ENSSER on 2010 EFSA guidance for ERA of GMPs

European Network of Scientists for Social and Environmental Responsibility

- Guidance for environmental risk assessment (ERA) of genetically modified plants (GMPs) is a quantum-leap forward, real progress in terms of scientific rigorosity, quality, and for environmental safety
- Recognising calls from scientists for such improvements were finally heard – rewarding, confidence building and for the greater good to the European people

Criteria for field trials in receiving environment

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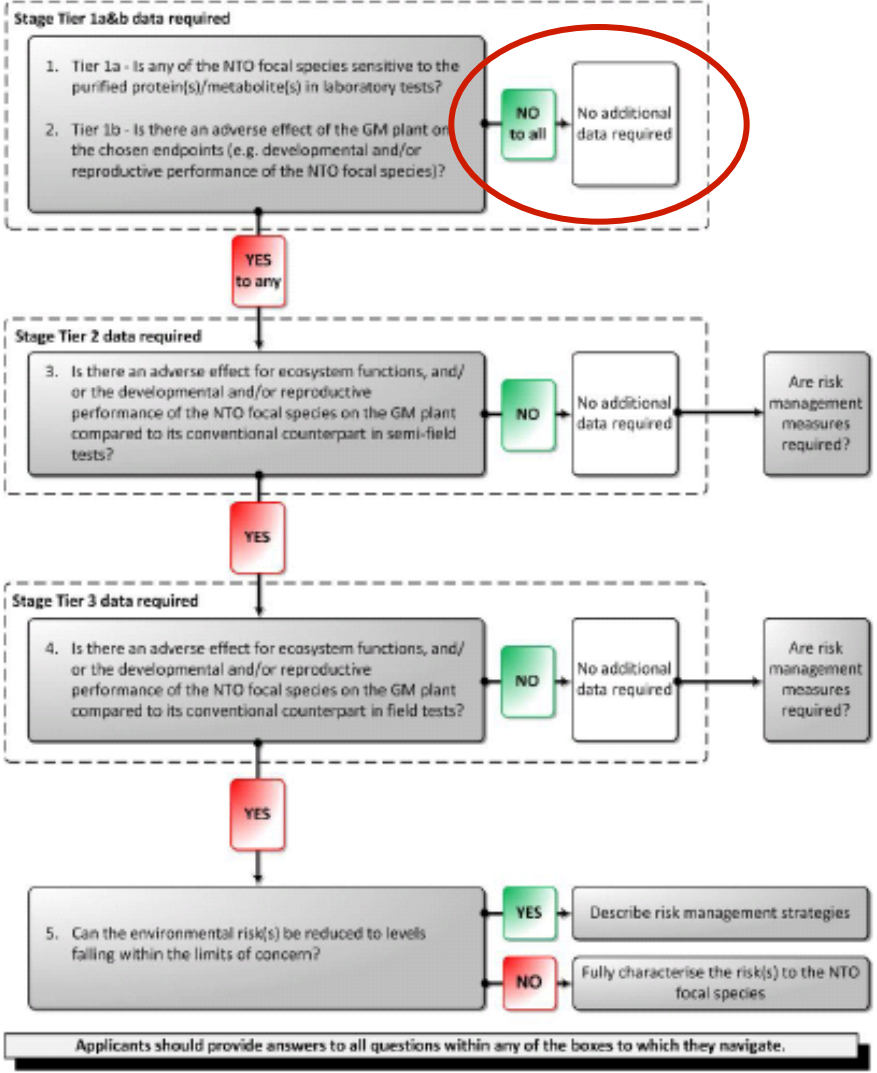
- Guidance recognises importance of field trials
- Guidance provides criteria on practical set-up, representativeness, statistical analysis
- Tiered approach for non-target organisms (NTO) is not appropriate for approval for cultivation

➢ Mandatory field trials on NTO effects, laboratory studies alone are not sufficient


