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DISCUSSION PIECE

Structured analysis of broader GMO impacts inspired by technology assessment to inform policy decisions

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Abstract
If genetically modified organisms (GMOs) are approved in the EU for experimental release or marketing authorization (placing on the market), a risk assessment (RA) is carried out beforehand to determine whether this may be associated with negative effects on human health, nature or the environment. Applications are reviewed by the European Food Safety Authority (EFSA) and the national Competent Authorities of the Member States. However, the potential ramifications of the GMOs that are systematically addressed in the current RA context are limited. Broader consideration can include environmental and health aspects beyond the scope of the statutory RA, as well as societal, ethical and cultural impacts. These other levels of impact may be considered during the comitology process of authorisation, but how this is done is typically not made explicit in a systematic way. However, with the dynamic developments of new kinds of GMOs, these considerations as well as transparency regarding the role of broader considerations in political decision-making become more and more relevant. Against this backdrop, we identified the requirements and suggest the main elements for such a broader assessment. We use insights from the field of Technology Assessment (TA) to explore the requirements for operationalising a rapid but still systematic, transparent and broad case-by-case GMO assessment compatible with the existing legislative framework.

Keywords GMO · Genome editing · Technology assessment · GMO regulation · Ethical aspects · Societal issues

Introduction

Genetic engineering technology is undergoing rapid transformations, ranging from the speed and depth of intervention to the diversity of new applications. At the same time, the pace of research and development might pose challenges to understanding the possible impacts on biodiversity and human health (CBD/AHTEG on Synthetic Biology 2019), which could include direct impacts and broader aspects such as socio-economic (SE) effects. Under the current EU regulatory framework, a risk assessment (RA) is required for the market authorisation of GMOs to identify risks to human health and the environment. In parallel, Member States may consider impacts in their decisions beyond those covered by statutory RA.

The need to consider broader aspects of the use and release of GMOs has been acknowledged internationally by the Convention on Biological Diversity (CBD) and at the EU and national levels. Norway, which is not an EU Member State but a European Economic Area (EEA) member, has the longest experience with a broader assessment (BA). In the Norwegian regulation, besides safety assessment, societal utility, contribution to sustainable development and ethical aspects need to be considered in marketing applications of the use and release of GMOs (Myskja and Myhr 2020).

Meanwhile, a BA based on sound methodology is becoming more relevant since the range of new types of GMOs has increased substantially in recent years due to scientific progress and technological transformations such as genome editing technologies like the CRISPR-Cas systems. These new GMOs target a wider range of species that can also

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have new features, such as RNAi or gene drives. The latter represents an excellent example of the transformational change in this sector since, for the first time, these GMOs are *intended* to spread within wild populations (Simon et al. 2018; Giese 2021; Federal Agency for Nature Conservation 2022). Several countries are in the process to revise their current legislative frameworks (Turnbull et al. 2021) by introducing a tiered system depending on the genetic change introduced. In addition, new challenges arise, like gene drives that could, for example, spread into indigenous people and local communities (IPLC) territories without their free, prior, and informed consent. However, from the beginning, concerns regarding GMOs were not only their unintended side effects. They also included contentious consequences of the GMO trait and its *intended* impact on the target system. In such cases, the controversies are often related to diverging conceptions of what agricultural practices are considered desirable (e.g., Sauter and Meyer 2000).

A well-known example is crop-trait herbicide tolerance which promotes monocultures with intensive use of complementary herbicides, which can, in turn, lead to herbicide tolerance in weeds due to intensive herbicide use (Schütte et al. 2017) or to the spread of the trait to weed relatives (Bonny 2016). At the same time, environmental, cultural, socio-economic, and ethical considerations have also been discussed since the advent of GMOs and are still open and remain pertinent in authorisation processes (see, for example, Bain et al. 2020; de Graeff et al. 2019; Hartley et al. 2023; Helliwell et al. 2019; Kjeldaas et al. 2021; Lassen 2018; Lindberg et al. 2023). However, they are not assessed systematically nor transparently in the authorisation process. So far, a suitable methodological basis has not been established for a structured and more comprehensive assessment of GMOs that goes beyond the statutory RA to cover further environmental and societal aspects.

