Routledge
Taylor & Francis Group

Journal of Responsible Innovation

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/tjri20

Paving the way for a softer regulation of CRISPR in Norway: public engagement as window dressing

Marit Svingen

To cite this article: Marit Svingen (2022): Paving the way for a softer regulation of CRISPR in Norway: public engagement as window dressing, Journal of Responsible Innovation, DOI: 10.1080/23299460.2022.2146863

To link to this article: https://doi.org/10.1080/23299460.2022.2146863

Published online: 30 Nov 2022.

JOURNAL OF RESPONSIBLE INNOVATION
https://doi.org/10.1080/23299460.2022.2146863

Routledge
Taylor & Francis Group

RESEARCH ARTICLE

OPEN ACCESS Check for updates

Paving the way for a softer regulation of CRISPR in Norway: public engagement as window dressing[1,2]

Marit Svingen

Centre for Technology and Society, Department of Interdisciplinary Studies of Culture, Norwegian University of Science and Technology (NTNU), Trondheim, Norway

ABSTRACT

Gene editing technologies like CRISPR have raised questions about the need for new regulations throughout Europe. In Norway, the Norwegian Biotechnology Advisory Board initiated a comprehensive process to formulate a proposal for a relaxation of the regulation of GMOs in 2016. This article investigates the Board's initiative as part of the prevailing RRI policy discourse and follows how the process unfolded as a public engagement exercise. A document analysis of the Board's statements and the public's written comments revealed that the Board managed to construct a nuanced public debate around GMOs; however, the Board did not acknowledge that the different interpretations of key terms in the proposal led to very different conclusions as to how CRISPR should be regulated. Therefore, the inclusion of the public appears more as a means to build support for the proposal than as a learning exercise as understood by the RRI-framework.

ARTICLE HISTORY
Received 22 October 2021
Accepted 9 November 2022

KEYWORDS
Crispr; gene editing technology; governance; science policy; responsible research and innovation; Norway

Introduction

Public engagement has an important role in the governance of science and technology and has become institutionalized as a policy tool and objective in science policies, such as the implementation of the responsible research and innovation (RRI) framework in EUs research policy and programmes. The concept builds on the argument that we need to align research and innovations with the values, needs and expectations of society, and that the involvement of the public will create a more socially robust science (Stilgoe, Owen, and Macnaghten 2013). Thus, efforts to engage the public in the governance of research and innovation have become widespread among a wide range of actors, ranging from individual scientists to research councils and national policy plans for research. In this article the author investigates an example of a public engagement initiative in the topic of gene editing technology, and what effect such an initiative can have. The empirical case is a process initiated in 2016 by the Norwegian Biotechnology Advisory Board (hereafter also abbreviated as the Board) with attempts

CONTACT Marit Svingen marit.svingen@ntnu.no
This article has been corrected with minor changes. These changes do not impact the academic content of the article.

to engage the public in the formulation a proposal for a new and 'softer' version of the Gene Technology Act of 1993. Through this process the Board: '(…) *placed public dialogue at the heart of the process*' (Bratlie et al. 2019), and for the first time in their 30 year-long history invited members of the public and stakeholders to give written comments on their statement and proposal. The Board has held a special position in the governance of new forms of biotechnology and gene technology in Norway since the early 1990s, with a mandate to assess and discuss the ethical and societal issues concerning those technologies. It has provided advice and information to the authorities, politicians and the public about the development and implications of emerging technologies (Antonsen 2017; Wahlberg et al. 2013). The purpose of such advice and information has been to aid the regulation process and allow the government to make knowledge-based decisions that are also publicly supported (Antonsen and Levold 2014). Through document analysis and interviews, the author will describe how the Norwegian Biotechnology Advisory Board formatted and performed an attempt to engage with the public in the process of formulating its proposal for the new Gene Technology Act, through facilitating '*(…) an inclusive, proactive and reciprocal dialogue*' (Bratlie et al. 2019).

The following research questions are addressed:

1. What significance did the inclusion of the public have on the Norwegian Biotechnology Advisory Board's final report, and
2. What can this tell us about the possibilities and challenges relating to public engagement in the governance of gene editing technology?

Previous research

Since the CRISPR technology was first harnessed for use in gene editing in 2013, extensive academic and political attention has been drawn to the regulations, frameworks and institutions governing the use of this as a gene editing technology. Current thinking is that the characteristics of the CRISPR technique and its products have rendered the current frameworks ill-equipped to govern and assess the use of the technology. Thus, the quest for appropriate regulatory solutions has been expressed by actors worldwide as a matter of urgency, as the technology raises broad issues that have highly significant consequences for both humans and non-humans (Braverman 2019). There have been increasing numbers of studies of issues relating to the governance of gene editing technology, including those with a focus on the conditions for a socially accountable and responsible governance (e.g. Kuiken 2017; Meyer 2022). Ideas about a particular need for a democratic governance of gene editing technology have become internationally widespread, and scientists themselves have called for a moratorium on particular applications of the technology[3] (Baltimore et al. 2015). Furthermore, the need for new ways of including the public in debates concerning gene editing technology has been problematized in recent empirical studies (e.g. Hartley et al. 2019; Macnaghten 2020), which show that the formatting of public engagement initiatives and the institutional dynamics shaping it are not adequately considered when planning and performing public engagement. Smith et al.'s exploration of and experimentation with ways in which pre-engagement activities and institutional reflexivity can enhance public engagement initiatives in a

UK national funding institution relating to the governance of gene editing technology demonstrate the fluidity and richness of public engagement initiatives and underline the importance of paying close attention to how this dynamic is approached by governance institutions (Smith et al. 2021).

