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DISCUSSION PIECE

With great power comes great responsibility: why 'safe enough' is not good enough in debates on new gene technologies

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Abstract

New genomic techniques (NGTs) are powerful technologies with the potential to change how we relate to our food, food producers, and natural environment. Their use may affect the practices and values our societies are built on. Like many countries, the EU is currently revisiting its GMO legislation to accommodate the emergence of NGTs. We argue that assessing such technologies according to whether they are 'safe enough' will not create the public trust necessary for societal acceptance. To avoid past mistakes of under- or miscommunication about possible impacts, we need open, transparent, and inclusive societal debate on the nature of the science of gene (editing) technologies, on how to use them, and whether they contribute to sustainable solutions to societal and environmental challenges. To be trustworthy, GMO regulation must demonstrate the authorities' ability to manage the scientific, socio-economic, environmental, and ethical complexities and uncertainties associated with NGTs. Regulators and authorities should give equal attention to the reflexive and the emotional aspects of trust and make room for honest public and stakeholder inclusion processes. The European Group of Ethics in Science and Technology's recent report on the *Ethics of Genome Editing* (2021) is important in calling attention to a series of fundamental issues that ought to be included in debates on the regulation and use of NGTs to ensure public trust in these technologies and in regulating authorities. With the great power of NGTs comes great responsibility, and the way forward must be grounded in responsible research, innovation, and regulation.

Keywords New genomic techniques (NGTs) · GMO regulation · CRISPR · Public trust · Post-normal science · RRI

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Abbreviations

CRISPR	Clustered regularly interspaced short palindromic repeats
EGE	European Group on Ethics in Science and New Technologies
GM	Genetically modified
GMO	Genetically modified organisms
NBAB	Norwegian Biotechnology Advisory Board
NGO	Non-governmental organization
NGTs	New genomic techniques
RRI	Responsible research and innovation
SDGs	Sustainable Development Goals

GMO regulation as balancing act

Balancing the potential benefits with the potential drawbacks of gene technology has long been a complicated exercise fraught with pitfalls; one in which EU processes de facto, if not purposefully, have tended to postpone final judgements (Mampuys 2021, pp. 35–36). The development of new genomic techniques (NGTs) has arguably added complexity to, rather than alleviated, the situation. Introducing genome-edited organisms that appear to blur the boundary between the natural and the unnatural/human-made, NGTs have generated increasing pressures to deregulate a wide variety of applications. In the EU, the regulation of genome-edited organisms was brought before the Court of Justice of the European Union in 2016 (Macnaghten and Habets 2020). On July 25th, 2018, the Court responded (ECLI:EU:C:2018:583) by stating that, according to EU law, genome-edited organisms legally come under the definition of genetically modified organisms (GMOs) and should be regulated under the current GMO directive (2001/18/EC). As this seemingly closed the door on a more lenient regulatory treatment of genome-edited organisms, the Council of the European Union ordered from the EU Commission "*a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of new genomic techniques under Union law"* (European Commission 2021, p. 2). Stating that we can "expect that [NGTs] will be increasingly deployed across the various biological kingdoms" (European Commission 2021, p. 14), the EU Commission's study rhetorically presents extensive deregulation and use of NGTs as inevitable.

The relatively low cost of use and easy accessibility of NGTs compared to more traditional modification techniques cause great optimism about their potential to contribute to sustainable development and emerging forms of bioeconomy. Some claim that NGTs, especially CRISPR/Cas9-based editing, can become instrumental in combating major threats to human health, such as dengue, chikungunya, Zika viruses, malaria, and Lyme disease (Long et al. 2020). This would involve the application of gene drives and self-disseminating genetic alteration agents, such as viruses designed to spread as fast as possible (DARPA 2016; Kupferschmidt 2018; Reeves et al. 2018). Others believe NGTs could help improve human and animal well-being; increase agricultural productivity; protect, conserve, and restore biodiversity (Long et al. 2020). Climate change challenges have caused many to argue for the use of NGTs to speed up traditional work in plant breeding to produce plants that are more heat, drought, and salinity resistant (Yu et al. 2019; Shi et al. 2017; Farhat et al. 2019; European Commission 2021). The success of NGTs is imagined not only in terms of their applicability across a range of organisms, but also in terms of their availability. The lower costs and ready-to-use kits of genome editing technologies could render them useful to small- and medium-size actors (European Commission 2021, p. 42; Schmidt et al. 2020; NBAB 2018a, p. 17), thereby leading to the wider dissemination of technological development in food production. Accordingly, there is fear that strict legislation leading to high-cost approval processes might hinder technological democratization processes and lead to a slowdown of scientific development.

