EuropaBio™

The European Association for Bioindustries

Draft Agronomic and Phenotypic Characterisation of Genetically Modified Plants

Safety of GM Crops

- *The comparative assessment aims to identify similarities and differences (intended or unintended) between the GM product and its conventional counterpart, evaluate their biological relevance and potential impact on the safety of the product* (Codex Guidelines)

- *The assessment of unintended effects takes into account the agro-pheno characteristics of the plant which are typically observed by breeders in selecting new varieties for commercialisation* (Codex Guidelines)

- The agro-pheno characteristics of GM crops have been under observation for more than 15 years and millions of hectares worldwide. **No** adverse effects have been observed in terms of food/feed/environmental safety.

- Numerous agro-pheno datasets have been assessed by EFSA and other global regulatory agencies concluding **no** adverse effect on the safety of GM crops and contributing to their history of safe use

EFSA Agro-Pheno Draft Guidance

- *ad hoc* EuropaBio Working Group to assess EFSA's draft Agro-Pheno Guidance
- EFSA's draft guidance as it stands now is for some issues **overly prescriptive** and deviates from what is globally regarded as acceptable and further expands the existing requirements, whereas for others is too **open-ended.**
- In terms of risk assessment, there is **a clear distinction** between a product to be imported into the EU and a product to be cultivated. Therefore, it is reasonable to have **two separate sections** on the generation of agro-pheno characteristics in support to 1) import dossiers and 2) cultivation dossiers.
- To avoid the creation of duplicative or conflicting requirements, any references to, or new requirements for, composition, expression analysis and ERA are not recommended in an agro-pheno guidance document.
- We propose performing a **science-based, case-by-case, hypothesis-driven risk assessment**, without increasing data requirements which are not likely to improve the quality of the risk assessment.

Outline: Comments on Draft Guidance

- Purpose of collecting agro-pheno data
- Representativeness of sites/materials
- Seed quality requirements
- Field trials design and documentation
- Agronomic and phenotypic endpoints
- Relevance for the ERA
- Implementation

Purpose of agro-pheno data

- Focus on the *"agronomic and phenotypic characterisation of GM plants"* ➔ should be considered only in the context of risk assessment

- Relevance of agro-pheno data for the food/feed safety assessment?

- Relevance for extensive list of mandatory endpoints for both import and cultivation applications?

Representativeness of sites/materials is hard to implement

- **An extreme emphasis on site representativeness is not scientifically substantiated** due to its lack of relevance for the comparative analysis and the food/feed safety risk assessment of GM products.

- **Literal interpretation of the draft guidance for site representativeness is not feasible to implement** - there is no need and no possibility to represent all combinations of environmental factors. Furthermore, some of the factors defining an environment cannot be reliably predicted in advance.

- The **representativeness and suitability of conventional non-GM reference varieties** is questionable in regions where GM cultivation is > 90% like soybean in Argentina, Brazil and US.
  - ➔ Propose to EFSA to accept approved GM varieties (with a history of safe use) as references for agro-pheno trials (which will be in line with other regulatory authorities).
  - ➔ As breeding advancements continue, refusal to allow inclusion of GM varieties will result in an increasing number of analyses falling outside of EFSA's I-VII categorization system.

Seed quality requirements

- What is the scientific relevance of assessing **the adventitious presence (AP) of a GM plant** for any agro-pheno characterisation?
  - Example: No impact of 1 GM plant among 200 plants (which represents 0.5% AP) on the flowering time
- It is not possible to guarantee that the comparator and reference varieties are totally free from AP
- **Re-testing quality of commercial seeds** (reference varieties) is not allowed in some countries (*e.g.* US)
- Proposal for tolerance of low level AP for all tested material and acceptance of official seed certificates for commercial lines to avoid breaching the law

Field trials design and documentation

- What is the relevance of **extensive and academic agro-meteorological characterisation** of the field trials for the risk assessment?
  - ➔ Would require the establishment of local stations and their protection.
- Larger field experiments would be needed without sound justification
  - ➔ The draft document suggests that applications may be rejected if there are data from less than 4 replicates per site due to occasional missing replicates or even missing individual plots.
  - ➔ No justification is provided for suggesting a minimum plot size of 25 m^2 independently of the crop and the GM trait. Field trials are performed at the beginning of the product development process, hence the seed availability is limited.
  - ➔ Could lead to delaying the field trials for compiling the EU dataset

Agronomic and phenotypic endpoints

- Some mandatory endpoints are neither currently assessed by other regulatory authorities, nor used in typical agronomic experimentation in contradiction of the Codex Guidelines:
  - *e.g.* number of fruits and seeds per fruit should only be requested through problem formulation;

- Most endpoints test hypotheses that are part of implausible pathways to harm

- The measurements of agro-pheno endpoints are overly prescriptive (*e.g.,* measuring grain moisture using moisture meters) and some might not take current field practices into consideration (*e.g.,* seed loss after harvest largely depends on the harvester)

Relevance for ERA

- The value of agro-pheno trials for most of the ERA's objectives is dissmissed without reasonable justification

- **Distinction between import and cultivation** applications is a fundamental first step

- The proposed **decision tree** increases duplication. The SD+ and SD++ data requirements only enumerate the number of potential studies that could be performed, but it is not clear how these studies contribute to the ERA

In the absence of pre-submission meetings these requirements only increase the uncertainty for applicants

Concluding remarks

- Unclear value of the additional requirements for the comparative assessment, and thus also for the risk assessment of GM plants.
- The added requirements contribute to **uncertainty** with regard to the design and acceptance of the experiments and there is **an increasing likelihood** that the actions undertaken by applicants to comply with the guidance will not be considered sufficient at the submission stage.
- Some additional requirements are **not feasible** to comply with.