The primary field that could be a source of inspiration for such methodological developments is technology assessment (TA), where the impacts of genetic engineering applications have been researched and assessed since more than 30 years. It has a broad scope and focuses on predicting technological impact (Rip 2015). But while there are established concepts and methods of Technology Assessment (TA) for broader scientific policy advice concerning novel technologies at the parliamentary level and beyond (for Germany, cf. Kehl et al. 2021), instruments for a systematic and transparent case-by-case assessment of these aspects are not yet available for GMO assessments. By assessing broader impacts, normative connotations can be made explicit (Myskja and Myhr 2020; Harfouche et al. 2021). Transparency and a systematic approach can help create an arena for discussing the choices at stake when diverging conclusions can depend on values, visions, and interests as well as assessment methods and drive decisions that consider such broader aspects and hence affect social acceptability. It is widely acknowledged in TA that these challenges of normativity, participation and integration of knowledge cannot be ignored in legitimate scientific policy advice (cf. Kehl et al. 2021).

Broadening the scope of GMO assessment requires robust methodologies throughout all steps of framing, data gathering, and assessment. It also requires other types of empirical data and broader expertise (Binimelis and Myhr 2016; Catacora-Vargas et al. 2018). Methodological frameworks developed in the field of TA are interesting and valuable because they are typically targeting a broad range of aspects. Importantly, they consider that factual aspects and normative connotations cannot always be fully separated and that we need to tackle a considerable lack of knowledge in assessing emerging technologies. TA also considers the societal and environmental context in which technology is to be applied. Beyond that, it frequently involves an analysis of possible alternatives. Scientific methods and robust criteria for assessing technologies have been developed within TA, and they are also suitable for GMO assessment by government agencies (see, e.g., Simonis 2013). Some approaches have already been used in the BA of synthetic biology (Rehbinder et al. 2009; Giese et al. 2015; Sauter et al. 2015; Engelhard et al. 2016), new self-replicating genetic constructs like gene drives or so-called Horizontal Environmental Genetic Alteration Agents (HEGAA) (Reeves et al. 2018; Frieß et al. 2019; Pfeifer et al. 2022).

This paper argues that methods and procedures can be developed to allow for systematic impact screening, a preliminary assessment of selected topics, and the identification of in-depth assessment needs. The first part will provide an overview of how broader societal issues are being considered during present pre-market assessments of GMOs. The second part explains the requirements and challenges for establishing a BA approach which would be compatible with established law enforcement requirements and routines and hence be relevant for revising the same laws. Against this backdrop, the third part suggests vital elements of such a broader approach.

Broader considerations of GMOs in national and international policies and regulations

Different regulatory systems have been implemented to assess GMOs worldwide (Spök et al. 2022; Turnbull et al. 2021), and to some extent, they acknowledge societal and ethical aspects. However, Binimelis and Myhr (2016) found that although many countries have legislation in place for assessing socio-economic considerations (SEC) in GMO-related decision-making, there is still a need for structured guidance for such assessments. A similar conclusion was reached in evaluating reports on the SE impacts of GMOs at

the EU level (Kathage et al. 2016). On the 5th of July 2023, the European Commission published a proposal for a new Regulation on certain categories of plants modified by new genomic techniques (NGT), a term that includes genome editing technologies (European Commission 2023). The Commission distinguishes between two categories of plants: (a) those that, according to the Commission, "could also occur naturally or be produced by conventional breeding" (European Commission 2023, p. 10) and that would according to their regulatory initiative be exempted from present regulatory requirements, and (b) other products that would be regulated, but the authorisation procedure would be simplified compared to the current EU GMO requirements. It is suggested that this could include an impact assessment and potential new labelling regimes connected to sustainability (European Commission 2023, p. 9f). In addition, the Commission points out that they would monitor "potential risks to health or the environment, impact of NGT plants on environmental, economic and social sustainability as well as impacts on organic agriculture and consumers acceptance of NGT products". The regulatory proposal is controversially discussed at EU and Member States level.