The very efficiency and accessibility of NGTs do, however, also create fear among citizens, NGOs, and scientific communities that the number of applications will increase and constitute new, cumulative, and hitherto unknown threats to already stressed ecosystems. They could further pose challenges to forms of production of high socio-cultural importance (European Commission 2021, pp. 82–83; Kjeldaas et al. 2021). Monitoring the long-term effects of genome-edited organisms in the environment may be difficult and cost-intensive, and there are concerns regarding who carries the weight of responsibility should something go wrong. European legislation, based on the precautionary principle, has arguably served European communities well in restricting the use of 'early' GMOs of limited environmental and societal benefit (NBAB 2018a, p. 17; Schulz et al. 2021; NASEM 2016, pp. 14, 22). Accordingly, many emphasize the need for potential legislative revisions to benefit local environments and society at large, rather than merely individual actors in large-scale food production systems. In Norway, the Gene Technology Act (1993) has for a long time demanded assessment of the sustainability, societal benefit, and ethics of proposed GMO applications and ensured that public hearings are part of all assessment processes (Norwegian Gene Technology Act of 1993).[1] In this country, there is at current concern that a 'technology democratization' in terms of some actors' access to new technologies and markets will come at the cost of the broader public's possibility for democratic involvement in assessment processes (NBAB 2018b).

Broad concerns versus the 'safe enough'

Traditionally, the assessment of applications for the deliberate use and release of GMOs into the environment has focused on whether the organism in question is 'safe enough' for human health and the health of the environment, from a natural science point of view. Accordingly, discussions about the desirability and use of GMOs centre on identifiable risks and scientifically established threshold levels of such risk. With this narrow focus on what is scientifically 'safe enough,' cultural and contextual conditions for what constitutes acceptable levels of risk tend to be ignored and it becomes easy to forget that GMOs below established threshold values are at all associated with risks (EGE 2021, p. 20).

[1] Scholars within this Norwegian context term these criteria the "non-safety assessment" criteria (Myskja and Myhr 2020).

For decades, scholars within the social sciences have argued that the scientific framing of questions related to gene technology has a detrimental effect on public trust in science and in food producers, authorities, and democratic processes (Wynne 2001; Jasanoff et al. 2015). Recent research has revealed the cause of this distrust to lie partly in the difficulties small-scale agriculturalists, agricultural, environmental, and humanitarian organizations have had in making their concerns part of the agenda (Kinchy 2010; Hartley 2016; Helliwell et al. 2019; Kjeldaas et al. 2021). Neither the *unforeseen* risks nor the long-term accumulation of *below-threshold, identifiable* risks to the health of organisms and ecosystems that these actors are concerned about fall within the framework of existing risk assessments.

The influence gene edited organisms may come to have on the well-being of established cultural, socio-economic, and democratic systems is also not covered by traditional risk assessments, but belongs to the additional and (in most countries) voluntary assessment of broader criteria, sometimes called "non-safety" criteria (Myskja and Myhr 2020). Issues associated with the maintenance of local production autonomies fall under the latter category. Related concerns include: the preservation of local crop varieties and genetic diversity; access to technology and technological advice; the right to select, propagate, store, exchange, and sell seeds; the right to refrain from using gene edited varieties and to maintain traditional forms of production; the right to be protected from adverse environmental effects like pesticide resistant weeds and novel toxins; and the right to be heard in assessments of novel GMOs (Fischer et al. 2015; Helliwell et al. 2017; Development Fund 2020; Lima et al. 2020). Coexistence between the farming of GM, traditional, and organic crops may be fraught with difficulties, and studies have shown the economic benefits to GM crop producers to be followed by economic as well as social costs to adjacent traditional and organic producers (Binimelis 2008; Bertheau 2013; Mancini et al. 2016).

The externalization of social, economic, and environmental costs of GMOs to non-GMO producers, consumers, and larger society thus constitutes a legitimate concern (Bertheau 2013; Helliwell et al. 2017). The value (economic and other) of already established social and bio-economic systems is rarely assessed and their biological functioning generally not the object of scientific enquiry. In skip-jumping the contribution of these 'other' social and ecological systems and their services, scientific debates on NGTs backed by national policies for the development of new, green bio-economies constitute an economic driving force marginalizing the voices expressing concern for these already existing systems.

In their recent report on the *Ethics of Genome Editing* (2021), the European Group on Ethics in Science and New Technologies (EGE) pinpoints precisely such mechanisms of marginalization to be an effect of how the 'safe enough framing' limits reflection on questions of governance, common goals, and values associated with the use of gene editing technologies. In the EU Commission's recent study (2021), however, there is little to suggest that European authorities will in any significant way move beyond this framing to engage in more profound discussions of how the development and use of NGTs might come to impact human and natural societies and the way we think about other living beings. To the contrary, the study keeps the focus of debate on what conditions would render a given genome-edited organism 'safe enough' for application.

We will here present a series of arguments for why the 'safe enough' framing is not 'trustworthy enough.' Believing that trust is of vital importance to fruitful debates on the application and legislation of gene technology, we will argue that framing the question of whether NGTs are 'safe enough' to be released into the world represents an oversimplification of the issues involved and will continue to create distrust between producers, users, different scientific communities, authorities, and the public. To improve this situation, we discuss why building and maintaining trust among different actors and stakeholders are important and suggest how this can be achieved through open, honest, transparent, and inclusive debate. We moreover highlight the promise of EGE's *Ethics of Genome Editing* report in engendering a new and more constructive climate for debate on NGTs and their regulation. Our hope is that this report will be given the same consideration as the EU Commission's more scientifically focused study (2021) in further discussions on the regulation and use of NGTs at European policy level.

