ENVIRONMENTAL RISK ASSESSMENT IN THE DOSSIER OF I&P APPLICATIONS

Meeting with applicants, 5 October 2023

EUROPEAN FOOD SAFETY AUTHORITY

BACKGROUND

- ERA needs to follow EFSA Guidance on the ERA of GM plants (2010), which covers APs with a scope for cultivation but also for import and processing
- No APs for cultivation submitted since 2012

BACKGROUND

ASSESSMENT

1. Introduction

This document provides guidance for the ERA of GM plants submitted within the framework of Regulation (EC) No. 1829/2003 on GM food and feed (EC, 2003) or under Directive 2001/18/EC on the deliberate release into the environment of GMOs (EC, 2001). It covers the ERA in case of cultivation of GM plants and in case of import of food and feed containing or consisting of GM plants or produced from GM plants. The document provides in particular guidance on drawing up of information to supplement Annex III B of Directive 2001/18/EC, on the preparation of the conclusion of the ERA as described in Annex II of that Directive and on the set up of a post-market environmental monitoring plan according to Annex VII thereof.

SCOPE OF THE PRESENTATION

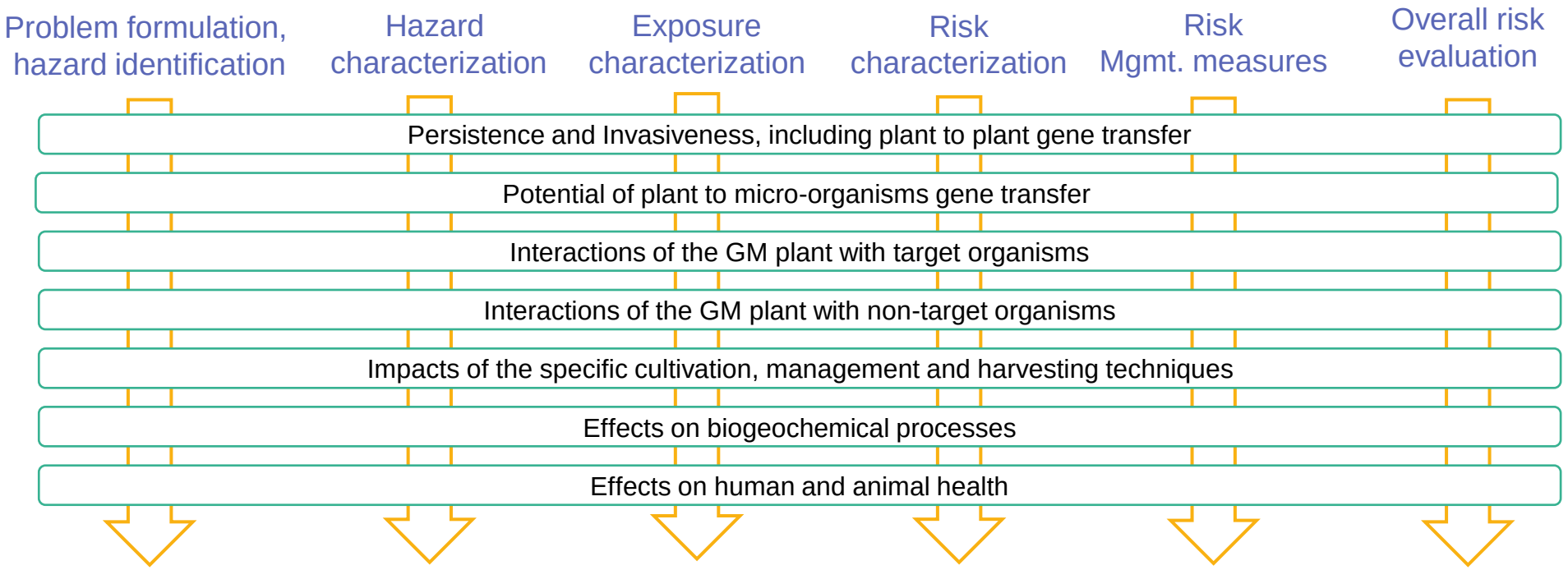
Over the last years we have assessed the ERA section of the dossiers of different APs following the requirements outlined in EFSA Guidance for the ERA of GM Plants (2010)

Also considering APs from new applicants, who present different ERA compared to those prepared by applicants that acquired more experience over the years.

