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Options to Reform the European Union Legislation on GMOs: Risk Governance

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Here, we discuss options to reform the EU genetically modified organism (GMO) regulatory framework, to make risk assessment and decision-making more consistent with scientific principles, and to lay the groundwork for international coherence. We discussed the scope and definitions in a previous article and, thus, here we focus on the procedures for risk assessment and risk management.

In a series of three articles in *Trends in Biotechnology*, we propose various details that may be reformed within the legislative framework for GMOs in the EU. In the first of our articles, we discussed the scope and definitions involved [1], whereas, here, we focus on the procedures for risk assessment and risk management (Figure 1).

Reforming Risk Assessment

Case-by-Case Approach

When the GMO regulatory framework was developed three decades ago, a case-by-case risk assessment approach was established, allowing for a simplified assessment procedure after sufficient experience had been obtained with a particular product or trait. This principle was retained in Directive 2001/18/EC (Article 7), but it has not been much applied in practice [2]. The risk assessment guidelines of the European Food Safety Authority (EFSA) have become increasingly detailed and also partly transposed into stricter law by Regulation (EU) No 503/2013 and Directive (EU) 2018/350. This has made the EU GMO risk assessment procedure increasingly static up to a point that it has become too cumbersome to cope with technological and scientific developments [3]. Therefore, we suggest that the annexes of Directive 2001/18/EC and Regulation (EU) No 503/2013 and Directive (EU) 2018/350 should be transformed into implementing acts, which would make them amendable by a comitology procedure (i.e., the set of procedures through which EU member states control how the EC implements EU law). This would enable the application of risk assessment requirements that are more tailored to assessing the actual risks of the respective products based on scientific developments.

Animal Feeding Studies

Regulation (EU) No 503/2013 requires an obligatory 90-day feeding study with whole food/feed for most submitted GMO dossiers. The added scientific value of animal feeding studies without a targeted hypothesis is very limited. Such feeding studies provide few valuable additional scientific insights, as demonstrated by a significant number of subchronic toxicity studies with whole GM food/feed as well as the outcome of the two EU-funded projects, GRACE [4] and G-TwYST[i]. Concerns justifying such studies can arise in the GMO risk assessment process, which includes molecular characterization, phenotypic, agronomic, and compositional analysis of the GM line in relation to its conventional counterpart and other non-GM lines (reference lines) as well as evaluating potential adverse effects of all the identified intended and potential unintended differences. In cases where a plausible concern is identified, studies relevant for that particular concern should be performed. This does not necessarily need to be an animal feeding study. Limiting the obligation to conduct feeding studies to products where they matter would be more compatible with the principles of Replacement, Reduction and Refinement (3R) of animal feeding trials, a requirement under EU law (see e.g., Article 4 of Directive 2010/63/EU on the protection of animals used for scientific purposes).

Environmental Risk Assessment

We propose to develop tangible regulatory goals within environmental risk assessment (ERA). These goals should ensure a high level of environmental protection. The recent amendment of the directive on ERA of GMOs [Directive (EU) 2018/350], which adds a problem formulation step including the identification of relevant assessment endpoints and the formulation of testable risk hypotheses, is testimony that the legislator shares our assessment. However, we would welcome further clarifications of the terminology of environmental harm, which should be independent of the nature of the regulated product, its characteristics, and potential use. While we appreciate the use of broad-based principles, such as protecting biodiversity, as policy objectives to allow for sufficient room for adapting to specific technologies, these principles need to be made workable in practice. Hence, further specifications in the form of operational protection goals [5–7] are necessary. In terms of the substance, these specifications may refer to the abundance of a particular species or an ecological function, and should also specify pertinent locations, time periods, and tolerated maximum impacts. Care must be taken to select the most appropriate endpoints for the assessment. Based on such specifications of relevant