Cartagena Protocol on Biosafety

A clear commitment to SEC regarding the impacts of GMOs is expressed in Article 26 of the Cartagena Protocol on Biosafety (CPB) to/under the Convention on Biodiversity (CBD) (Convention on Biological Diversity 2000). To specify the implications of Article 26, an Ad Hoc *Technical Expert Group (AHTEG)* was assigned, and it developed a guidance document on the assessment of SEC (Convention on Biological Diversity 2018). The guidance document proposes a stepwise approach, starting with scoping before entering the assessment and ending with a final monitoring step. According to Article 26 of the CPB, including SEC in regulatory decision-making is voluntary and can be applied in (a) decisions on import and (b) GMO issues included under national laws and regulations.

GMO regulation in the European Union

Within the EU and the European Economic Area (EEA), Member States can adopt measures restricting or prohibiting the cultivation of GMOs based on SE impacts, avoidance of GMOs in other products, national environmental policy objectives, or public policy reasons. The basis for this opt-out option is the 2015 amendment to Directive 2001/18/EC on the deliberate release of GMOs into the environment (Directive (EU) 2015/412 2015). The procedure, however, is not meant to be part of the pre-market authorisation process. Instead, it allows invoking restrictions in cultivating a particular GM crop in regions or the entire area of Member States. In case Member States want to invoke such restrictions during the approval or renewal process and if the applicant agrees, no justification is needed. If restrictions are raised after authorisation has been granted, "compelling reasons have to be provided such as environmental or agricultural policy objectives, town and country planning, land use, coexistence, socio-economic impacts, or public policy".[1] So far, all opt-outs were made according to transitional provisions (ibid, Article 26c), which do not require justification. Hence, there is no experience, so far, neither in putting together such an assessment.

According to Directive 2001/18/EC, Member States must report their experience with the releases of GMOs on the market every 3 years, including "the socio-economic implications of deliberate releases and placing on the market of GMOs" (Article 31, § 7d). Based on these reports, the European Commission would release a report on the socio-economic implications. However, insufficient experience and lack of data to make such assessments prompted the establishment of the European GMO Socio-Economics Bureau (ESEB) in 2013 to facilitate information exchange on this topic among EU members (Kathage et al. 2015, 2016).

EU Members States are entitled to consider aspects beyond health and environmental risks during decision-making, i.e., voting on authorisation in the Standing Committee on Plants, Animals, Food and Feed and the Appeal Committee. If the Appeal Committee disagrees, the European Commission decides based on the comitology procedure. Member States can consider broader political considerations, including SEC, to inform their voting on market authorisation in the Standing Committee (cp. Mühlböck and Tosun 2018). However, it is often not transparent which SE or other aspects are considered and how.

There are, however, two exceptions to this: France and (back-to-back with the EU authorisation process) Norway. France's dedicated body, the High Council for Biotechnology, informs the French competent authority in voting at the EU level. To this end, a stakeholder committee assesses GMOs' SE and broader social aspects parallel to the health and environmental RAs. Norway, an EEA Member, has established provisions for systematically assessing sustainability, ethical, and social impacts beyond environmental and health risks in their Gene Technology Act of 1993 (Norwegian Government 1993, 2005). Regarding a specific GMO application for deliberate release, the Biotechnology Advisory Board advises Norwegian authorities on the GMO's contribution to sustainable development, its societal utility, and if it raises ethical concerns. The Board has developed guidelines for assessing GM crops' sustainability and societal utility, which are

[1] https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-authorisation/gmo-authorisations-cultivation_en#restricting-or-banning-gmo-cultivation.

used in their advisory work. The inclusion of these criteria is intended to be used both to promote GMOs that positively contribute to sustainability or are of societal utility and can also be used to decline an application that raises concerns. As such, Norway may thus be the country with the longest experience in performing assessments that go beyond safety considerations. However, this has been challenging due to the lack of empirical data and the fact that the applicants seldom provide information on non-safety aspects (Myskja and Myhr 2020). On the 6th of June 2023, a governmental appointed committee published their report on gene technology where the majority suggested a level-based regulation with the exemption as in EC and the minority a modernisation of current legislation (NOU 18, 2023). However, they all agree on the need to assess broader impacts but that the process needs to be simplified by acknowledging ethical justifiability that is evaluated according to four central principles: utility, sustainability, fair distribution, and transparency,

Taken together, the overall situation indicates that EU and EEA Member States consider—to some extent—aspects beyond health and environmental risks when deciding on market access to GM crops and products such as food, feed, and fibre. However, except for Norway and France, no EU/EEA Member State has established a procedure for the systematic and transparent assessment of these aspects. As in Norway, international treaties, especially the CBD, the EU/EEA legislative framework, and national regulations provide leeway for such a process. The challenge is that such a process would need to fit into the requirements and timelines of the existing EU GMO regulatory framework. It should be applicable transparently and systematically in established regulatory procedures.