Why trust is important

In modern democratic states, trust is foundational for the relation between authorities and the public. In the case of gene technology, citizens not only want to know that GMOs are judged to be safe, but they also demand that scientific experts and competent authorities can provide clear and transparent reasoning for their judgement.[2] Issues of regulatory approval of NGTs are, however, complex and 'wicked problems' (Mampuys 2021; Rittel and Webber 1973) fraught with lack of knowledge, uncertainties, and feedback mechanisms across a range of scales from the molecular to the ecological and socio-economic. No individual actor can come to know these problems in all their aspects. Precisely in such situations *trust* between actors

[2] With 'competent authorities' we mean authorities which officially possess the mandate, competence, and responsibility to treat issues concerning the regulation and use of gene technologies.

across different sectors and social systems is necessary to facilitate better and more effective communication and decision-making processes. Significantly, this trust is anchored in the conviction that actors behave responsibly and consider (or at least acknowledge) the full range of complexities relevant for the issue or system they represent. Arguments or decisions are considered trustworthy to the extent that they are based on knowledge (what we know and what we do not know) and address values and emotions associated with the issue(s) in question (Carson 2019).

Aspects of trust

Carson's (2019) framework for corporate social responsibility and ethical justifiability provides important insights into the many facets of building trust, several of which we consider applicable also with respect to NGTs. NGTs are fraught with identifiable as well as possible unidentifiable risks, and public trust in them is *reflexive, emotional,* and dependent on the *credibility* of the actors involved in their use, just as Carson (2019; cf. Beck 1992) has shown trust in corporations to be.

NGTs represent novel technologies with the power to modify actual living systems of great complexity and raises a series of concerns regarding their safe use and ethical soundness. Public trust in NGTs is *reflexive* in the sense that it depends upon rational arguments about the safety and value of NGTs and the empirical verification of such arguments. These arguments must evoke trust across the entire chain of development, use and regulation: in the scientific foundation and knowledge construction about NGTs; in the assessment process and how knowledge limitations are handled; and in politicians' willingness to acknowledge and heed the full diversity of public and stakeholder perspectives and assign responsibility in situations in which risks have become threats.

While scientific texts now provide ample evidence of how the new techniques work, much remains obscure about what does *not* work, and why. In their assessment of the status of current knowledge production, the public has to rely on the *credibility* of research institutions and research-funding authorities. Involving ideas of the *Ethos*—the distinguishing character, moral nature, or guiding beliefs of institutions and their practitioners (Carson 2019)—public assessment of the credibility of research and research institutions relies to a great extent on perceptions of basic research. Importantly, such perceptions involve normative ideals like the covering and transparently reporting on all aspects of developing research fields, including their uncertainties and drawbacks. They moreover presume that research produces benefits for the public good. As new developments in gene technology increasingly emerge from applied research performed within science and innovation clusters seeking profitable outcomes in the form of patented products, the credibility of research takes a strain as transparency is weakened and broader societal benefit comes under question.

The *emotional* aspect of trust involves an act of faith that cannot fully be rationalized (Carson 2019, 177; cf. Giddens 1990). Arguably, because the nature and extent of scientific efforts are rarely known to the public, trust in the credibility of science involves in part such an act of faith. For industries or companies harnessing new techno-scientific developments, a significant part of this faith-based, emotional trust depends on whether they are perceived to *belong* in the society in which they operate (Carson 2019, p. 178). Encompassing a sense of place deeply rooted in socio-economic organization and cultural identity, this aspect of trust cannot be satisfied through narrow safety-assessments alone. What it requires are enquiries that already form part of broader assessments, for instance of the actual societal benefit of each specific application of the technology, of its influence on (the environmental, social, or economic aspects of) sustainability, or of the ethics involved in its use.[3] Neither the scale nor the agent of the application of NGTs must be allowed to disrupt the functioning of already existing environmental, socio-cultural, or economic structures the public (or community) finds to be of value.

EGE shows how trust in gene technologies can be (re)built

The EU Commission's study (2021) focuses on questions of safety and scientific technicalities highlighting gene edited organisms' difference from 'old' GMOs and similarity with 'natural' organisms. To some, this line of argumentation comes across as a poorly disguised attempt to rebrand gene technology in ways that legitimize regulatory relaxation (eg., Helliwell et al. 2019; Helliwell et al. 2017). The supplementing report on the *Ethics of Genome Editing*, authored by the EGE (2021), makes a substantial contribution in showing the way such an emerging sense of distrust may be appeased. This report was requested by the EU Commission, which in recognition of the substantial technological power and possible impact of NGTs wanted

[3] These are aspects that are sadly under-researched (Catacora-Vargas et al. 2018; Fischer et al. 2015) and under-represented in debates on gene technology, which might explain the apparent standstill in such debates over the past decades (cf. Bertheau 2013).

the EGE's "Opinion and recommendations" on this technology (EGE 2021, p. 11).

The EGE report represents one among seven sources of expert knowledge providing the evidence on which the Commission will base its proposal for a revision of regulations for plants developed through the use of NGTs.[4] It identifies issues associated with the use of these technologies that are either "particularly ethically problematic," or "new and distinctive to this technology" (EGE 2021, p. 11). We would like to emphasize the value of the EGE report in including and treating in some detail a broad range of issues that ought to be considered in connection with the regulation and use of NGTs. These include (1) the role of humans in relation to nature; (2) the role of genes in defining humans and other species; and (3) the role of science in giving direction to development and shaping public policy.