Kjeldaas et al. (2021) has paid close attention to the Norwegian Biotechnology Advisory Board's proposal-formulation process with the aim of exploring how the traditional Norwegian 'non-safety considerations' are handled under strong pressure with a view to relaxing the regulation of gene technology in Norway. They apply a poststructuralist discourse analysis and Latour's model of political ecology to show how the Board and the public's comments coproduce the efforts towards relaxation, and they find that the Board has contributed to maintaining a clear distinction between scientific facts and values, favouring public comments that support scientific aspects more than ethical concerns (Kjeldaas et al. 2021). Whereas Kjeldaas et al. (2021) are primarily concerned with the new proposal's treatment of the 1993 Gene Technology Act's 'non-safety considerations', my aim is to use the case as an example of a responsible research and innovation (RRI) process. Accordingly, my analysis concerns the formatting and results of the Board's proposal-formulation process as conditions and results of particular academic and political demands, such as those of RRI, and calls for public engagement. This article contributes to the STS literature on public engagement by analysing a specific empirical case to make visible the current possibilities and challenges of participatory governance and provide knowledge of how this is formatted by a bioethical institution such as the Norwegian Biotechnology Advisory Board. I show how the Board organized such a process, how the public was involved, and how they responded to the process, and in turn how the Board responded to the comments made by the public. Through an analysis of its proposal-formulation process, I present an empirical example of a process that attempts to 'do RRI' and explore what happens in governance processes that involve public engagement.

Theory – the public in focus

A perceived need for public involvement and democratic assessment of new technologies has become established and developed within academia and research governance since the early 1990s (Irwin 2006; Wynne 2005). Responsible research and innovation (RRI) is the most recent of many concepts aimed at describing the implementation of a more democratic governance of research and technology, and the concept is used by Western scholars and in national and international research policies. RRI has gained notable traction in Norway, where institutions such as the Norwegian Biotechnology Advisory Board have embraced the development from the previous ELSA (Ethical, Legal and Social Implications) programme guidelines to RRI as a concept guiding its work and organization. Ethical reflection was institutionalized in Norway through the Norwegian Biotechnology Advisory Board as early as 1991, thus being one of the first ethical boards focusing on biotechnology in Europe. As the controversial field of biotechnology has vastly developed since the 1970s, new innovative institutions also developed to govern these highly complex and unknown technologies in more democratic manners (Jasanoff 2005), pushed forward by a lack of existing appropriate institutions. One such innovation was 'mediating institutions'; the institutionalization of ethical reflection as a

means to evaluate the ethical consequences of the new technologies (ibid). Ethics as such became a governance tool, but the participation of *laymen* in the effectuation of these ethical considerations was of essence. The Board can thus be considered a manifestation of the policy trends that has pushed the democratization of science and RRI forward, while at the same time being an institution that enforce this very concept in its' practice.

The RRI framework as posed by Stilgoe, Owen, and Macnaghten (2013) focuses on four key aspects: anticipation, reflection, inclusivity, and responsiveness. These aspects represent 'societal concerns and interest in research and innovation' (Stilgoe, Owen, and Macnaghten 2013, 1570), and the institutionalization of the RRI framework is an attempt to embed deliberation on them within the innovation process (ibid). The four aspects can be seen as intersecting and overlapping, and all work towards making the targets for innovation more ethical, inclusive, democratic, and equitable. Thus, inclusion and upstream public engagement are a central part of the RRI concept, which implies that 'social actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society' (European Commission n.d.). This means that questions concerning the broader social and economic goals that emerging technologies should serve should be opened to wider public discussion. The Board's attempt to open up the governance of gene editing technology to wider public discussion is analysed and discussed using the RRI framework and it's four key aspects for responsible governance as both normative and analytical conceptual tools for pertaining public engagement, as well as related STS theory on public engagement.

The idea of public engagement in the development and governing of science and technology builds to a great extent on ideas and research that are rooted in STS, with a tradition for studying controversies relating to the regulation of research and technology (e.g. Callon 1999; Irwin 2008; Jasanoff 2005; Latour 1996; Nowotny, Scott, and Gibbons 2001; Stengers 1999). Such studies show in different ways how the social, contextual and cultural are co-produced with science and technology, affecting our social structures as much as our technological ones. This has given rise to the idea that the development of technology and research is as much a political practice and thus democratic practice as any other, and that the public has a role to play in governing it (Horst 2007; Irwin 2001; Jasanoff 2004). These claims have been made even more apparent in debates about CRISPR and its ability to alter something perhaps more personal than anything else: '(…) the human genome is not the property of any particular culture, nation, or region; still less is it the property of science alone. It belongs equally to every member of our species, and decisions about how far we should go in tinkering with it have to be accountable to humanity as a whole' (Hurlbut, Benjamin, and Jasanoff 2015).

While there are examples of attempts to include the public, such initiatives have proven to have certain limitations. STS critiques have been directed at the underlying motivations and conditions for engagement, and its impact (e.g Stirling 2007; Hartley 2016) and argued against a 'residual realist' assumptions of the public:

> (…) where both democracy and 'the public' are rendered as highly specific, pregiven, and external categories imported into the design and evaluation of participatory practices' (Chilvers and Kearnes 2020).

The first issue deals with the lack of reflection on the performative role of such processes since the public as a stable category does not exist a-priori but must be 'constructed' for each initiative of public engagement (Antonsen 2017; Macnaghten and Guivant 2011). The second critique argues that the concerns deliberated upon are determined by experts and does not deal with the issues concerning the public themselves (Hurlbut, Benjamin, and Jasanoff 2015). Concerns about GMOs have for instance proven to have less to do with the technical issues associated with gene modification, and more to do with cultural and ethical concerns (Macnaghten 2015).

A third critique deals with the impact of public engagement efforts, where the publics' ability to affect the decisions consulted on has been proven to be lacking (Macnaghten 2015). Processes masked as public engagement exercises have proven to be more instrumentally motivated and initiated to secure public trust rather than for the public to help shape the relevant trajectories and decisions (Hartley 2016). Different typologies have been developed to evaluate the degree of influence such initiatives have and can be used for analysing what impact the public had on the Boards' process. Arnstein's 'ladder of participation' is one such tool, evaluating the public's actual power and impact in citizen participation processes through a typology of eight levels of participation: Manipulation, Therapy, Information, Consultation, Placation, Partnership, Delegated power, and Citizen control (Arnstein 1969).