EU policy reports calling for a broader assessment

The European Group on Ethics in Science and New Technologies (EGE) provides ethical guidance for the European Commission. In 2009, EGE published an opinion on the ethics of modern developments in agricultural technologies, where GM crops were also discussed (European Commission 2009). Besides a commitment to the precautionary principle, the group also recommended re-evaluating risk management procedures per an impact TA. The EGE recognised the need for a broader technology impact assessment and a health and environmental RA. It proposed to also consider social implications by noting the need to be aware of the potential increase of the technological gap between developed and developing countries.

In its recent report on ethical aspects of genome editing (EGE 2021), which covered humans, animals, and plants, the current EGE members elaborated on the need for broad assessments to avoid a narrow focus and one-sided framing. They explicitly argued for extending the scope of analysis and debating the underlying concept and approaches regarding biodiversity, naturalness and the value of living beings (EGE 2021, 85). One of the recommendations was to develop international and national standards for the ethical and safe use of genome-edited organisms (ibid.).

Requirements for a broader approach

There is a need to develop a nationally applicable methodology to acknowledge SE aspects and broader environmental issues that include cultural values and moral claims. By extending the scope of assessment to include broader criteria, it is necessary to invest considerable effort regarding validity, transparency, and harmonisation in developing the methods. The current RA methodology has its roots in an analysis based on principles of the natural sciences and is especially influenced by principles for RA of chemicals. The question arises whether these paradigms will be appropriate and or sufficient for the aspired BA that considers social effects. Instead, it seems more reasonable to base a proper methodology on what has been learned in TA because its focus goes far beyond just RA and has come to include issues of sustainability and social, cultural, and ethical implications. Several TA concepts have been developed in recent decades.

Possibly suitable examples are Rational Technology Assessment with its rational analysis of the justification of moral claims and the acceptability of consequences based on rules of distributional justice (Grunwald 2002, 155; Lingner 2013). In addition, the investigation of causal effects in predefined impact dimensions in the TA approach of the Association of German Engineers (VDI) (Zweck 2013). Here, the impact dimensions are attributed to value orientations considering functionality, economic efficiency, prosperity, security, health, environmental quality, personal development, and social quality. And there is Prospective Technology Assessment (proTA) according to Liebert and Schmidt (Liebert and Schmidt 2015) and according to von Gleich (2013). The latter complements an indicator-based method of technology characterisation with a vulnerability analysis of potentially affected systems (cp. Lalyer et al. 2020).

Suppose an improved approval of GMOs for experimental releases and their placing on the market should profit from elements of TA methods. In that case, approaches are preferred that make predictions based on a set of criteria that serve as early indicators of the potential impact of a technology in its intended context of use. Respective methods need to cover developmental phases, the application itself as well as the entire life cycle of products.

We assume that a BA would be most useful if conducted as a first step parallel to the statutory RA of individual GMO applications for placing on the EU market and environmental releases. The aim would be to advise national policymakers about health and environmental risks as required in the EFSA

guidance documents on GMOs (EFSA 2022) and possible broader environmental, socio-economic, and ethical impacts.

However, several limitations must be considered if the BA is to take place in the same time frame as the statutory RA, especially concerning the availability of time and resources for this additional, comprehensive procedure. Therefore, an approval strategy oriented at TA approaches will be severely limited compared to "traditional" TA concepts.

