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POLICY BRIEF

How to Do What Is Right, Not What Is Easy: Requirements for Assessment of Genome-Edited and Genetically Modified Organisms under Ethical Guidelines

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Summary/Abstract
An ethical assessment is a complex, dynamic and comprehensive process that requires both ethical expertise and practical knowledge. An ethical assessment of a genetically modified organism (GMO, including genome edited organisms) must follow accepted and transparent methods and be based in relevant considerations. In addition, the Ethical guidelines must include a broad and adequate range of values, so that no groups, stakeholders, agents or areas are left out.

Keywords GMO · Non-safety factors · Ethical justification · Ethical matrix · Genome-editing · Practical knowledge

Recommendation

We recommend that ethical assessments of GMOs (including genome-edited organisms) are performed by professionals with competence and practical knowledge of ethical judgements, and that users, non-users, stakeholders and interest groups are actively involved. In addition, we recommend that the Ethical guidelines include a wide range of ethical values.

Background

The Norwegian Gene Technology Act (GTA) of 1993 requires GMOs to be sustainable, ethically justifiable, and beneficial to society for them to be approved for production and use

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(GTA 1993). In addition, use and release must be free from harmful effects on human health and the environment. Risk analyses on the effects on health and the environment are carried out according to international standards and are based on data mainly provided by the applicant/developer.

The most important internationally binding agreements to consider for European countries are requirements through membership in the European Union and the Agreement on the European Economic Area (EEA) as well as internationally through the World Trade Organization and the General Agreement on Tariffs and Trade (GATT). On the one hand, the EEA Agreement allows a member State (or region) to adopt measures restricting or prohibiting the cultivation of GMOs based on grounds of non-safety criteria such as socio-economic impacts, avoidance of GMO presence in other products, national policy objectives or public policy (Directive (EU) 2015/412 Article 26b, amending Directive 2001/18/EC). On the other hand, the latest version of the GATT allows its members to implement measures necessary to protect public morals (WTO 1994). Furthermore, the Cartagena Protocol (article 26 of the Cartagena Protocol on Biosafety) recognizes the relevance of socio-economic considerations.

The requirements for sustainability, ethics and societal benefit are uniquely Norwegian. So far, the requirements for societal benefit and sustainability have been operationalized through guideline documents. Based on the Ethical guidelines developed by Forsberg et al. (2019) the Norwegian Environment Agency (NEA 2020) recommends a framework for the assessment of ethical justifiability. This recommendation is submitted to the Norwegian Ministry of Climate and Environment and it is expected that they will make a decision in 2021. Norway's Ethical guidelines will then be the first national standard for assessing the ethics of GMOS.

The proposed Ethical guidelines draw from a rich background of philosophical traditions as well as public values. The framework is grounded in common morality (Beauchamp and Childress 1994; Tranøy 1998). The purpose is to make it both universally applicable and readily adaptable to various contexts as well as societal and political requirements for assessment. Thus, the framework can be an inspiration for national authorities also in other countries that wish to ensure ethical justifiability of GMO approval. This policy brief offers access to the experiences and challenges with developing Ethical guidelines within the Norwegian context and presents, explains and justifies the requirements necessary for the guidelines to be a sound, inclusive and practical decision tool for the assessment of ethical justifiability of GMOs and genome-edited organisms by national competent authorities.

The Significance of the Ethical Guidelines

In Norway, assessments of ethical justifiability are made by the Norwegian Biotechnology Advisory Board (NBAB) which then submit their evaluation to the NEA. The NEA may recommend approval if all criteria required by the GTA are met and approval is ethically justifiable. In this scenario the proposed ethical guidelines will be a tool for assessment and suppose to function as a decision aid for the responsible case officer. The case officer completes an ethical evaluation on the basis of the methods and values described in the guidelines. The methods and ethical values described will thus guide the case officer's ethical assessment and subsequent recommendation. The Ethical guidelines do not only define which ethical values and principles that are relevant to the assessment, but it also defines the method to be used. In other words, how the case officer should reflect and justify their recommendation.

Ethics and Methods of Genetic Modification

Ethics helps us to decide on how to act in situations characterized by uncertainty related to both normative and empirical aspects. Regulation of GMOs is characterized by such uncertainty. There is uncertainty as to how (un)safe a GMO is regarding its impact on human health and natural environment, which interests the product will serve, which groups are affected by its use and release, and in what way the technology may threaten some of the fundamental values our society is built on. GMO regulation is thus a field where ethical and value-based choices must be made by weighing and balancing the various dimensions of uncertainty against each other (Preston and Wickson 2016; Stirling 2010, Wynne 2001).