I draw from the STS critique that the chosen format of the proposal-formulation process and the Board's motivations for including the public in the making of the proposal for a new Act, will have significant effect on how the topic in question can be discussed and what conclusions that can be drawn (Delgado, Kjølberg, and Wickson 2011). It is the specific formatting of the proposed participation initiative, and how governance and decision-making are being performed concretely, that will determine who participates and how the public is heard and what they can express. Therefore, it is relevant to investigate both the formatting and outcome of the Norwegian Biotechnology Advisory Board's proposal-formulation process, as this both determines and limits what and how the topic can be discussed by the public. A further aspect that makes the process interesting to investigate, is the novelty of the chosen approach. Hearing statements are a normal part of formal parliamentary procedure in Norway and therefore inviting the public to participate was a new and experimental practice for the Board as a non-parliamentary body. The novelty of the process studied in this article suggests that the Board's ideas about public engagement have shifted, as it attempted a new form of public involvement. In the past the Board's work has ranged from activities that provide the public with information (dissemination) and those that attempt to engage with the public (communication), such as expert debates open to the public and so-called laypeople conferences. As part of this initiative the Board also held open meetings, 7 of them, in different Norwegian cities. These are however not a part of this analysis as it is the development and experimentation of new ways of engagement that I consider most interesting to study. Hearing the public's opinion through written statements in turn informs the parliamentary institutions in a new way, as they formally belong under the government label, rather than the wider and more informal label of governance. To understand the potential implication of such a presumed shift, I investigated how the Board has succeeded in opening up its processes to include the opinions of the public, and I aim to shed light on whether or not this has been done.

Method

The Norwegian Biotechnology Advisory Board's process of engaging the public in gene editing technology in Norway is studied as a concrete example of how an RRI process has been organized. This constitutive work also means exploring which institutions and forums are appropriate for resolving the issues arising from the new technology (Hilgartner 2019). The proposal-formulation process, and hence my analysis, has been informed by a number of written documents that were produced between 2016 and 2019. Documents have been found to play a significant role in negotiations and decision-making in organizations and public administration (Asdal 2015; Justesen 2005). The Board has produced statements with the purpose of both providing information to the public and influencing the governance of genetic engineering and gene editing. The documents are contextual and given meaning through the network of the other related documents, actors, and actions. Written documents enable the transportation of knowledge and power across time and space (Justesen 2005), and it is through the above-mentioned documents the Board can construct 'GMO' and 'CRISPR' as something that can be regulated.

In order to answer the first research question I have analysed 50 different written reports, written submissions, and statements from a number of actors engaged in the proposal-formulation process using a grounded theory approach (Charmaz 2006). The Board produced two statements on the future regulation of GMOs. The first statement was the preliminary proposal published in December 2017, *The Gene Technology Act: Invitation to Public Debate* (Bioteknologirådet 2017). This proposal was originally published in Norwegian (Bioteknologirådet 2017) and subsequently in English in 2018 (Norwegian Biotechnology Advisory Board 2018). The second statement was the revised and 'final' statement published in December 2018, *Proposal for Relaxation of Norwegian Regulations for Deliberate Release of Genetically Modified Organisms (GMO) with Applicability also for EU Legislation* (Norwegian Biotechnology Advisory Board 2018). This version was published after the public had given their written submissions relating to the first statement, following an invitation from the Board. The comments were written by a number of actors, including scientists, representatives of academic institutions, industry, industry organizations, consumer organizations, NGOs, farmer organizations, and the policy sector, as well as private members of the public (a full overview of the actors' written submissions is provided in Table 1). All of the analysed documents can be found on the Board's website.[4] I also held interviews with two central members of the Board's Secretariat: the Director Ole Johan Borge and Senior Advisor Sigrid Bratlie.

With the exception of the two statements issued by the Board, all of the documents analysed in this study were translated into English by me. In addition, two members of the Board were interviewed in Norwegian, and the transcript of those interviews were translated into English. The analysis focused on whether or not and why the different actors saw a need for a revision of the 1993 Gene Technology Act, and how this was reflected in the final statements. The evaluation of the synergies between the statements and the comments has facilitated my discussion of the initiative of engaging the public. I start my analysis with the first document that was produced, the preliminary statement made by the Board.

Table 1. An overview of the actors who responded to The Norwegian Biotechnology Advisory Boards' invitation with written comments, as published on the Boards website. For reasons unknown, there is a discrepancy between the number of actors listed on the website, and the number of actors that the Board report in their final statement.