In the current approval process for GMOs in the EU, at the national level, two-time slots could be suitable for including aspects beyond RA. The first option is immediately after Member States have received information from EFSA granting them access to a new application dossier. A 90-day period starts for reviewing both the applicant's RA and EFSA's opinion. For food/feed applications, only comments within the scope of statutory RA will be considered. For applications aiming at cultivation, a BA could advise national policymakers on a possible opt-out notification. The second option is before the final political decision is made. The result would be advised to national policymakers to inform their voting in the EU Standing Committee on Plants, Animals, Food and Feed (Section Genetically Modified Food and Feed) and—if applicable—the Appeal Committee. The Member State vote can legitimately consider aspects beyond health and environmental risks. Here, the time window varies from some months to years. Thus, a BA could provide a better basis for the political voting on the application in all cases: cultivation and food/feed. Due to the short time frame of the *first option*, only a rather cursory assessment that could make existing knowledge accessible and point to open questions seems possible, whereas for the *second option,* depending on resources, an assessment of aspects beyond RA can be more thorough. The function of a quick assessment during the first available time slot would thus also indicate whether more thorough assessments may be warranted and hence be an approach that can be used in a novel GMO framework based on a more level-based regulation.

In conclusion, this implies that an appropriate method includes the points listed in Box 1.

Box 1: Requirements for a method of broader GMO impact assessment.

- should be able to be carried out in a relatively short time frame to meet the limited resources and time constraints of administrations,
- should provide good indications of potential open questions that require a more thorough assessment,
- relies on existing and readily accessible evidence and/or other forms of knowledge (scientific studies, policy reports, indigenous knowledge), ideally collected in a searchable database or other open-source platforms
- is applicable with no or minimal consultation with the applicant,
- is oriented on decision support,
- relies on indicators for criteria of prospective TA to allow a systematic characterisation,
- is based on openly accessible and relevant considerations, and follows accepted and transparent methods,
- provides guidance and information on potential socio-economic impacts as well as possible conflicts with public values, cultural practices, and international agreements (again, early indicators are necessary to derive subsequent impacts from an initial characterisation of the technology and its potential context of use)
- can point out a lack of knowledge and open questions.

In the following, we outline the key elements of such an approach.

Elements of a broader approach

TA does generally require substantial amounts of time and resources. However, the TA approach to investigating technology's connection with the environment and society is crucial for the proposed practical framework. Importantly, our proposed approach can also draw on an existing body of comprehensive GMO and synthetic biology TA literature (Meyer et al. 1998; Sauter and Meyer 2000; Sauter 2008; Schmidt and Liebert 2014; Giese and von Gleich 2015; Sauter et al. 2015; Engelhard 2016; Schmidt 2016; Frieß et al. 2020). Nevertheless, characterising a technology's potential environmental, economic, societal, and cultural impacts is a complex task. It will most likely be possible only in part through an approach that concludes subsequent impacts based on characteristics of the technology and the systems that may be exposed. Therefore, it will be necessary to draw on experience in previous related cases, which could be collected in a publicly accessible source, for example, a database. In addition to a potential database that could provide this reference information, such a comparative approach requires judgments about the extent to which general data of similar cases can be used for a specific case, the extent to which such data can be generalised to other agro-economic contexts, environments, and social constellations. A useful database must be constantly updated and developed to meet the needs of rapid assessment.

Given the procedural constraints on approval described above, the assessment proposed here for the EU Member State level is envisioned as a two-step process (Fig. 1). The first step entails an assessment that can be performed within a few weeks. For example, it is meant to be applicable within the first short period of a GMO approval process, during which the EU Member States reviews the application and RA. This step should lead to a first recommendation and identification of open questions. If, for example, the results of the first step are inconclusive or the prediction of the impact of the technology application is too uncertain, the recommendation can lead to a more in-depth second step of the assessment. The period before the final political decision has to be made within the EU approval process might be appropriate for this purpose. The assessment would be performed at the Member State level at the same time as the EU procedures and could result in the form of an EFSA opinion. During 3 months, the proposed first step in the BA (see Fig. 1) could be integrated into this process, and its output could be formulated as scientific policy advice. Depending on resources and if the period for reaching a decision is extended, the second step of the BA could be undertaken, and its output results in a report.

