adequately take into account the associated risks. This reduced the overall effectiveness of the control system in place"1. This is an important point because it clearly raise the issue of adequacy and conflicting views in the assessment of risks, which needs to be discussed.

6.3. Audit activities

Module Description

- Preparation (research, desk review, risk-based targeting, checklist development, etc.);
- Performing the audit, collection of audit evidence, drawing findings and conclusions; and making recommendations (relationship between these steps in the process).
- Reporting on the audit and follow-up.

Key concepts, information and messages for this module

The objective of an audit in the context of GMPs is to evaluate the systems of official controls for food and feed, seed and propagating material containing, consisting of, or produced from GMOs including their deliberate release into the environment.

Audits are carried out under Article 45 of Regulation (EC) No 882/2004.

The legal interpretation of the Commission confirmed that Directive 2001/18/EC should be considered as part of the rules, the control of which falls under the scope of Regulation (EC) No 882/2004.

Based on the EFSA "Guidance on the environmental risk assessment of genetically modified plants" (2010) ERA should be carried out on a step by step approach following 6 fundamental steps (Directive 2001/18/EC): hazard identification, hazard characterization, exposure characterization, risk characterization, risk management strategies, and overall risk evaluation.

6.4. – 6.5. Case study on ERA and management

Module Description

Teamwork and plenary discussion wrapping up all the contents of Topic 6.

[1] OVERVIEW REPORT OF A SERIES OF AUDITS CARRIED OUT IN MEMBER STATES BETWEEN 2011 AND 2013 TO ASSESS THE OFFICIAL CONTROLS OF GENETICALLY MODIFIED ORGANISMS INCLUDING THEIR DELIBERATE RELEASE INTO THE ENVIRONMENT