No	Name
1	De nasjonale forskningetiske komiteene (NENT)/The National Research-Ethical Comitees
2	Universitetet i Oslo/University of Oslo
3	Statens legemiddeltilsyn/The Norwegian Medicines Agency
4	Norges Bondelag/Norwegian Farmers Union
5	NMBU/The Norwegian University of Life Sciences
6	Sjømat Norge/Seafood Norway
7	Vitenskapsmuseet NTNU/Science Museum NTNU
8	NHO Mat og drikke/NHO Food and Drink
9	Geno Norsvin AquaGen
10	Natur og Ungdom/Nature and Youth
11	Landbruksdirektoratet/The Norwegian Agriculture Agency
12	Uni Research
13	Havforskningsinstituttet/ The Institute of Marine Research
14	Norges Bygdekvinnelag/Norwegian/Association for rural women
15	Universitetet i Bergen – Institutt for biovitenskap/University of Bergen
16	Norsk Industri/Association for Norwegian Industry
17	Oikos/Ecological Norway NGO
18	GenØk/Centre for Biosafety
19	Norsk Landbrukssamvirke/Norwegian Agricultural Cooperation
20	Norsk Gartnerforbund/Norwegian Gardners Association
21	Bondens marked Norge/Farmers Market Norway
22	Benchmark Genetics
23	Norsk Legemiddelindustri/The Norwegian Pharmaceutical Industry
24	Naturvernforbundet/Friends of the Earth Norway
25	Småbrukarlaget/The Norwegian Farmers and Smallholders' Union
26	Graminor
27	Nofima/Institute for applied research within fisheries, aquaculture and food research.
28	Kirkerådet/The Council of the Norwegian Church
29	Heidner Biocluster
30	ACD Pharma
31	Tekna/Student Association
32	Ryggvoll melkeproduksjon/Ryggvoll Milk producer
33	German Federal Office of Consumer Protection and Food Safety
34	Nettverk for GMO-fri mat og fôr/Network for GMO free food
35	Uavhengige forskere ved NIBIO, NMBU og UiO/Independent researchers
36	Dorothy Dankel
37	Liv Langberg
38	Øyvind K Nilsen
39	Audun Nerland
40	Knut Morten Nyberg
41	Sigmund Ramberg
42	Pritam Bose
43	Åsmund Kaupang og Camilla Jensen
44	Sigmund Berg
45	Finn Kolberg
46	Thomas Tichelkamp
47	Johannes Gaare

Empirical data – a necessary revision of the gene technology act?

On 5 December 2017 the Norwegian Biotechnology Advisory Board published the first document: *The Gene Technology Act: Invitation to Public Debate* (Bioteknologirådet 2017). The 52-page statement was the result of an extensive process whereby the members of the Board as well as members of the Board Secretariat took part in an 18-month process to produce it. The process lasted from mid-2016 to the end of 2017,

during which time the regulation of GMOs was put on the agenda of each Board meeting. Contrary to ordinary practice, the regular members (16 members) and deputy board members (5 members) were allowed to pass votes on the various suggestions raised during the proposal-formulation process. The number of members voting decreased out of organizational reasons by the second voting, from 20 members in the first round, to only 14 members in the second.

In its published statement, the Board proposed a 'new way forward' for the regulation of GMOs, and it put emphasis on fostering a renewed public dialogue and debate. For the first time, the Board invited 'the public' to submit their comments and discuss how GMOs should be regulated. The comments were subsequently incorporated into the final statement, but as is shown in the following, only to a very limited degree. A proposal for a revision of the Gene Technology Act was presented to the Norwegian Government one year later, on 4 December 2018.

The preliminary statement expanded on a range of issues relating to genetic engineering techniques but primarily focused on the regulation of the deliberate release of GMOs. The Board acknowledged a multitude of issues that new gene editing technology raises. Chapter by chapter, it discussed alternative ways of looking at these issues, including the following: the relevance of the debate; the technical aspects of new versus old genetic engineering techniques; existing regulations; alternative ways forward; labelling requirements and the internationally established assessment criteria; risk, health and safety; and the particular Norwegian criteria of sustainability, societal benefit and ethics.[5] The Board selected four questions that necessitated input from the public:

1. What should be covered by GMO regulation?
2. How should these organisms be regulated?
3. What are appropriate requirements for labelling, traceability and monitoring?
4. How should contribution to societal benefit, sustainability and ethics be weighted?

The Board provided its own answer to these questions through its preliminary statement. The majority of the Board members argued that new gene editing technology invoked a revision of the 1993 Act, and the most central part of the statement was the proposed level-based approach to a new regulation of GMOs. The Board emphasized that the new regulation could provide a more effective approval process. It argued that this level-based system should be product-based, meaning that the level of regulation would be determined by what changes had been done to the genome of the organism and/or product, rather than determined by which method had been used, as in the current legislation. This opened up for the possibility that 'traditional' methods that are currently exempt from regulation, such as mutagenesis, could be regulated similarly to classical gene modification and new gene editing techniques, something that the majority of the Board members supported in the preliminary statement. As in the 1993 Act, the proposed level-based system, would use the category of 'natural' as a dividing line for determining the severity of the alteration made: techniques that produced changes that occurred or could occur naturally by biological processes would be considered safer than those that would not occur naturally. The statement suggested that first and most relaxed level, where small changes to the gene that existed or could have occurred naturally, would only require a 'Notification', as shown in Figure 1.

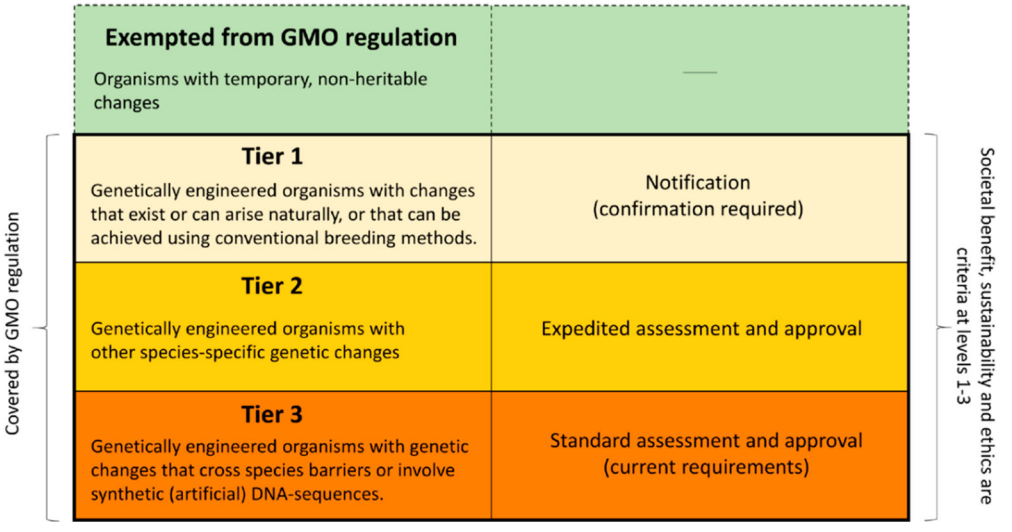

Figure 1. The proposed tiered regulatory framework for GMOs (Bioteknologirådet 2017, 27).