In bringing forward the issue of human relationship to nature, the EGE report recognizes how ideas of custodianship and responsibility influence judgements on the use of NGTs. The freedom to change the genomes of other living organisms for our own benefit and according to our own standards of productivity, robustness, and nutritional value depends to a great extent on whether we consider such acts to fall within the limits of good custodianship, and whether we are willing to take on custodian responsibilities. Similarly, our views on the role genes play in defining humans and other species will influence considerations of the ethical limits to edits. How much of an organisms' genome can we change before we have altered a fundamental part of its genomic functioning and/or its species characteristics? How many unwanted or redundant traits should we accept as part of our valorization of genetic diversity? And does extensive use of NGTs come with the danger of genetic determinism – a reductive understanding of living beings as first and foremost determined by their genetic makeup? Finally, concerns regarding the role of science in shaping development address structural power relationships and the possibilities for democratic involvement in decisions-making processes on the regulation and use of NGTs. As all of the above are issues associated with fundamental cultural values like freedom, equality, and valorisation of diversity, debates on regulation evading these issues are unlikely to be perceived as comprehensive and trustworthy. Both directly and by bringing these issues and values to the table, the EGE report challenges the standard scientific 'safe enough' framing of debates on gene technology.

[4] Unlike the European Commission, we denominate the document prepared by EGE a 'report' instead of an 'opinion' to underscore the fact that it was prepared by a group of professional (medical, biomedical and health care) ethicists at the request of the Commission. As stated, the report "draws on an already wide range of opinions and statements of national ethics councils, scientific academies, professional societies and other organisations, … on scientific literature" and dialogues with stakeholders (EGE 2021, p. 11). In this sense we find it no more an opinion than the Commission's *Study on the status of new genomic techniques*.

Why 'safe enough' is not 'trustworthy enough'

EGE insists that deliberations on the regulation of gene technology should move beyond the 'safe enough' because this framing is reductive, linked to the technological imperative, and obfuscates the larger questions associated with the development and use of gene technologies: questions like "What world do we want to live in and what role can technologies play in making it reality?" (EGE 2021, p. 5). The expert group critiques the way the 'safe enough' framing allows great power to scientific experts and risk assessments and implies that "it is enough for a given overall level of safety to be reached in order for a technology to be rolled out unhindered" (EGE 2021, p. 5). Critiquing the implicit understanding that "'if it is technologically feasible … it ought to be done'" (EGE 2021, p. 21), EGE argues that the 'safe enough' framing tends to relegate ethical evaluations to "a 'last step' of 'ethics-clearing'" for the approval of a new gene technology or product (EGE 2021, p. 5). As safety is moreover understood in a reductive way which includes only scientifically identifiable risks, the 'safe enough' framing fails to engage precisely with safety aspects that socially and environmentally concerned citizens find most profoundly problematic.

As indicated earlier, one of the features of the'safe enough' framing causing distrust is that it retains the assumption that the science of gene technology occurs in the laboratory and that the organisms produced (although 'deliberately released' [EU 2001]) will be contained within intended production sites. This reinforces the idea that gene technology primarily is a matter for molecular/genetic scientists. Yet with current new techniques vastly broadening the fields of application and introducing the intentional dissemination of organisms carrying edited genetic material, the science of gene technology has moved beyond the core science of laboratories and contained use. It now takes on a form in which the final stages of experimental practices take place in complex and dynamic natural and social systems. In such systems, the full effects of novel technologies are "emergent" and fraught with uncertainties (Funtowicz and Ravetz 1993). The science of such systems has for a long time been recognized as "post-normal" (Funtowicz and Ravetz 1993; Ravetz 2004). However, while gene technologies have evolved, ideas about the science of gene technology and how and where it is performed seem stuck in conceptualizations of what Funtowicz and Ravetz (1993) have termed 'core' (experimental and contained, laboratory)—or at best 'applied'—science. Considering the application and impact of NGTs in real-life settings leads to the acknowledgement that the community of 'reliable witnesses' to the production of scientific facts (the scientific peers of 'core' science) needs to be radically expanded. It needs to include a series of other witnesses (Funtowicz and Ravetz 1993; Haraway 1997; Latour 2004; Ravetz 2004)—like farmers and ecologists, retailers, and consumers. Although these actors (or witnesses) might not perform science, they are nevertheless important producers of knowledge about the effects of scientific inventions in the real-world systems they are released into. Recognizing this will help re-establish the public's trust in scientific experts and make it better equipped to evaluate what kind of expertise—including yet extending beyond the purely technical expertise of gene technologists—will be needed to evaluate the full range of environmental, cultural, ethical, and socio-economic impacts of NGTs.

The'safe enough' framing may also seem less than trustworthy in maintaining the assumption that science itself is value-free, even as it is applied in the resolving of social (policy) issues. Decades of research within fields like science and technology studies have shown such assumptions to be highly problematic (cf. Funtowicz and Ravetz 1993; Latour 2004; Stirling 2012; Jasanoff 2005; Nielsen and Myhr 2007). With EGE, we would like to emphasize how sustaining the idea that decisions regarding the utility and benefit of NGTs are best left to scientific experts in fact strengthens "the tendency of scientific and technological developments to mould governance and indeed ethics" (EGE 2021, p. 21; cf. Latour 2004).[5] Significantly, this tendency is one the public is increasingly aware of (NBAB 2018b; cf. Wynne 2001). We believe it threatens to compromise the public's trust in science (Wynne 2001; Jasanoff 2005; Stirling 2012), as well as in political structures promoting new techno-scientific innovations based on not yet proven claims of future benefits.