The challenge of making an ethical decision is that one cannot blindly follow rules or laws independent of context and situation. Eventually every ethical assessment requires some form of practical value judgement as to how to act. One could argue that value judgments are purely subjective. An ethical evaluation is different from statutory risk assessment. Depending on the context, as well as their background, personal and professional values, culture and religion, different case officers may potentially prioritize different ethical values. Furthermore, it has been shown that professionals belonging to the same epistemic community have been educated, trained and socialized into a professional identity that in no way is free of normative commitments (about what is doable and desirable, what problems are important, what solutions should be considered, and what concerns that should be taken seriously). They also work within an institutional context that may set both formal and informal, clearly visible as well as almost invisible, constraints on what is considered to be an important or legitimate concern or a relevant issue (Haas 2008). Thus, an ethical guideline must be designed to counteract the problem of random variation of the individual case officer's values and worldviews but also the bias imposed by professional identities and institutional constraints.

When performing an ethical assessment, one cannot cherry-pick values that already correspond to one's own attitudes or based on the normative constraints of their professional background and training (their epistemic community). Rather, it requires argumentative reasoning and consideration of a broad and adequate set of ethical values that depend on the context of the application. This requires ethical training, skills and practical knowledge of ethics, as well as a good guiding procedure. Even in legal judgments, the application of the law is a matter of interpretation by judges who are trained to apply general laws to concrete circumstances. Like in the interpretation and application of the law, it is important that there are general guidelines for the process and the person(s) who will make the ethical assessment of a specific case. However, while education in law includes practical training, there is no or little such formalized training of practical ethical judgements in for instance education in philosophy. And even less in educating assessors of GMO applications with a background in molecular biology. Even when the person(s) are ethicists or philosophers they might lack training relevant for doing an ethical assessment of GMOs. So, in order for the individual case officer to be able to arrive at a transparent and justifiable ethical decision, the method and tools used must cover a variety of values that (potentially) go beyond the case officer's own. In addition, the method should provide a tool for reasoning (asking the right questions), as well as a tool for justification (systematizing the analysis and its values in a verifiable way).

The Ethical guideline's Method

In the Ethical guidelines suggested by Forsberg et al. (2019) an ethical matrix, as well as a set of support questions, is proposed for finding ethically relevant aspects for the assessment of GMOs. An ethical matrix is a practical tool to assist decision-makers with identifying a broad overview of relevant ethical questions and issues, before focusing on issues that seem most relevant, as in this case - the regulation of GMOs. The competent use of an ethical matrix as a decision support framework exposes case-relevant and ethically relevant aspects, includes multiple perspectives, ethical arguments and important values at stake (Kaiser et al. 2007). An ethical matrix also has the potential to be used as a participatory tool in cases when the involvement of different interest groups is relevant (Mepham et al. 2006). It is a dynamic map showing how different normative and empirical aspects of GMOs are linked and thus an ethical matrix can contribute to openness, transparency and verifiability of the assessment. One of the challenges with an ethical matrix is that it may give a static impression of the ethical assessment, as something that can be "calculated" according to given checkpoints and principles. It also remains an open question what the "tipping point" is, that is, when are the reasons for concern identified by the matrix enough to consider a product or an organism ethically (un)justifiable?

The proposed ethical matrix in the Norwegian guideline is comprehensive, as it represents and includes a variety of ethical perspectives and traditions (utilitarian ethics, deontology, virtue ethics and care ethics). In addition, Forsberg et al. (2019) propose several important ethical principles that are relevant in the assessment of GMOs as these are deeply rooted in Norwegian society and western culture. In order to guarantee a comprehensive and adequate assessment of GMOs the authors argue that the generally accepted principles of common morality "no harm", "beneficence", "autonomy" and "justice" should be supplemented with other relevant values such as "trust", "stewardship", "care", "solidarity", and "naturalness and respect for dignity/integrity" (See Table 1).

Table 1: An example of the ethical matrix including a selection of relevant dimensions, principles and ethical values based on common morality and an analysis of European Regulation and policy objectives as well as Norwegian legislation. This blueprint of a matrix for the assessment of ethical justifiability developed by Forsberg et al. (2019) also

Table 1 The ethical matrix for the assessment of ethical justifiability of GMOs as proposed by Forsberg et al. (2019)

Ethical Matrix	Country of Production	National	Sustainability/ Future generations	Animal well-being and environment
Non-harm principle				
Beneficence				
Well-being				
Justice/Fairness				
Autonomy				
Trust				
Stewardship				
Care				
Solidarity				
Naturalness and respect of dignity/integrity				

includes a comprehensive catalogue of support questions to be place in the various cells and answered by the case officer doing the assessment.