Other (more substantial) changes to the genome within species would generate the need for an 'expedited assessment and approval'(Figure 1), while changes between species would require a standard assessment and approval, the same as the 1993 Act requires of all genetic engineering techniques on a case by case basis.

The proposed level-based system would mean a liberalization of the regulation of GMOs compared with the existing legislation, and the importance of a more efficient and simpler approval process was heavily underlined by the Board: 'the current regulatory landscape will prevent the use of gene editing to rapidly develop novel agricultural products to deal with the impact of climate change and human population growth' (Bratlie et al. 2019, 1). The Board took the position shared by many researchers and industries within the field of biotechnology in that it regarded the gene editing technique CRISPR as having great potential that needed to be harvested. Such actors have contributed to shed a new and positive light on genetically modified food and products, arguing that it will lead to new and better ways of developing food production and breeding. This optimistic position attributes CRISPR as having great potential and future possibilities to develop aquaculture and agricultural products that are thought to benefit humans, animals and the environment. From this position, the current legal frameworks in both Norway and the EU are thought to hinder the fulfilment of this potential, and the realization of this perceived potential is thought to depend on a more lenient and innovation-supportive regulation (Bratlie et al. 2019).

How did the public perceive the need for a revision of the Gene Technology Act, and to what extent was the foundation sufficiently solid enough? In the following section, I analyse the written submissions to highlight the main tendencies in the opinions of the public.

Calling for a revision

The Norwegian Biotechnology Advisory Board argued in its preliminary statement that new technology was challenging the current Gene Technology Act, the 1993

Act, to such an extent that it needed a revision, and that a new level-based system was necessary to simplify and expedite the approval process (Bioteknologirådet 2017). A large group of actors agreed with this view to varying degrees: some expressed agreement with the need for a revision to adapt to the recent technological development, while some actors had already long thought that the existing regulation had been too strict.

In a written submission to the Board, the Norwegian University of Life Sciences (NMBU) expressed agreement with the Board's view on the need for a revision, and showed support for a level-based regulation system for the deliberate release of GMOs:

> In the light of the rapid development and use of new techniques for gene editing, particularly the CRISPR technique, it is completely necessary. Gene editing makes it possible to do genetic changes that cannot be separated from natural or induced changes (mutations) in the DNA. It is therefore necessary that the regulation of GMO is based on an assessment of the characteristics that are changed or added, and not on which technique that is used, like in the current regulation. (Norges miljø- og biovitenskapelige universitet 2018)

NMBU's arguments for this revision focused primarily on the technical characteristics of new gene editing technology. Additionally, both the Norwegian Medicines Agency (Statens leggemiddelverk) and the Pharmaceutical Industry Association (Legemiddelindustrien) expressed support for the proposed level-based system in their written submissions, and they were concerned with a need to open up for a simpler and less bureaucratic regulation (Legemiddelindustrien 2018; Statens legemiddelverk 2018). The Pharmaceutical Industry Association argued that the regulation of gene editing needed to become 'timelier,' suggesting that the old regulation is outdated and not equipped to regulate the development of medicine today. It expressed a desire for a simpler approval process for gene editing and gene modification that allows for more research and practice of these methods. The Association argued that this would contribute to the development of necessary medicine and to the benefit of patients. In its written submission, the Norwegian Medicines Agency (Statens legemiddelverk 2018) argued that Norway should be a 'driver for a pragmatic approach to this field, so that unnecessary hindrances do not slow down the development of new therapies for diseases where there is a great uncovered need today'.

Furthermore, in its written submission, the Norwegian Medicines Agency pointed to Norway being left lagging behind if the regulation remained as restrictive as today. It claimed that the USA and many Asian countries have facilitated clinical studies in a better way than Norway (Statens legemiddelverk 2018). The matter of international competitiveness was an even stronger argument for the breeding companies Norsvin, Geno, and AquaGen, as well as the trade organizations Benchmark Genetics and FoodDrinkNorway (NHO Mat og Drikke). In their written submissions, the three companies Norsvin, Geno, and AquaGen emphasized the importance of Norway having similar rules and regulations as the EU for Norway to stay competitive in the international market (Norsvin and Aquagen 2018). They argued that gene editing is potentially a strong tool within genetics and breeding, and the regulation of the Gene Technology Act might prove to have significant impact on them (the three companies) in the years to come.

No new regulation needed

A substantial part of the comments on the Norwegian Biotechnology Advisory Board's first statement voiced disagreement on the need for a new regulatory system for the regulation of deliberate release of GMOs. A substantial group of actors argued that the 1993 Act is sufficient to regulate the use of new gene editing technology. They opposed the proposal for a new regulatory framework, arguing that there is too little knowledge and experience of the new technologies to introduce a level-based regulation.

Both the Norwegian Famers Union (Norges Bondelag) and the Norwegian Farmers and Smallholders Union (Norsk Bonde- og Småbrukarlag) framed consumer rights and trust as important reasons for why they rejected the need for a new Gene Technology Act. The Farmer's Union argued that the 1993 Act has benefited the country well, as it safeguarded the food that Norwegians consume: 'Norwegian agriculture is completely dependent on the trust of the consumers. We can therefore not support a management of the GMO field that could jeopardize this trust' (Norges Bondelag 2018).

The Norwegian Farmers and Smallholders' Union argued that the current law contributes to a high level of trust, as it does not hinder products from reaching the market and it ensures the safety of each GMO product individually. The Union also argued that Norwegian consumers' trust in the food produced by its members is an important factor, and another reason the law should not be revised.