The 'safe enough,' 'reversed ethics,' and human relationships to other living beings.

A significant feature of current debates on NGTs is that their proponents turn the 'old' question of whether the use of gene technology is morally defensible around to ask whether it can be ethically justified to *not* use this technology (European Commission 2021; Det Etiske Råd 2019; NBAB and GENEInnovate 2020). This rhetorical reversal of the ethics of gene technology is associated with two correlated narrative framings. One is the consistent framing of edits performed through NGTs in terms of changes that might as well have happened through natural processes of mutation. Ideas of the 'naturalness' of NGTs seem particularly compelling for organisms for which humans feel little kinship, and have influenced debates towards more relaxed regulatory regimes for gene edited plants and microorganisms. Such ideas hide the fact that NGTs—like all genome modifying techniques—at cellular level constitute invasive technologies (Shah et al. 2021). Narratives focused on the emergence of a range of new, 'like natural' GMOs hide both this invasiveness and the high-tech, high-energy requirements of the technology itself. Combining naturalness with a regulative focus on end-point products, they carry less obvious ethical implications than narratives highlighting the processes of applying NGTs to edit important genetic components of a variety of living organisms, potentially in great numbers. Diverting attention away from the processes of development moreover downplays the need to ensure that this development—at all stages of the process—proceeds according to the high standards for Responsible Research and Innovation (RRI).

The second narrative aiding a reversal of the ethics of the debate presents climate change as an oncoming threat necessitating faster genetically based adaptations to changing environmental conditions for a range of different organisms, but for important agricultural crop plants in particular. In this narrative, good human stewardship involves the use of novel technologies to induce targeted and efficient genomic changes that ensure crop plants' survival and flourishing under adverse environmental conditions. Concerns that climate change may exacerbate the challenges of feeding a growing world population strengthen the impact of this narrative and the perceived need for more efficient forms of production (Det Etiske Råd 2019; cf. Schmidt et al. 2020). Exemplified in the Danish Council on Ethics' report on *GMOs and Ethics in a New Time,* the re-framing of the present and immediate future in terms of climate crisis justifies the speedy implementation of new technological measures, like NGTs, and a new direction in ethics.[6]

Climate change narratives like the above tacitly reinscribe ideas about gene technology's status as a form of 'applied science' (Funtowicz and Ravetz 1993) capable of producing

[5] A recent case-study on Canadian policy decisions to allow genetically modified salmon exposes the existence of a positive cognitive bias towards 'science only' arguments at the level of institutional policy uptake (Williams and Kuzma 2022). The study further displays that "the predisposition of those in positions of power and expertise … is to go beyond the science when arguing *for* the approval of GM animals by making appeals to the economy, markets, or sustainability, but to refute arguments of those who oppose GM animals … by forcing them to stick to the scientific risks" (Williams and Kuzma 2022, p. 29). As the authors themselves point out, the study adds to the evidence of the historical "marginalization of anti-GM perspectives that are not 'science based'" (Williams and Kuzma 2022, p. 29).

[6] Emma Foster (2021) and Andrew Stirling (2019) have shown how sustainability discourse after the introduction of the concept of the Anthropocene (and associated ideas of anthropogenic climate change) changed in ways that promoted such more techno-scientific and controlling 'green growth' narratives.

predicted outcomes in (more or less) controlled production systems and under anticipated future climatic conditions. They correspond with product-focused framings of NGTs in promoting the idea that natural (or wild-type) living organisms will be incapable of meeting the recently heightened requirements for climate change adaptation or production efficiency—and need to be improved (Kjeldaas and Antonsen 2021). The pressure for change caused by the emergent climate crisis becomes cast upon individual natural organisms whose genetic 'fixing' comes to represent an appropriate response. This line of argumentation diverts the focus away from the structural causes of anthropogenic climate change and leads to developments that intensify rather than critically assess human systems of control and exploitation of other living beings.

To people with less anthropocentric perceptions and a higher regard for the intrinsic value, integrity, and individual agency of other living beings (Preston and Antonsen 2021), such a reductive and strictly instrumental view will appear untenable. Similarly, the recent reversal of ethics is likely to be perceived as a hollowing-out of ethical arguments based on more respectful, relational approaches. It is therefore important that ethical discussions acknowledge that the power aspects affiliated with the use of NGTs extend beyond issues of structural power within human societies. NTGs will extend the biopower of high-tech human societies over the natural world—giving it new force and taking it along new avenues of development. Accordingly, ethical arguments advancing the need to apply NGTs ought to be balanced by careful considerations regarding what kind of modifications should be allowed (and in what organisms); whether the benefit(s) in question should always be measured from the perspective of the human (or whether the benefit[s] to the organism itself should be considered); and how possible limits to the extent of modification (e.g., the stacking of traits) could be established.