Stage Tier 1a&b data required
1. Tier 1a - Is any of the NTO focal species sensitive to the purified protein(s)/metabolite(s) in laboratory tests?
2. Tier 1b - Is there an adverse effect of the GM plant on the chosen endpoints (e.g. developmental and/or reproductive performance of the NTO focal species)?
NO to all
No additional data required
YES to any
Stage Tier 2 data required
3. Is there an adverse effect for ecosystem functions, and/or the developmental and/or reproductive performance of the NTO focal species on the GM plant compared to its conventional counterpart in semi-field tests?
NO
No additional data required
Are risk management measures required?
YES
Stage Tier 3 data required
4. Is there an adverse effect for ecosystem functions, and/or the developmental and/or reproductive performance of the NTO focal species on the GM plant compared to its conventional counterpart in field tests?
NO
No additional data required
Are risk management measures required?
YES
5. Can the environmental risk(s) be reduced to levels falling within the limits of concern?
YES
Describe risk management strategies
NO
Fully characterise the risk(s) to the NTO focal species
Applicants should provide answers to all questions within any of the boxes to which they navigate.

Chapter 2.1: Comparative safety assessment as a general principle for the risk assessment of GM plants

Concerns: on Chapter 2.1

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- EFSA introduces „comparative safety assessment“ as „general principle“ in a legally binding EU document on ERA
- „Comparative safety assessement“ is a new expression for the concept of substantial equivalence
- Used and criticised in the context of GM food safety assessment
- Not accepted as useful approach in ERA

In contradiction with:

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Regulation 1829/2003: „Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, **it is not a safety assessment in itself**."

Codex GL 45-2003: "The concept of substantial equivalence is a key step in the safety assessment process. However, **it is not a safety assessment in itself**; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart."

In contradiction with Directive 2001/18 EC

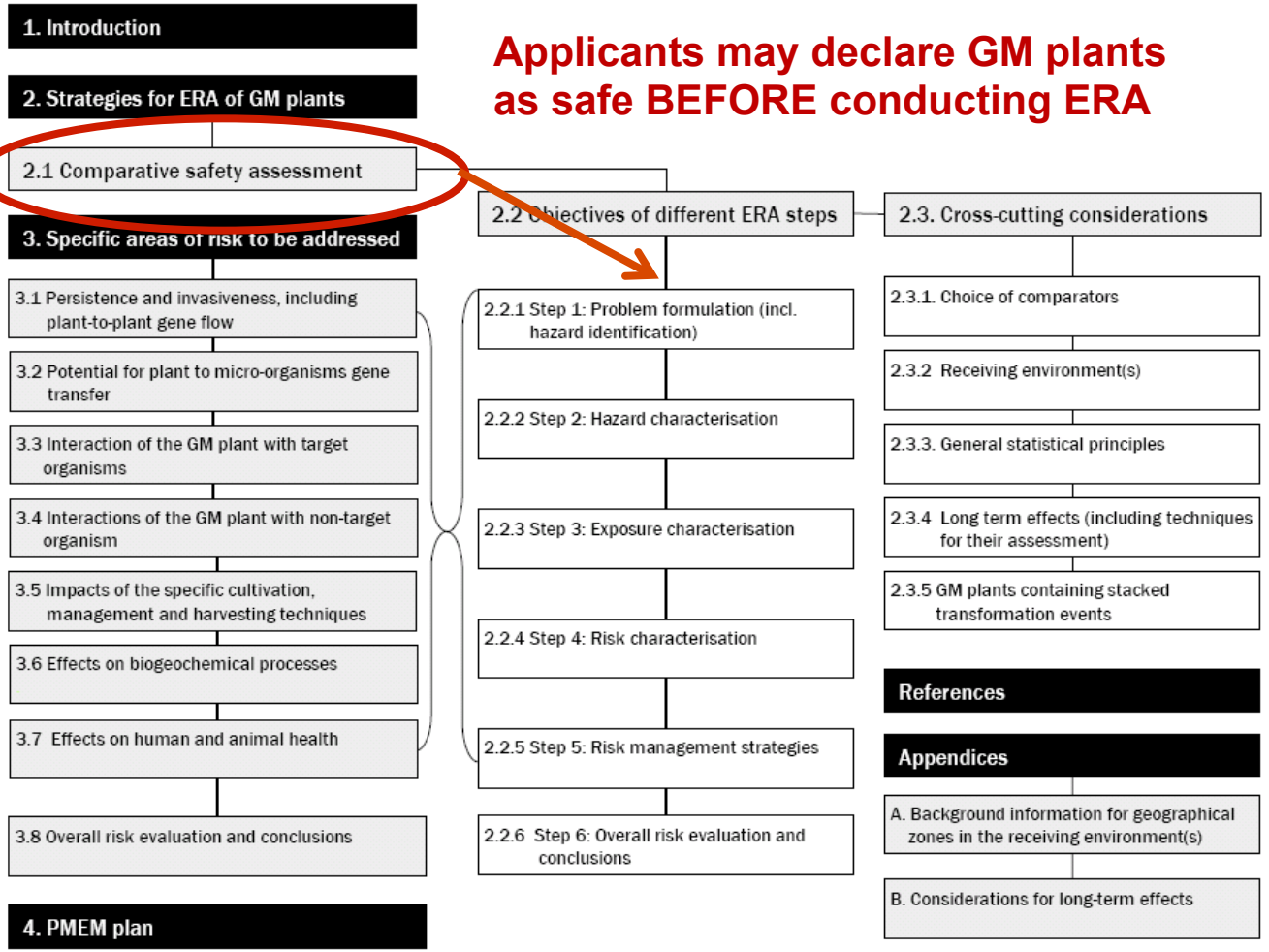
5 general principles working in accordance with the precautionary principle as basis for ERA:

- analysis of the ‘cumulative long-term effects’
- comparison of GMO with parental organisms
- scientifically sound and transparent manner
- case by case basis
- readdress ERA when new information becomes available

EFSA's Principles

1. tiered approach
   analysis of the cumulative long-term effects'
2. comparative approach
   comparison of GMO with parental organisms
3. scientifically sound and transparent manner
4. case by case basis
5. concept of familiarity
   consideration when new information becomes available

Applicants may declare GM plants as safe BEFORE conducting ERA



Elements of comparative safety assessment

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- Determination of the **consistency** of the observed differences;
- Determination of the **non-transient nature** of the observed differences;
- Determination of the **biological relevance** of the observed differences
- Observed statistically significant unintended effects will only be included in ERA when passing all three tests

Biological relevance decided by Concept of Familiarity

- Differences between GM plant and parents compared with range of differences between other comparators
- None of the criteria are defined or described
- Concept of Familiarity only proposed for ERA by OECD in 1993
- Rejected in negotiations on Cartagena Protocol in 1998
- Not taken up in Directive 2001/18

ENSSER recommendations

- Deletion of Chapter 2.1 and abandonment of concept of „comparative safety assessment“ and concept of familiarity
- Strict application of the 2001/18 general principle „comparison of GMO with parental organisms” in ERA
- Establishment of scientific criteria to interprete statistically significant differences in unintended effects

2016 Amendment of the EU Directive 2001/18 on ERA

ANNEX to Commission Directive (EU) ../.. of XXX amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms

3. Data: To carry out an e.r.a. the notifier shall generate the necessary data. Where applicable, data already available from scientific literature may be used.

Requirements for toxicological data in ERA

(b) Toxicological studies carried out to assess risk(s) to human or animal health shall be conducted in facilities which comply with the:

(i) requirements of Directive 2004/10/EC; or

(ii) 'OECD Principles on Good Laboratory Practice' (GLP), if carried out outside the Union.

Requirements for environmental data in ERA

(c) Studies other than toxicological studies shall:

(i) comply with the principles of Good Laboratory Practice (GLP) laid down in Directive 2004/10/EC; or

(ii) be conducted by organisations accredited under the relevant ISO standard.

ENSSER conclusions

- 2010 Guidance on ERA for GMPs remained unchanged
- Applicants can circumvent ERA by using the concept of familiarity
- 2010 Guidance uses obsolete concepts contradicting the legal framework to facilitate GMP application procedure

ENSSER conclusions

- Standard of Good Laboratory Practice is NOT a scientific standard BUT a technical standard for documentation of procedures in commercial research
- Public organisations are not GLP-certified
- If an ERA would take place at all, the use of data from public science would be prohibited from being recognised in ERA
- EU GMO legislation abandons itself