Another group of actors who argued against the Board's proposed level-based system is Friends of the Earth Norway (Naturvernforbundet) and their youth branch Nature and Youth (Natur og Ungdom). The two environmental NGOs framed risk and uncertainty as important reasons for their opposition to the proposed regulation, as they considered a softening of the regulation to be a great risk for ecosystems and the environment as a whole (Natur og Ungdom n.d.; Naturvernforbundet 2018). They were concerned about unforeseen consequences of altering genetic material and therefore thought that regulation would be the only firm way to deal with the possible negative impacts of gene editing. They also argued that the consequences of developing gene editing technology in general are unknown and that implementing a level-based approval system before more is known about the consequences would be a mistake. Both groups of environmental actors were strongly against the proposal of a level-based system, as it would mean a drastic change compared with present-day practices under the Gene Technology Act. They wanted the existing regulation to be kept and would rather use the built-in flexibility that exists in it. This flexibility has not been used to a great enough extent so far, and in its written submission, Friends of the Earth Norway stated: 'the existing Gene Technology Act will not be of hindrance for the approval of GMOs that can be useful' (Naturvernforbundet 2018).

A third group of actors was opposed to the immediate implementation of a level-based regulatory system as suggested by the Board, due to too little knowledge and experience of gene editing technology. Like the actors concerned with the agricultural and environmental aspects, GenØk (Centre for Biosafety) and Nofima (Norwegian Institute of Food, Fisheries and Aquaculture Research) emphasized the need for more scientific knowledge in order to address the issues of uncertainty and risk concerning gene-edited products (GenØk-Senter for biosikkerhet 2018; Nofima n.d.). The two research institutions argued for a need for more focus on the unintended consequences of alterations to the

DNA, and that the possibility of off-target mutations suggests a need for a case-to-case assessment that can be done with the current Gene Technology Act. They emphasized that the complexity of gene-edited products makes it difficult to regulate with pre-set levels of assessment, and that the range of relevant considerations for approving GMOs are broader than what can be determined by regular risk assessments. Nofima additionally argued for openness and inclusion, and that the public should be given the chance to comment on each product that is assessed.

The reviewed comments exemplify the differences in opinions on the first and second questions that the Norwegian Biotechnology Advisory Board raised in its statement about what should be covered by GMO regulation and how the covered organisms should be regulated. There is diversity in reviewed actors' arguments about why they were opposed to or in favour of a new regulation. To summarize, a scant majority (23) were in favour of the proposed framework, and almost as many (20) were against it. The commentaries relating to the Board's third question concerning labelling and traceability show that almost all of the actors agreed that GMO products should be labelled in one way or another, regardless of how they perceived the need for a revised Act. In the next section, I discuss how the actors responded to the fourth question, which concerned how contributions to societal benefit, sustainability and ethics should be weighted.

Sustainability, societal benefit and ethics

In the Norwegian Medicines Agency's written submission, the Agency argued that the demand for sustainability, societal benefit and ethics is not at all relevant for the approval of new treatments (Statens legemiddelverk 2018). The Agency argued that this is not considered relevant for the level of risk; rather, it is only the characteristics of the final product that effect the level of risk. By contrast, in a separate written submission to the Board, the Norwegian Institute of Marine Research argued that sustainability, societal benefit, and ethics should be included in an approval process for GMOs, as it would be an asset for the approved products: 'This will help gene-edited products to gain legitimacy' (Havforskningsinstituttet 2018). The Institute saw the criteria as potential hallmarks that would benefit the competitiveness of products that are approved. These contrasting opinions can also prove illustrative of the differences between the assessments of medical health and agriculture/food production application.

In common with both the Norwegian Medicines Agency and Norwegian Institute of Marine Research, the University of Oslo (UiO) was positive towards a revision of the current regulation, yet it argued that in order to prevent the development of unwanted effects, the three assessment criteria (i.e. sustainability, societal benefit, and ethics) should be followed strictly under a new Gene Technology Act (Universitetet i Oslo 2018). It can be argued that UiO considered the criteria more as parameters of a precautionary approach, than as labels that provide competitive advantages on the market. In complete contrast to the Norwegian Medicines Agency, UiO argued that ethics is too difficult to assess according to pre-set rules and that it should rather be determined case-by-case, allowing for discretional assessments depending on the case at hand. This argument is in strong opposition to that of Tekna (Norwegian Society of Graduate Technical and Scientific Professionals), which considered previous efforts to operationalize the aspects sustainability and societal benefit as being negative and the criteria as

preventing discretional assessment: 'Tekna expect that personal conceptions and principles will guide the demands for consequence analysis to less an extent when it comes to health, environment, sustainability, societal benefit and ethics' (Statens legemiddelverk 2018).

Thus, there were different conceptions of what can be expected of a framework for assessing ethics, societal benefit, and sustainability, and there were differing opinions as to whether such assessment is at all possible. The actors also disagreed on the level at which these criteria should be assessed, namely whether they should serve as symbolic visions that are encouraged for all new innovations in society or whether the criteria should be demanded for gene technology specifically or even assessed for each individual product.