The 'reversed ethics' of current GMO and NGTs debates appears untrustworthy because it neither acknowledges nor discusses these conditions. It moreover tacitly inscribes an intensification of modern progress narratives at the very moment in which such narratives are critiqued for contributing to current environmental degradation (e.g. Stirling 2019; Tsing et al. 2017). We contend that if the history of modern industrial (food) production practices and their detrimental effects on natural environments and social systems (e.g. Rockström et al. 2013; Zimdahl 2018; Haraway et al. 2019) are not brought into debates, promises of how NGTs will come to solve sustainability issues will seem little trustworthy and little attuned to the actual and complex problems of the present. We are therefore concerned by the ease with which the EU Commission's study (2021), like other recent reports (Det Etiske Råd 2019; NBAB and GENEInnovate 2020), presents the new and 'reversed' ethical arguments as equally important to 'traditional' ones rooted in the need for precaution in the application of gene technologies. Decoupled from the systemic critique necessary to reform current industrialized food production practices, the presentation of these new, climate-focused ethical considerations promotes the use of NGTs on organisms within existing production systems at the expense of alternative solutions involving changes to the systems themselves.

We find the EGE's report valuable for the way it brings precisely such missing structural critique and under-communicated environmental concerns into the debate on NGTs. It does so by emphasizing how issues of responsibility arise once problems like biodiversity loss are linked to climate change specified to be of anthropogenic origin, and to the land use and environmental impact of current (food) production systems. The implications of this for the regulation and use of NGTs is that it is not enough merely to claim that NGTs will "contribute to the objectives of the EU's Green Deal and in particular to the 'farm to fork' and biodiversity strategies and the United Nations' sustainable development goals (SDGs) for a more resilient and sustainable agri-food system" (European Commission 2021, p. 2; cf. European Commission 2020). Rather, the assessment of benefits should be sensitive to the specific frameworks of production in which the NGTs will be used. Because these technologies "may both offer possibilities to preserve and diversify biospheres, and come with risks of reducing genetic pools and, hence, diversity" (EGE 2021, p. 4), decisions on whether to use or not use them must be performed case-by-case. Their potential effects on local, cultural, and socio-economic realities indicate that they should also be assessed place-by-place. The benefits of using NGTs in agri- and aquacultural environments will depend largely on already existing frameworks of production and the problems faced (or created) by them. They will vary with the intended scale of the application and to what extent this deviates from current production practices. Furthermore, and to a significant degree, the manifestation of benefits will rely on the existence of legal and political structures ensuring that land left untouched or released from genetically enhanced (and intensified) production systems is allowed to remain untouched and/or become rewilded. Such biological, socio-cultural, and political contexts should all be considered in trustworthy evaluations of the possible benefits of NGTs.

The way forward

NGTs have the potential to contribute positively to the development of more resilient and sustainable forms of food production. Our intention here is not to deny this, but to highlight that it is necessary to better balance hopeful visions with multi-actor, contextualized, and realistic accounts of the *relative importance* of NGTs and how they may come to influence existing ecological, socio-economic, and cultural environments in both beneficial and harmful ways. We need debates about these technologies that are not detrimental to people's perception of the trustworthiness of authorities, scientific environments, and/or food producers. Specifically, competent authorities must take care not to advance anthropocentric and utilitarian principles at the expense of other ethical frameworks promoting a sense of stewardship and care for the environment. As the latter are important to many environmental, agricultural, aquacultural and scientific organizations (Wickson et al. 2016; Stirling 2019; Kjeldaas et al. 2021) neglecting them will damage people's trust in the ethical foundation of regulatory practices.

Generating public trust in NGTs will entail performing research and innovation on gene technology in responsible ways. Instead of claiming that regulation based on the precautionary principle causes unfair treatment of new (genome-edited) GMOs in comparison with other products, one could question whether a shift towards a green and more sustainable economy does not require a *move in the other direction*—towards more precautionary approaches towards other novel scientific innovations whose potential impact on the environment is great. The past decade's (European) focus on RRI and the aims of the *Farm to Fork Strategy* suggest the importance of this directional change. It is also the case that a multitude of NGOs, environmental, agricultural, and research organizations call for more independent, publicly funded, and transparent research on the benefits *and possible drawbacks* of the application of NGTs (Kjeldaas et al. 2021; cf. Gordon et al. 2021). Such research should apply a post-normal science framework on genome-editing technologies and recognize (1) how the role of science changes once it is set to work to solve grand (societal and environmental) challenges; (2) the novel scientific uncertainties and environmental and socio-economic risks introduced by these technologies; and (3) the need to broaden the sense of who counts as reliable witnesses or knowledge producers about NGTs and its products.

Credibility and value transparency through public engagement in research and development projects

The use of genome-editing technologies and novel GMOs involve complex and multi-dimensional 'real-world' problems. Acknowledging this entails conducting research and development projects according to the principles of RRI. Ideally, such projects should be radically transdisciplinary and involve extensive forms of knowledge co-production. The principles of RRI highlight the need to actively engage a range of stakeholders to "substantially better decision-making and mutual learning" (Wickson and Carew 2014, p. 255). Implicit in such statements is precisely the recognition that real-world 'wicked problems' demand different and collaborative forms of knowledge production (Wickson and Carew 2014; Norström et al. 2020), as knowledge developed within existing disciplinary science and innovation frameworks may not be able to account for the long-term, second order, and/or sociocultural effects of novel innovations. In the case of emerging technologies like NGTs, responsible research would involve serious attempts to anticipate potential problems their use might engender and assess available alternatives. The latter may involve avenues of development difficult both to identify and valorize from within environments of science and innovation, which constitutes one of many reasons to involve actors and knowledge holders from beyond the sciences.