For the first step, we propose several concrete methodological elements:

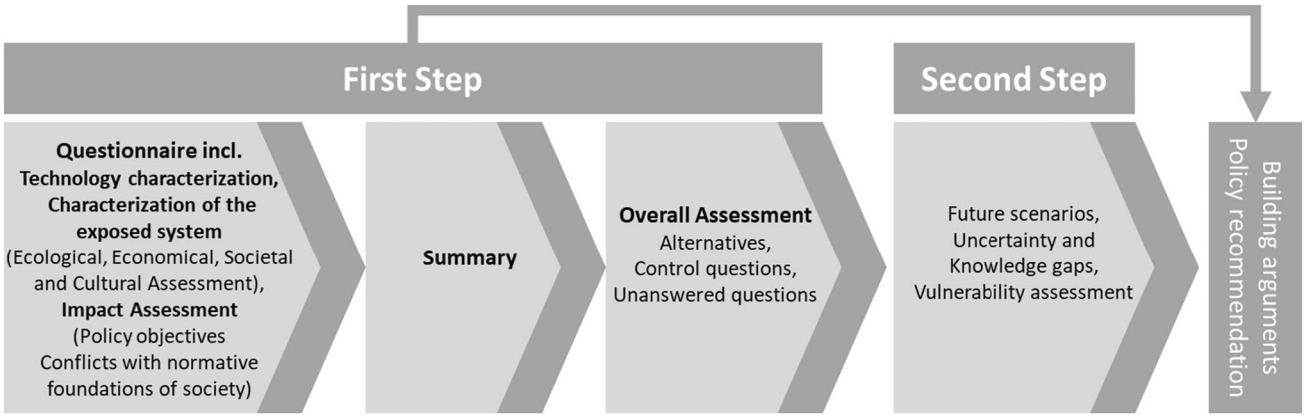

Fig. 1 Stepwise approach of a broader assessment for GMOs

Characterisation of the technology

At the beginning of the analysis, a characterisation of the technology lays the foundation for further assessment. We recommend focusing on aspects that make it possible to derive assumptions about the scope and nature of the impacts of applying the technology. In Frieß et al. (2019) and Pfeifer et al. (2022), we have presented such a characterisation for new GMO techniques. Here, technology characterisation focuses on (a) the depth of technological intervention to estimate hazard and exposure potential, (b) the intensity of the intervention, (c) the reliability of the technology, and (d) its corrigibility (which for GMOs includes retrievability). This step can also draw much information from the regular RA.

Characterisation of the exposed system

After the characterisation of the technology—possibly also in parallel—four essential dimensions of the exposed system are characterised: ecological, which goes beyond the regular RA, economical, societal and cultural. Each of these four dimensions can be impacted using a GMO, as Catacora-Vargas et al. (2018) suggested. Indicators for the assessment should be framed within the national policy objectives and normative foundations of society. Characterisation of the exposed systems, be it an ecosystem, the society or its subsystems, is the prerequisite for estimating possible impacts, where special care should be taken with respect to all the potentially affected stakeholders and future generations. In addition, depending on the application context, prerequisites for the application (resource requirements, etc.) and the life cycle of products (application) should be considered.

In this context, the vulnerability of the exposed system (Williams and Kapustka 2000; Turner et al. 2003; Adger 2016), including its additional stressors and preloads, is also of particular importance. Analysing the vulnerability of a system entails examining pathways to exposure, the system's sensitivity to a disturbance and its coping abilities. Due to the compact format, performing a complete vulnerability analysis in the first step of the tiered assessment will not be possible. However, a translation of "vulnerability" into social, cultural, and economic aspects is necessary to allow at least a rough collection of indications for vulnerability. A first impression of vulnerability can be achieved by determining the affected elements of a system. These could, for example, be vulnerable groups of society, such as rural populations with specific traditions in food production or groups most sensitive to applications that have a negative impact on the distribution of benefits and burdens within society. The susceptibility of these system elements needs to be identified and described. Lastly, assumptions concerning the ability to cope with these changes in the system could be described.