A good guidance document for ethical examination and justification will be able to help the individual case officer to separate their personal views and values from their professional role. Not because personal views are irrelevant, but because they are not the only relevant perspective to consider. This is where the ethical matrix should do its job: The matrix's many interest groups mean that the case officers must start their thinking from different points of view and perspectives. In addition, a broad, representative and adequate selection of support questions ensures that it is not the case officers´ intuition or background that determines the relevant values and norms. The support questions in the matrix function as guiding questions that can provide orientation and inspiration in the ethical assessment. They are not meant to be used as a "mechanical list" one must work through step by step. In each individual assessment, one can and must choose relevant questions and important consequences to focus on. Guiding questions that are considered important should provide the most representative selection of aspects that may be of importance. On a good day the guiding questions will help the case officers to discover relevant aspects that they may not have thought of before and thus function as a practical support tool for the ethical assessment.

Ethical Values

The Ethical guidelines by Forsberg et al. (2019) have sparked debate and disagreement. In response to the guidelines The Norwegian Biotechnology Advisory Board (NBAB 2020), which in Norway is responsible for performing the ethical assessment, has issued a statement. Here, the NBAB proposes to omit four values from the ethical guidelines: non-harm, stewardship, care and naturalness. NBAB argues that this will simplify the ethical matrix and (thus) make it more applicable.

There are no good reasons to remove these values. First, it may make the matrix a less inclusive tool for the assessment. Fewer values and less flexibility in the framework will make it easier to apply, but ultimately decrease the chance that the case officer will find basis for their reasoning in the guidelines. We risk instead that the assessment will not arrive at a sound judgement since it relies on unarticulated underlying values. Secondly, the values that the NBAB proposes to omit are prominent and relevant in the debate on the regulation of GMOs. We can look briefly at each of these.

Care

The ethics of care emphasizes that living a good life and doing good are possible only through creating and maintaining positive and healthy relationships between people, and between human and non-human nature (Gilligan 1982; Pettersen 2008). There are several reasons why care is relevant in the assessment of GMOs. Care is essential to build *trust*. Only to the extent that citizens can be confident that both authorities and producers are concerned about and care for their and society's best interests (that they care for individuals, society, and the planet) will trust be created in regulation, the technology, and its products. Care ethics also takes into account *context* and *relationships* when doing an ethical assessment (Dassler 2016). It captures how human-human and human-nature relations can be changed through genetic engineering. It emphasizes the issue of *power* in human-nature relations and places (and justifies) *responsibility* for safeguarding nature, ecological systems, and biodiversity on people

and society (Preston and Wickson 2016). In other words, care for people and nature is source and foundation for why the precautionary principle, stewardship, ecological, social and economic sustainability and societal benefit are important ethical categories for political decision-making in general and in the assessment of GMOs in particular.

The NBAB proposes to remove "care" as this, "in the council's opinion, is not [relevant] for an ethical assessment of a GMO" (NBAB 2020). The NBAB does not provide any further justification for this recommendation. One reason why NBAB does not see the relevance of "care" may be that care ethics is a relatively new ethical perspective, which is not yet as popular for understanding ethical dilemmas compared to more traditional ethical theories. It is also possible that some of the meaning, nuances and important aspects of the word ´care´ are lost when it is translated from the English word ´care´ into the Norwegian ´omsorg´. If this is the case, the need for ethical expertise and competence in considering different ethical perspectives as part of an ethical assessment becomes clear.

Naturalness

Naturalness is a vague and ambiguous concept, which receives a lot of attention in the GMO debate, and which is often interpreted differently among different actors (Siipi 2008). According to the NBAB, the value ´naturalness´ should be omitted for this reason.

There may also be good reasons to be both critical and to try to look beyond naturalness in ethical assessment as crucial to what should be allowed and not allowed by genetic engineering (Preston and Antonsen 2019; 2021). Anyhow, the fact that ´naturalness´ is interpreted and used differently in different context and by different actors, is not a good reason to remove the concept from the ethical assessment of GMOs. All societal values, including the law, allow for interpretation and (potential) disagreement. We see that both proponents and opponents of new genome editing tools such as CRISPR, use the concept of naturalness. (de Graeff et.al. 2019; Doxzen and Hendersen 2020) This suggests that naturalness is a value important to all sides in the debate, even if we disagree about its meaning. We should rather use this knowledge to initiate important deliberation on what we consider to be natural and why naturalness is important.