Implementation

- Need for a **standard procedure for clear and timely communication** of new requirements to the applicants
- Need for **sufficient and realistic transition periods** before attaining mandatory compliance with the requirements set out in new guidance documents
- EFSA guidance should not be applied retroactively
- Need to justify the **relevance for risk assessment**

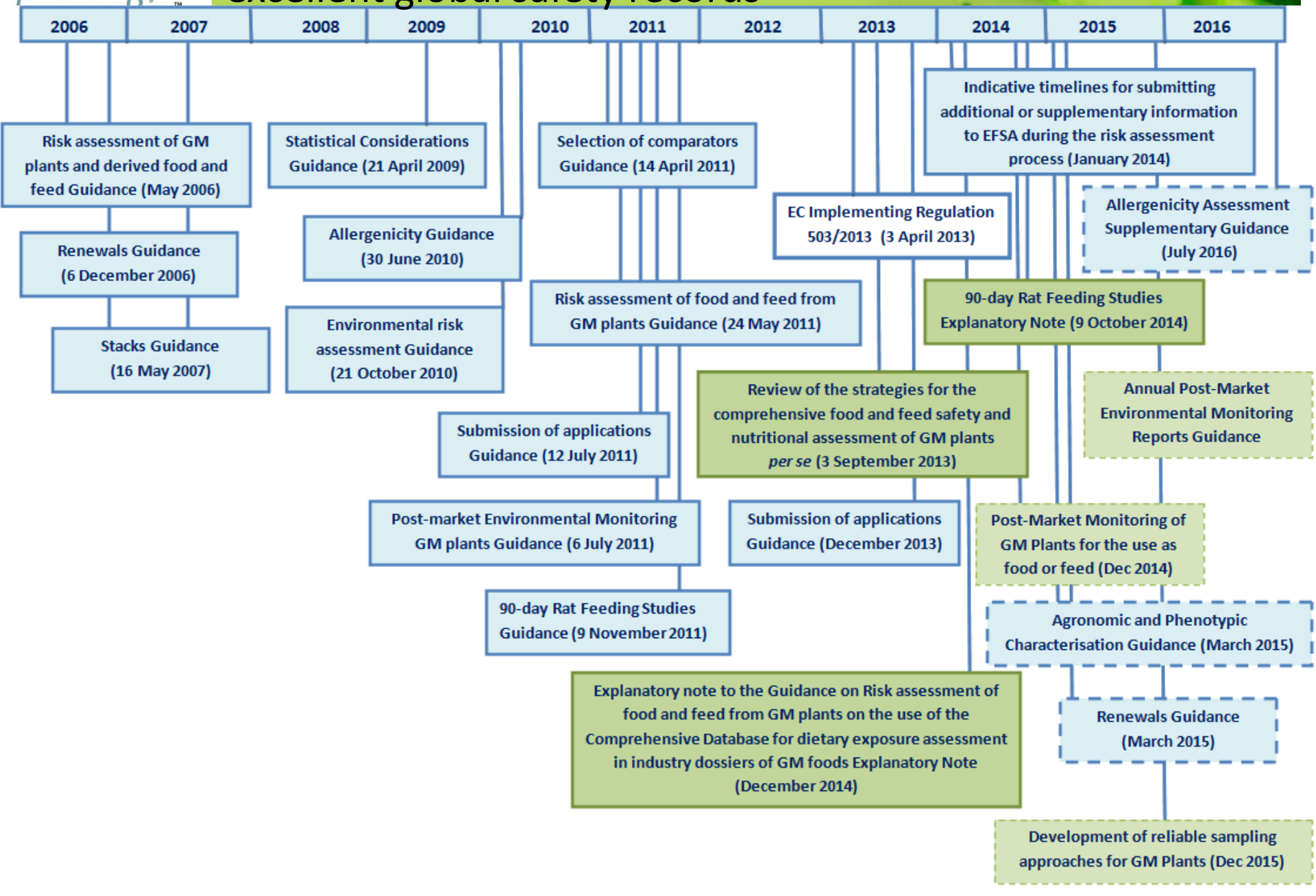
(hazard x exposure)

More specifically, …

- **Need for maintaining the validity of previous agro-pheno data**
- **Need for acceptance of studies**

Field trials are planned years ahead of the date of submission of a new application.

Exponential increase in requirements in the EU despite excellent global safety records



Thank you!

Additional information

Background

Timelines

- 19 July 2013 – self-mandate of the EFSA GMO Unit
- 25 September 2014 – draft guidance for public consultation
- Until 6 November 2014 – submission of comments
- 18-19 December 2014 - technical meeting with stakeholders for discussion of the comments received during the public consultation

Objective

- assist the applicants in the generation, analysis and interpretation of the agronomic and phenotypic dataset submitted as part of the applications for authorisation of GM products
- harmonisation of the endpoints to be measured in the comparative assessment