Assessment of impacts

In a broader assessment, potentially adverse effects on the societal and environmental status quo can include a variety of impacts beyond those covered by statutory RA, e.g., on the use of natural resources, animal welfare, freedom of choice and additional costs for consumers, threats or benefits to established farming practices, path dependencies within production systems, and the limitations for research and saving of seeds by intellectual property rights (de Graeff et al. 2019; Lindberg et al. 2023; Helliwell et al. 2019; Glenna 2023). Not to be neglected are the effects in the country of cultivation (in the case of imports) or by the release of gene drives, e.g., if the rights of the local population are violated, or environmental protection standards are not met (Hartley et al. 2023; Myskja and Myhr 2020). The assessment of adverse effects should be complemented by identifying a technology's societal utility and/or sustainability, which entails more inclusion of stakeholders and the public and transparency in regulation processes (Bain et al. 2020; Lassen 2018). Promises can be analysed by comparing proposed

benefits with realistic possibilities, which is also part of Prospective TA as defined by Liebert and Schmidt (2015). A related approach has been proposed as a 'needs assessment' (Van Calster et al. 2018). Here, the envisioned application is analysed considering relevant societal objectives for the agricultural and environmental policy. The aim is to see whether a GMO contributes to the development of society in a preferred direction and to analyse whether the technology has the potential to achieve the goals stated by the applicants. Here, in analogy to the precautionary principle, comprehensible reasons for expected benefits are necessary during the assessment (Vos and de Smedt 2020, 44f).

Estimates about the potential range of at least direct effects should be derived from this first step. A central issue in this regard is the degree of significance and likelihood of potential impacts by these effects. However, obtaining a comprehensive overall picture of possible ramifications is more relevant for a first scanning of issues. A checklist with control questions can be utilised to validate the assessment before building the arguments. In this way, the potentially critical unanswered questions can be scrutinised or identified as uncertainties or knowledge gaps. These gaps and uncertainties could be dealt with in the second step. Finally, it is important to estimate the limits of prognosis and control.

Outlook to the second step of the tiered assessment approach

A more elaborate second step of the tiered assessment approach may connect to the first step by further investigating the most relevant issues for political decision-making (which might depend on the political priorities of the Member State). In addition to pointing out the need for extended research to reduce uncertainties and fill knowledge gaps, this elaborate step could also include scenario building and considering specific national policy goals. Such scenarios could express a preferred state of the future society, including societal objectives and impact goals or roadmaps. Societal objectives are relevant in this sense if the adoption of GMOs influences them. Overall goals are, by their definition, overarching and general and thus do not need to be quantified. Instead, they are a point of orientation. They should be considered without (reference alternative) and with the GMO approval to determine whether the GMO contributes to developing society in the desired direction. Prognoses of effects must be compared with those by introducing and using the GMO in question and the non-GMO alternatives that will address the same overall goals or societal problems. Furthermore, the quantifiability of the intended effects should be investigated.

A vulnerability assessment could complement the characterisation of the exposed socio-ecological systems in the second step of the assessment. Beyond exposure levels, this would involve analyses of ecological and social systems' sensitivity and coping mechanisms in response to a stressor/change (Adger 2016; De Lange et al. 2010). Possibilities of how an ecological and social system could deal with changes/stressors could be examined by investigating different scenarios, legal frameworks, roadmaps etc. The results of such a vulnerability analysis as part of a BA would provide a more comprehensive understanding of potential impacts on the affected systems.

Summary

The lack of broader social acceptance and the need for coherence with national sustainability policies suggests consideration of a broader range of possible impacts before approval for release into the environment and placing on the market of GMOs. This paper explores the challenges and opportunities for implementing a systematic and transparent two-step assessment process for providing complementary policy advice on the national level during statutory assessment and authorisation for the marketing of GMOs in the EU and EEA countries. In the first step, the potentially most relevant impacts, knowledge gaps and open questions should be identified to alert decision-makers to possible sensitive social, ethical and cultural issues. Existing knowledge should be considered to characterise the nature of these issues. Filling identified knowledge gaps by using TA methodology would be the subject of a subsequent, more thorough investigation as part of a second step in the proposed assessment. The suggested process entails procedures and systematic and transparent assessment of broader issues that can fit current approval processes and are highly relevant for authorities that are currently revising or adapting the regulative requirements on GMOs and genome edited organisms.

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Declarations

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