Stewardship

The NBAB believes that stewardship and non-harm (see below) can be removed as these have already been considered during the assessment of societal benefits and sustainability. Stewardship must be understood in the context that genetic engineering is a man-made disruptive technology that has the potential to change human-human and human-nature relationships. Care for people, society, nature and the relationships between them is the reason that gene technology with its disruptive potential should be managed and regulated by us. Our responsibility to care for and manage the natural world, that can be expressed through the concept of stewardship, is debated because it puts us in a special dominant position as active providers of care in relation to a more "passive" and receiving nature that lacks agency. One could also object that the concept of stewardship rests on a sharp distinction between humans and nature that cannot be maintained. Nevertheless, the link between stewardship and the precautionary principle is close. It also has deep historical and religious roots, that are still prevalent in part of society, and in agrarian ethics (Antonsen 2017; Smith 2003; Thompson 2010). Removing stewardship from an ethical assessment also removes a significant guiding principle that places

special responsibility on us as humans to be pro-active in our protection of nature. The relationship between humans and nature today is undoubtedly complicated, and both experience and broad ethical practical competence are required in the assessment of such complex relationships.

Non-harm

The non-harm principle is to some extent considered in the statutory risk assessment of GMOs to the extent that the risk assessment ensures that that the technology is not harmful to either humans or nature. Nevertheless, statutory risk assessment is limited to a purely biological approach toward safety. Including the non-harm principle in the ethical assessment emphasizes that there are several important "non-safety" aspects that go beyond biological activity and ecosystem services that may be affected negatively. In addition to the potential for physical harm, GMOs can also alter and possibly hurt different types of relations. Gene technology can affect how we understand and conceptualize nature and what we can justify doing to it. GMOs are also a patentable technology and can disrupt power relations and who has control over a product (the seed, the plant, etc.). This can be significant for which social groups can and should have access to these products (Myskja and Myhr 2020). Consequently, this may affect the welfare of various societal groups and their ability to live a good life, and should thus be considered as part of the ethical assessment.

We should keep the non-harm principle in the Ethical guideline because it leads us (the case officers) to ask important questions; Who will benefit from the GMOs developed? Who should have access to it, those who need it the most, or those who can pay for access? Including, how can technology potentially change our practices regarding food and nature? In summary, non-harm is an important principle in the ethical assessment that is closely linked to trust and care and that requires us to take into account non-safety aspects that go beyond a pure bio-physical understanding of harm.

Summary and Policy Recommendation

An ethical assessment is a complex, dynamic and comprehensive process that requires both ethical expertise and practical knowledge. An ethical assessment of a GMO must be carried out according to accepted and transparent methods and be based on relevant considerations.

The Ethical guidelines must also cover a broad spectrum of values, so that no societal groups, actors or areas that society wants to protect are left out. The Norwegian debate actualizes the dilemma we face when we attempt to operationalize an ethical framework for a competent authority: Should we create very specific rule-based procedures, or should we allow for ethical deliberation? And if we allow for ethical deliberation and practical judgment, how can we avoid the assessment becoming a mere expression of particular individual or institutional constraints and professional identities? Above we have argued that in order for an Ethical guideline to be a solution to this dilemma and a useful decision support aid, public authorities need to have a broad and flexible framework. Furthermore, the guideline must avoid judging what is relevant to the public. Rather, it must cover a wide range of the public's values, reactions to and attitudes towards genetic engineering and food, thus protecting democratic values. To guarantee that different ethical, ecological and cultural priorities are reflected in (democratic) decisions, the ethical assessment should reflect people's and society's

perceptions of morality. Both to give legitimacy to the assessment, ensure predictability for developers and safety for users and consumers by guaranteeing that important safety and ethical criteria are included in the assessment of GMOs. This is a task that requires both ethical expertise, experience and competence from the ones performing the assessment.

We therefore recommend that an ethical assessment needs to be carried out by professionals with ethical expertise and practical knowledge, and that users and relevant actors and interest groups are actively involved. Furthermore, we disagree with the limitations proposed by the NBAB and recommend that the Ethical guideline includes a wider range of ethical values and principles, especially "non harm", "stewardship", "care" and "naturalness".

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Code Availability Not applicable.

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Declarations

This policy brief is based on a Norwegian text that has previously been published at genok.org (Antonsen and Dassler 2020) and sent to the Norwegian Environmental Agency and The Norwegian Ministry of Climate and Environment. It has been expanded as well as adapted to an international audience both in language, content, composition and relevance.

Conflicts of Interest/Competing Interests We declare we have no competing interests.

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