The Centre for Biosafety (GenØk) was positive towards ensuring that GMOs are considered sustainable, societally beneficial, and ethical; it went farthest among the actors in acknowledging the three assessment criteria as very important in the regulation of GMOs (GenØk-Senter for biosikkerhet 2018). However, GenØk argued that too little is known about what it means for a GMO to be sustainable, societally beneficial, and ethical. Similarly, there was disagreement among the other actors' as to the meaning of three terms. The Norwegian Biotechnology Advisory Board argued that new gene editing techniques could be used to make products that resonate with the three aspects – societal benefit, sustainability and ethics – because they allow for less use of pesticides and artificial fertilizers. This view was also shared by the Norwegian University of Life Sciences (NMBU) in its written submission to the Board:

> We place emphasis on our research's capacity to be useful to society and contribute to sustainable development from sea and land. A level-based system will ensure the use of gene technology in a socially beneficial and sustainable manner without negative consequences for health and the environment. (Norges miljø-og biovitenskapelige universitet 2018)

The Norwegian Farmer's Union argued that new gene editing techniques can be considered unsustainable, not beneficial to society, and unethical because they interrupt nature's ecosystem. Thomas Tichelkamp, writing in a private capacity, presented a similar argument in his submission, and considered societal benefit, sustainability and ethics as aspects that support fundamentally different developments than the development of GMOs: 'A sustainable solution to save agriculture would, for instance, be a less destructive consumer pattern, and farming that is on-board with nature and the stimulation of biologic diversity' (Tichelkamp n.d.). The Norwegian Ecological Society (Norsk økologisk forening), Oikos, argued similarly that CRISPR and gene drives are not sustainable, socially beneficial, or ethical because they maintain the development of 'unnatural' and industrial farming: 'In hopes of solving problems in the industrial agriculture. From what we have seen so far, GMOs do not represent a sustainable solution. Instead, it is in all manners possible an attempt to repair a highly unethical and unsustainable agriculture' (Oikos 2018).

The comments presented above show that the actors differed in their understanding of the terms 'societal benefit', 'sustainability', and 'ethics'. Furthermore, the conflicting understandings and interpretations of what sustainability can be in terms of gene editing make it difficult to take a stand on a proposed regulatory framework that suggests assessment according to the criteria. The conflicting interpretations also lead to very

different conclusions as to what kinds of regulation are needed. Some actors argued for the need for a revised Gene Technology Act in order to comply with the three assessment criteria, while others argued for the need to keep the 1993 Act because it already complies with them.

The Norwegian Biotechnology Advisory Board's final statement

The selected commentaries demonstrate diversity in the public's reception of the Norwegian Biotechnology Advisory Board's proposal and reveal disagreement with both the current regulatory system for GMOs and the use of new gene editing technology in Norway. The range of different answers to the four questions posed by the Board reveals that the actors disagreed on what should be covered by a new Act, as well as what it means to assess GMOs based on the criteria sustainability, being of societal benefit and being ethical. How did the Board accommodate this difference in opinions when preparing its final statement?

The Board's final statement was issued in December 2018 and ceremoniously presented to the then Minister of Climate and the Environment, Ola Elvestuen. In the statement titled *Proposal for Relaxation of Norwegian Regulations for Deliberate Release of Genetically Modified Organisms (GMO) with Applicability also for EU Legislation* (Norwegian Biotechnology Advisory Board 2018) the Board took an even more progressive attitude towards the revision of the Gene Technology Act of 1993, as reflected in the title of the statement. This proposed softening is in opposition to actors who wanted the current Act to remain as it is for the future or even to become more restrictive.

Of the relatively few adjustments made by the Board in the final statement in response to public comments, all relate to the specific four questions asked in the preliminary statement. Comments that addressed other aspects of GMO and/or new gene editing technology or that addressed the issue of GMO and/or gene editing technology more broadly were not addressed in the final statement. The Board considered that those comments fell outside the scope of the final statement and were not relevant to it. Thus, the Board was not open to comments other than those relating to the questions it had asked, and the specific handling of the proposal-formulation process played a large role in determining what could be discussed and, even more importantly, what it considered to fall within the scope of its statement.

In both the final proposal and the interviews, the Board underlined that the proposal-formulation process and comments from the public had led to a change in the voting on certain aspects and thus proved the value of having this type of process. One of these changes was a shift in the votes relating to labelling and monitoring. While a majority vote by only 17 members was in favour of a differentiated labelling system in the first round of voting, the members were unanimous in pushing for the system in the second round of voting. This was a point that almost all actors who commented on the preliminary proposal agreed upon too. This could indicate that some of the members were uncertain in the first round, and that the comments from the public helped to change their view, thus making this the most evident effect that the process had on the Boards' voting.

Another shift in the voting from the preliminary statement to the final proposal concerned the question of whether all GMOs should be regulated by the Gene Technology

Act. In the first round of voting, a majority of the Board members (12 out of 20) voted in favour of all organisms being covered by the Gene Technology Act and that no exceptions should be made. In the second round, a majority of the members (9 out of 14) voted for making a distinction that would keep 'conventional methods outside the regulation due to 'pragmatic reasons,' consequently making a framework that only covered organisms edited with 'gene editing technology' (Norwegian Biotechnology Advisory Board 2018). Thus, the methods used to alter genes were regarded as more significant than the actual alterations made, or even the end-product. This view differs from the level-based regulation framework proposed initially, when the Board emphasized the need for a regulation that would focus more on the product and the changes being made, than on a process-based regulation, and it is a substantial change that is recognized by the Board itself in its final statement.

Furthermore, the analysis of the two statements issued by the Board and the reviewed comments by the actors shows that some aspects related to changes in the voting that are not acknowledged in the final statement. In the preliminary statement, the vote on the proposed tier-based framework revealed that 90% of the Board's members voted in favour. In the second and final statement, the percentage dropped to 78%. The numbers indicate that the Board members were less positive to a softening of the law by the time the final statement was published, yet the Board pushed forward with a clear message towards a national audience, as well as to an international audience.