RRI frameworks differentiate between 'prediction' and 'anticipation.' In the case of NGTs, predictions formed by developers and scientific communities often involve details on the ways in which these technologies will contribute to the alleviation of environmental and/or sustainability problems. Anticipation, on the other hand, recognizes how "the complexities and uncertainties of science and society's co-evolution" may come to influence the effect of novel technologies (Stilgoe et al. 2013, p. 1571). The RRI distinction between prediction and anticipation implies the need for a more critical attitude towards the way in which "the dynamics of promising" (Stilgoe et al. 2013, p. 1571) shape ideas of the future to accommodate new technologies. Accordingly, promises advanced on behalf of NGTs should be actively balanced with *foresight analysis* (Stilgoe et al. 2013; Jordan et al. 2017) identifying potential problems arising from their use – and the assessment of feasible alternatives.

A recent proposal for responsible governance of genome-edited crops highlights the need for early (narrative-based) and inclusive multi-sector foresight analysis that may bring out complex, polarizing issues and previously unanticipated results (Jordan et al. 2017).[7] The inclusion of actors from beyond biotechnological environments and academic institutions is vital to the identification of unanticipated results precisely because such actors are in different ways affiliated with—and possess knowledge of—the economic and socio-cultural structures of production and the markets

[7] Jordan et al. (2017) (1684) defines narrative-based foresight analysis as a method which "constructs scenarios of broad adoption of genome-edited crops to assess and evaluate their social, environmental, economic, ethical and cultural effects." For an example of unexpected results arising from the application of traditional GMO crops, see Binimelis' (2008) case study on the effect of the introduction of GMO maize on existing production practices and socio-economic structures in the Spanish countryside.

of final products. For food producers in particular, foresight analysis may help identify ways in which the use of NGTs and the introduction of new GMOs may influence the actual *places* in which the production occurs; places in which tradition, sense of identity and community take distinctive forms and function to maintain established practices. Broad participation in processes of knowledge production and assessment in this manner strengthens the quality of research and honors the emotional requirements of trustworthiness.

Multi-sector foresight analyses involving a diversity of actors (Jordan et al. 2017) promise several benefits. They may highlight a range of challenges not identified through scientific risk-assessments alone and a diversity of values and value systems existing beyond those of scientific environments and research-funding bodies. Unveiling other value systems may increase the reflexivity of scientific environments and higher levels of scientific governance (Stilgoe et al. 2013) and offer insights into other ways of framing questions regarding the development and use of new technologies. Broad and inclusive foresight analyses may in this way constitute important supplements to more well-established RRI practices of 'midstream modulation,' in which researchers are encouraged to reflect on the social and ethical consequences of their own scientific practices (Stilgoe et al. 2013, p. 1571).[8] When coupled to similarly inclusive (post-market) assessments of the effects of NGTs on local natural environments and socio-economic structures (e.g., Binimelis 2008), we believe they may moreover prevent the externalization of negative economic consequences arising as a result of changes to existing value systems and/or systems of social organization. In this way, the inclusion of a broad range of actors throughout development and assessment processes contributes to a democratization of values in ways that foster social and environmental aspects of sustainability and engender public trust. Recent calls for responsible governance of gene editing technologies highlight the need for this broad and iterative public engagement (Gordon et al. 2021; Jordan et al. 2017).

To be effective, foresight analysis should occur in the early, planning stages of product or technology development. It should moreover involve the different actors in empowering partnerships that enable real negotiations, and allow for "costs to enhance transparency, alterations in the development process, or [even the] abandonment of certain projects" (Jordan et al. 2017, p. 1685). This is very different from including the public in development processes only to inform, officially consult (but not heed), or placate dissenting voices (Arnstein 2019), which in the long term causes only frustration and distrust. In line with good RRI practice, responsiveness must be the premise of public inclusion. Knowledge production throughout research, development, and assessment processes should moreover be inclusive, transdisciplinary, context sensitive, and anticipatory—and acknowledge intricate social and environmental complexities and systems uncertainties. Current assessment systems focused on human and environmental health arguably fall short of this because they primarily respond to post-development ('downstream') and post-market effects of GMOs and gene technologies.[9] By not allowing 'upstream' multi-sector, multi-actor foresight analyses to broaden the range of possible beneficial *and* detrimental outcomes, such safety-focused assessment systems block the early withdrawal of disadvantageous GMOs or GMO products and contribute to keeping societal cost high for regulatory rejections. Foresight analysis presupposes the use of novel technologies as a tool only when necessary; when better solutions are not available and (substantial) damage to other economic, social, cultural, or ethical values is unlikely. Avoiding the valorization of scientific development *in itself*, and at the cost of other values, inclusive foresight analysis causes trust by allowing a broader horizon of alternative pathways towards the future reflecting a broader variety of values.