The aim of the presentation is to “refresh” about ERA requirements outlined in the EFSA Guidance of 2010, which need to address the relevant areas of concern and follow the problem formulation approach. No change to the current guidance/requirements is proposed

GOALS OF THE PRESENTATION

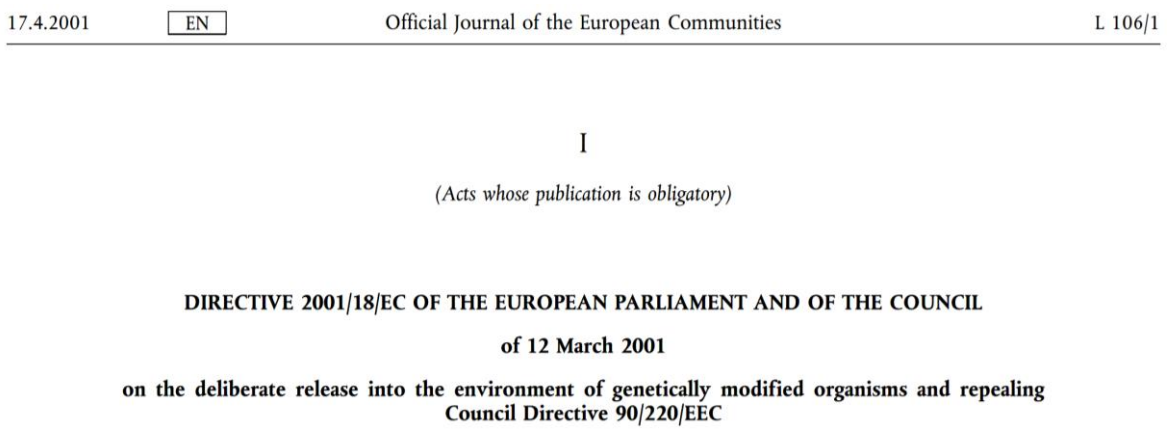
1. The ERA should be performed in agreement with the principles laid down and the steps described in EFSA's Guidance (2010), and cover the relevant areas of concern



2. Streamline the assessment of the ERA section of dossiers, which will help reduce the overall assessment time

LEGISLATIVE FRAMEWORK

- Environmental risk assessments should be done as requested in Directive 2001/18/EC, amended by Commission Directive (EU) 2018/350 as regards the ERA of GMOs
- If the applicant refers to the Directive, the amended Directive 2018/350 should be cited



17.4.2001 EN Official Journal of the European Communities L 106/1

I

(Acts whose publication is obligatory)

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

L 67/30 EN Official Journal of the European Union 9.3.2018

DIRECTIVES

COMMISSION DIRECTIVE (EU) 2018/350

of 8 March 2018

amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms

STRATEGIES FOR THE ERA OF GM PLANTS

1. Comparative assessment approach

- ERA should be based on the results of the comparative assessment, and feed on information provided by the:
  - Molecular characterization
  - Compositional analysis
  - Agronomic and phenotypical characteristics
  - Interactions GM plant-receiving environments (biotic and abiotic)
- The results of the comparison with its comparator should be summarized in the ERA, and structure it.

STRATEGIES FOR THE ERA OF GM PLANTS

2. Identification of **pathways of exposure**

- Should be clearly identified in the Problem Formulation
- Should be consistent across different ERA sections, with scope of the AP and with type of GM material that aims to be imported
- General pathways of exposure for APs not including cultivation:

"In the case where the use of GM plant does not include cultivation in the EU, the problem formulation will consider exposure (1) via the accidental release into the environment of propagules, such as seeds, of the GM plant during transportation and processing potentially leading to sporadic feral GM plants and (2) indirect exposure, for example, through manure and faeces from the gastrointestinal tracts mainly of animals fed the GM plant, and/or (3) organic plant matter either imported as a fertiliser or soil amendment or derived from other bioproducts of industrial processes."

(EFSA ERA GD, 2010)

STRATEGIES FOR THE ERA OF GM PLANTS

3. Problem formulation approach

- Should follow the structure outlined in the ERA Guidance for each area of concern:
  - Problem formulation including hazard identification
  - Hazard characterization
  - Exposure characterization
  - Risk characterization
  - Risk management measures
  - Overall risk evaluation
- The magnitude or likelihood of the harm should be quantified in a quantitative (favoured) or qualitative (from “negligible” to “high”, justification for categorization to be provided) fashion.

STRATEGIES FOR THE ERA OF GM PLANTS

3. Problem formulation step

- In each area of concern addressed in the ERA, the PF step should clearly define **specific**
  - Protection goals – based on the environmental protection goals legally as outlined in EU legislation (examples provided in Table 1 EFSA Scientific Opinion on Potential impacts of GM Plants on NTOs, 2010)
  - Assessment endpoints
  - Testable risk hypotheses
  - Measurement endpoints – they should be relevant to the scope of the AP (i.e. for I&P APs there is no point in indicating "degradation of GM material not harvested" as an assessment endpoint in the section on Effects on biogeochemical processes).
- This can be done in the form of tables, to facilitate the assessment

STRATEGIES FOR THE ERA OF GM PLANTS

- Example, for persistence and invasiveness:

Policy protection goals	Operational protection goals	Assessment endpoints	Test hypotheses	Measurement endpoints
Protection of sustainable agricultural production	The cultivation of the GM crop X in country Y should not result in worse agronomic problems in managed crop areas as a result of increased persistence of the GM crop compared with cultivation of non-GM varieties of this crop	Establishment and size of volunteer populations of the GM crop in the managed crop area causing harm to agricultural production in the next crop following the cultivation of the GM plant	The genetic modification has not resulted in potentially harmful changes to the agronomic or phenotypic characteristics of the donor crop that may lead to increased persistence in managed crop areas	Comparison of characters[a] indicative of persistence or invasiveness between the GM plant and a suitable comparator[c] (e.g. seed germination; plant establishment and vigour; time to flowering and maturity; plant height; pollen viability and pollen shed, etc.)
	The cultivation of the GM crop X in country Y should not result in agronomic problems in managed crop areas as a result of increased persistence of wild relatives of the GM plant that have acquired the GM trait	Establishment and size of populations of sexually compatible wild relatives that have acquired the GM trait in managed crop areas causing harm to agricultural production in the next crop following the cultivation of the GM plant	Introgression of the trait into sexually compatible wild relatives[b] has not resulted in potentially harmful changes to characteristics that may increase the invasiveness of the wild relatives in managed crop areas	Comparison of characters[a] indicative of persistence or invasiveness between the GM plant and a suitable comparator[c] (e.g. seed germination; plant establishment and vigour; time to flowering and maturity; plant height; pollen viability and pollen shed, etc.)

Extracted from:
García-Alonso and Raybould, 2014

STRATEGIES FOR THE ERA OF GM PLANTS

4. Uncertainties

- Uncertainties should be considered in each step of the ERA, so that they are quantified as much as possible for each of the areas of concern assessed and also in the overall risk evaluation
- Nature of uncertainties need to be described, and their magnitude quantified as much as possible

STRATEGIES FOR THE ERA OF GM PLANTS

5. ERA of stacked events

- Applicant should provide an ERA for each single transformation event or refer to already submitted notifications from them
- Special consideration needs to be given to potential interactions between the NEPs
  - Persistence and invasiveness: synergistic effects leading to enhanced P&I compared to the single events?
  - Interactions with target & NT organisms: do insecticidal NEPs have synergistic/antagonistic/ additive effects?

1. PERSISTENCE & INVASIVENESS

- This section should address both the persistence & invasiveness of both the GM plants and of their hybrid offspring with wild compatible relative.
- For APs for I&P and food and feed uses, the ERA on persistence and invasiveness is concerned mainly with the environmental consequences of accidental release of viable GM seeds or propagating material

1. PERSISTENCE & INVASIVENESS

- This section should follow the staged approach outlined in the Guidance (p. 41)
- **All GM plant APs should answer the questions of Stage 1**, including APs for I&P of viable propagating plant material.
  - Can GM plant overwinter under EU conditions and/or reproduce & hybridize with sexually compatible relatives that can overwinter
- Next stages needed for APs in which reply to Stage 1 is YES, will assess their ability to:
  - Stage 2: increase P&I of the GM plant (or hybrids with sexually-compatible relatives) within the production system and form feral populations in semi-natural habitats
  - Stage 3: alter fitness or range of feral plants or compatible relatives
  - Stage 4: increase population size of feral plants or compatible relatives

1. PERSISTENCE & INVASIVENESS

- Hazard characterization should provide species-specific information on:
  - Reproductive biology
  - Characteristics associated with weediness and invasiveness (e.g. seed dormancy, synchrony of flowering, propagule shattering, competitive ability)
  - Biotic and abiotic factors limiting persistence and invasiveness
  - Hybridization and introgression potential with any sympatric sexually compatible relatives: includes both cultivated & wild plants occurring in the EU (i.e. not only indigenous ones or species subject of protection)

2. HORIZONTAL GENE TRANSFER

- Align the assessment of the potential risk of HGT to the scope of the application
  - E.g. Persistence of GM plant material after harvesting is not a relevant measurement endpoint if the scope of the AP does not cover cultivation

3. INTERACTIONS WITH TARGET ORGANISMS

- Only relevant in cases of
  - GM plants with insecticidal or disease resistance traits
  - Scope of the AP includes cultivation

4. INTERACTIONS WITH NON-TARGET ORGANISMS

- References should be provided when statements made on the results of field or laboratory studies

5. IMPACTS OF THE SPECIFIC CULTIVATION, MANAGEMENT AND HARVESTING TECHNIQUES

- Not relevant for applications for import and processing

6. EFFECTS ON BIOGEOCHEMICAL PROCESSES

- Area of concern that always needs to be assessed, including APs that exclude cultivation from the scope
- Should consider exposure to products through manure/organic plant matter (imported, derived from faeces of animals fed imported GM plants, or derived from industrial processing)

7. EFFECTS ON HUMAN AND ANIMAL HEALTH

- Area of concern that always needs to be assessed
- Assessment focused on whether GM plant/products presents new hazard for people working with the GM plant, coming into contact with it or exposed to products such as pollen/dust from processed plants
- Also in this case a six-step PF approach required, including a conclusion

8. OVERALL RISK EVALUATION AND CONCLUSIONS

- There needs to be consistency with the conclusions reached for each of the areas of concern assessed and those listed in the overall risk evaluation
- It needs to include an assessment of overall uncertainty

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