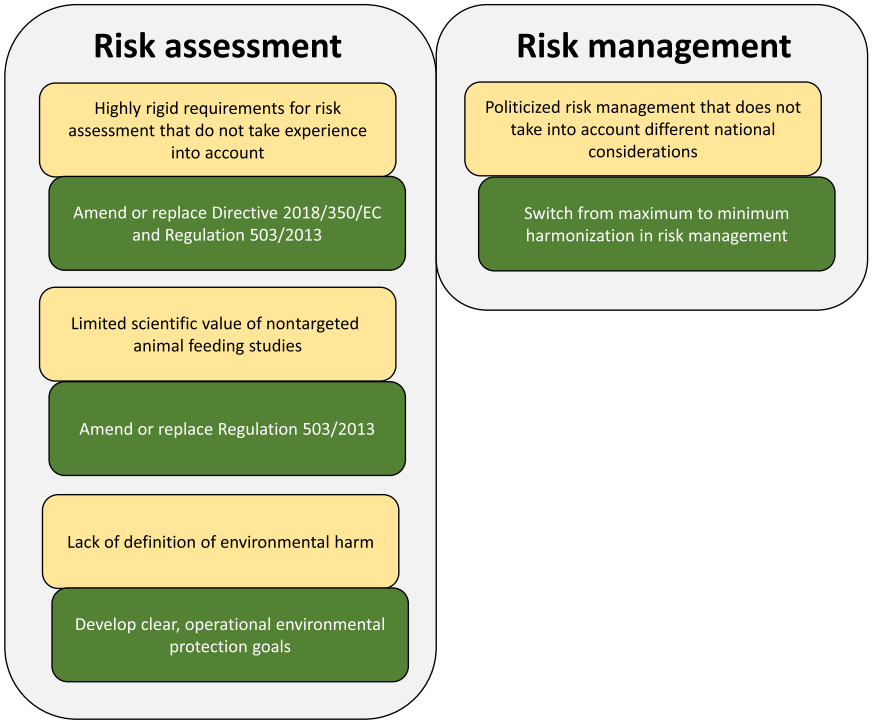

Figure 1. Reform Options for the Legislative Framework for Genetically Modified Organisms in the European Union, Concerning the Risk Assessment and Risk Management. Yellow boxes detail the problematic issues identified with the regulatory framework, whereas green boxes show the suggested potential solutions.

endpoints, risk hypotheses can be formulated for testing during the analytical phase of the ERA.

Reforming Risk Management

Strengthening Risk Management at the National Level

Despite favorable risk assessments by EFSA, a qualified majority is almost never reached in the Regulatory Committee for Directive 2001/18/EC or the Standing Committee on Plants, Animals, Food and Feed – Section Genetically Modified Food and Feed, or in the subsequent Appeal Committee for any GM product under consideration [8]. The requirement of a qualified majority is in line with the general principle that, due to the potential cross-border effect of GMO release (see Recital 4 of the Directive 2001/18/EC), risk management measures need to be decided jointly at the EU level. However, particularly with the widening of the EU, this system is also increasingly under pressure because it may not account for the socioeconomic differences in farming and consumption structures in the 28 Member States [9]. The Directive (EU) 2015/412 (the 'opt-out directive'), which allows EU Member States to prohibit the cultivation on their own territory of GM plants that have EU-wide authorization, was a first attempt to account for these differences. However, it would only be effective if Member State voting behavior changes (i.e., that states that reject the use of GM products do not block other countries from deploying the technology). This change has not yet materialized. To properly account for the differences in the EU, we propose a switch in harmonization strategy from maximum harmonization to minimum harmonization in risk management: while risk assessment remains fully harmonized at the EU level, risk management decisions would be transferred, at least in part, back to the Member States. One possibility for Member States is then to judge the test outcomes in relation to what is regarded as acceptable for alternative (existing) agricultural practices and, thus, balance potential risks against potential benefits [10]. Such a system of 'incomplete centralization' would resemble the default in EU law concerning risk regulation, which is, for example, prominently realized in EU food law, where risk assessment is with EFSA and risk management is (with exceptions) with Member States [11]. Ultimately, this would also mean the end of an EU-wide authorization of GM products for cultivation, because the last decision for the release into the environment would remain with Member States (overseen by the Commission). We assume that, when realizing this proposal, criticism with EFSA-led risk assessment will be taken up. To not circumvent potential harmonization efforts and constitutional requirements that may stem from Article 114 (4) TFEU (also in analogous reading) or the precautionary principle, any of such authorizations would need to be notified to the Commission, which could then reject such authorizations.

As an alternative, a 'middle-way' approach in the form of an 'opt-in' procedure has been suggested [12]. In one scenario, this would keep the current fully harmonized risk management procedure, but allow the individual Member States to 'opt in' to the cultivation of GM plants whenever the committee voting procedure fails (i.e., when a qualified majority is not reached) [13].

The suggested minimum harmonization procedure for risk management would keep a level of harmonized risk

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governance in the EU, realize the subsidiarity principle as strengthened by the Lisbon Treaty[ii], and focus on regulating issues where there is consensus across the EU. Therefore, we propose that the EC initiates an investigation of this model. The approach towards coexistence policies in the EU may serve as an example.

In the third of our articles [14], we present certain reform details regarding the postauthorization requirements as well as discuss the current political landscape in the EU and whether any regulatory reform is currently feasible.

Author Contributions

D.E. took the initiative and prepared the first draft of the manuscript. All other co-authors each contributed a section to the manuscript and were involved in finalizing the manuscript.

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[i]www.g-twyst.eu/files/Conclusions-Recommendations/G-TwYSTandGRACEPolicyBrief-Def.pdf

[ii]www.europarl.europa.eu/factsheets/en/sheet/5/the-treaty-of-lisbon

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Geneva Statement on Heritable Human Genome Editing: The Need for Course Correction

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As public interest advocates, policy experts, bioethicists, and scientists, we call for a course correction in public discussions about heritable human genome editing. Clarifying misrepresentations, centering societal consequences and concerns, and fostering public empowerment will support robust, global public engagement and meaningful deliberation about altering the genes of future generations.

Heritable Human Genome Editing: Nearing a Critical Juncture

The impending decision about whether to develop and use heritable human genome