Transparency and public trust

Public involvement in innovation and development processes may enhance the *credibility* of biotech developers, research institutions, and competent authorities and address issues important to *emotional* aspects of trust that need to be met in order for NGTs to become welcome additions to already existing food production systems. To satisfy *reflexive* aspects of trust, the results of research on the application of old and new GMOs in different production systems and different regions should be registered in national

[8] Midstream modulation practices acknowledge the influence of researchers and their scientific practices in shaping the form, the function, and the use of technologies under development (Fisher et al. 2006). Accordingly, they seek to foster in researchers and developers the kind of reflexive awareness of the "processes, structures, interactions, and interdependencies … within which they operate" that allows them to regard their own practices in light of broader societal concerns and to reintain an openness towards doing things differently (Fisher et al. 2006, p. 492).

[9] A systematic review of post-market monitoring programs for food, feed, human and animal health performed in 2015 concluded that "several changes would be required in order to conduct comprehensive PPM [post-market monitoring] of GM food and feed in the EU" (ADAS 2015, p. 1). Even with a focus on human, animal, and environmental safety only, the necessary changes included "greater detail on traceability requirements of GMOs, a database of which food and feed products contain which GM traits at specific quantities, consumption data at the branded/product level and a system for reporting the relevance and intensity of effects and unintended effects" (ADAS 2015, p. 1).

and international databases of GMOs open to the public (European Commission 2021; Gordon et al. 2021). Such registers could be supplemented with (or in countries with less strict regulations, substituted by) community-led labelling schemes in which individual GM plant products are labelled as responsible in acknowledgement of developers' sharing of information on the type of crops modified and the modifications performed in open-access data repositories (Kuzma and Grieger 2020).

Labelling will be central in securing public trust in NGTs because it permits post-market tracing through food systems and monitoring that ensures the possible withdrawal of GMOs (or products containing specific GMOs) found to constitute a threat to human, animal, or environmental health. It moreover secures the individual citizen's right to use or refrain from using products developed through NGTs. With respect to the latter, it is important to emphasize that labelling regimes should be understood primarily as a safety valve securing the public (cast merely in the role of consumers) a last chance of communicating its acceptance or rejection of new GMOs (or GMO products) when the possibility of otherwise debating their desirability has been hampered or closed.

Going beyond the 'safe enough'

Going beyond the natural ('core') science focus of the 'safe enough' framing allows discussions of the socio-economic and cultural aspects of possible coexistence of GMO-based and GMO-free forms of production, and of the benefits, drawbacks, and alternatives to NGTs. As claims regarding the NGTs' potential to contribute to the alleviation of climate change effects and to the stable production of food for a growing world population now intensify (European Commission 2021; NBAB and GENEInnovate 2020; Det Etiske Råd 2019), it is the time to activate a larger society of 'reliable witnesses' to critically investigate and nuance these claims. Their robustness should be evaluated in relation to the specific context and scale of the intended use of NGTs; their possible impact on local and global production systems and on the path of research and innovation. This will help avert the risk, identified by EGE, "that genome editing could be hailed as a technological solution for issues of a social nature" (2021, p. 5). It will also avert the risk that the application of this technology is presented as the *only* alternative to business as usual in times of environmental crisis (Wickson et al. 2016). For debates on the regulation and use of NGTs to be trustworthy, they must address the question of whether the need is for higher yield efficiency; for more ecologically and socially sustainable food production systems; for better, more resilient, and just distribution systems; or all of the above. Trustworthiness also depends on the authorities' ability to limit the use of patents to ensure that the application of NGTs and their correlating new products and practices serve broader public interests, not merely private ones (Gordon et al. 2021).[10] This principle must apply for low-income as well as for middle- and high-income countries. Last, but not least, trustworthiness depends on the authorities' willingness to broaden the terms of debate to include values, voices, and concerns originating beyond scientific communities—and to give them equal weight in decisions determining the direction of future societal development. We believe the inclusion of 'non-safety' considerations in multi-actor foresight analyses and assessment processes would be an efficient way to accomplish this.

Conclusion

New powerful technologies with large potential impacts on society, such as NGTs, need to be managed and regulated responsibly to engender public trust that their potential will be released in ways that serve society, the planet, and future generations. The 'safe enough' framing enacted in current regulations through standard risk assessment will not be able to create this trust because it rests on outmoded ideas about core science, on novel and delimited forms of 'reversed ethics,' and on technological progression narratives supported by (yet) unproven benefits and opaque economic interests.

To avoid the conflictual standstill of past debates on gene technology, we need to build trust among different societal actors. This can only happen if all actors' concerns are treated thoroughly and respectfully, and ethical and *emotional* aspects of trustworthiness receive the same attention as *reflexive* (rational and empirically verifiable) ones. Visions promoting the benefits of NGTs should be balanced with inclusive *foresight analysis* and open exchanges regarding the kind of future we want—and the role NGTs could possibly play in this future. Open, transparent, and inclusive societal debate on NGTs' scientific foundation; their benefits and drawbacks within specific geographic, ecological, socio-economic, and cultural contexts; and their overall alignment with agreed-upon development goals seem necessary. There is also a need for honest stakeholder inclusion processes which treat people not as unenlightened and passive receivers of new products and technologies but actively engage them in evaluations of the desirability and potential use of these technologies.

[10] The issue of patents is a complex one associated with a variety of rights among a variety of actors; with distinct ethical issues; and with upcoming complications associated with end-of-patent (or off-patent) events. It warrants separate treatment elsewhere.

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