A lesson for the EU

The Norwegian Biotechnology Advisory Board's report 'A novel governance framework for GMO', was published in 2019, and extended its recommendation for the tiered regulatory framework to the EU (Bratlie et al. 2019). In the report, the Board emphasizes the importance of developing a regulatory framework that supports technological development within the field of genetically modified organisms, and describes the EU's current regulation as a hindrance to innovations in the field: 'We therefore propose a differentiated regulatory framework that would considerably lower the regulatory hurdles for certain uses of genetic engineering, and would stimulate innovation and development to the benefit of society, while allowing flexibility in terms of risk assessment' (Bratlie et al. 2019). The report provides an even clearer narrative of the Board's future-oriented visions, in which its motivation is framed as being progressive and pro-innovation. The Board emphasizes that its recommendations were supported by the majority of the members of public whom they consulted during the proposal-formulation process, and points to the actors who have shown support for the revision of the Gene Technology Act and for the Board's proposed tiered regulation framework:

> There was broad support for our proposal, but we also received important feedback that has helped us to fine-tune the model. A large majority of scientists, academic institutions and industry viewed the proposed framework not only as acceptable for commercial development, but also as a potentially enabling framework to ensure that safe, societally beneficial and sustainable products have a clear and manageable path to market authorisation. (Bratlie et al. 2019)

Despite citing central arguments from the minority that voiced concern and resistance to the novel framework, the Board emphasized that those actors also had positive recognition of future potential use of gene editing within food production. The Board described how public dialogue was at the heart of the process, suggesting that its initiative also serves the EU as demonstration of 'how to facilitate an inclusive, proactive and reciprocal dialogue' (Bratlie et al. 2019). However, as I have shown, only a scant majority of 23 actors who commented on the preliminary statement expressed support for the proposal, and almost as many, 20 actors, were opposed to the framework proposed by the Board. Those who opposed the recommendation seem to have been somewhat overlooked in the final statement and the 2019 report, suggesting that the Board was more sensitive to the echo of its own voice and the answers that supported its suggested framework. Only answers that conformed to the specific format of the proposal-formulation process outlined by the Board were acknowledged, thus hindering other views from being considered relevant. The formatting of the proposal-formulation process serves to limit what is allowed to be discussed and what is considered relevant concerns in the statement. It neglects to consider the perspectives of those who are concerned with issues such as the overarching organization of agriculture or market structures. This makes it of interest to look closer at the impact of the public consultation and what the Board had to advice the EU about how to facilitate public dialogues.

Creating room for the nuances

In interviews with the two central members of the Norwegian Biotechnology Advisory Board's Secretariat, the need for the proposal-formulation process and renewing of the Gene Technology Act was mainly narrated as motivated by the legal controversies that were being raised internationally due to the new gene editing technology, CRISPR. However, the chosen approach and formatting of the process was determined by past experiences of discussions about GMOs in Norway. According to the Senior Advisor, the Board saw the invitation for debate and comments from the public as a means not to end up with a repetition of a polarized and locked debate:

> The GMO debate that everyone has been aware of has been quite polarized […] there hasn't been any overlap in the attitudes. But what is happening now is that there actually is [overlap]. We've seen it through this societal debate that there are things that people agree on. And to be able to make that little overlap, to get people to discuss things constructively, that's a progress, right? […] And there is still debate and there is still disagreement, but the debate has become more constructively directed. (Sigrid Bratlie, interview 20 May 2019)

Arguably, the new formatting of the proposal-formulation process can be claimed to have had the desired effect in opening up the traditionally locked debate, and the Board managed to create room for the public to discuss the regulation of GMOs more constructively than in the past. Members of the public were given the opportunity to address societal and ethical issues and not just technical questions, which served an effective means of shoving the GMO debate out of its current stalemate (Jasanoff 2019). The opportunity aligned well with the RRI frameworks' ambition to 'interrogate the social and ethical stakes associated with new science and technology' (Stilgoe, Owen, and Macnaghten 2013, 1573), and suggest that the Board is one of few actors in Norway that can be said to perform anticipatory work on the topic of gene editing technology. The Board's

preliminary statement suggest that it aims at providing anticipatory foresight on a broad range of issues, but the Board's favouring of certain aspects (which are only technical, according to Kjeldaas et al. 2021) indicates that its motivation to be anticipatory is also founded upon its wish to shape the agenda for the regulation of gene technology in Norway in a pre-set mould.

The debate relating to the assessment criteria – sustainability, societal benefit, and ethical concerns – had particularly strong bearing for the actors, arguably due to the terms' inherent universal validity and the fact that they underpin societal values and purposes; they are co-productions of social, ethical and technical knowledge. I would argue that such 'boundary objects' (Star 2010) – terms that had meaning for all the actors – can be considered useful when creating spaces for public deliberation and nuanced discussion. The format of the proposal-formulation process gathered the actors around a common basis of discussion, and in this respect the public engagement initiative was successful in allowing the public to discuss matters that were relevant to them. Many actors expressed explicit gratitude for being granted a role in the proposal-formulation process and for the opportunity to comment and demonstrate the democratic value of asking questions that addressed issues that were relevant to them. In this respect, the Board has succeeded in embedding the RRI dimension of inclusion in its work, but the extent of this inclusion as a learning exercise still depends on how it succeeded in accommodating the answers to its four questions. In the Board's summary of the received comments, it stated that there was disagreement among the public about the weighting of the three particular Norwegian assessment criteria:

> A majority thought that societal benefit, sustainability and ethics should still form part of the assessment of GMO. However, there was disagreement about how the criteria should be weighted. Some argued that there should be a positive contribution, while others argued that requirements should be differentiated. (Norwegian Biotechnology Advisory Board 2018, 6)

The focus on how the criteria should be weighted in an approval of GMOs implied that the disagreement concerned whether the criteria should be differentiated based on the level-based framework. However, as the comments showed, the reality was that the disagreement among the actors on the question was much more extensive. The different opinions relate not only to what role sustainability, societal benefit and ethics should play as assessment criteria, but also how they relate to gene technology in a broader perspective. The Board only acknowledged that a majority of the comments on its preliminary statement claimed that these criteria are important in the assessment of GMOs. However, there is an important distinction between those who see novel gene editing technology innovations as beneficial to society, and those who see it as beneficial to society to keep the current and more strict regulation.

Despite the successful efforts to create room for public debate, the choice to 'close the black box' (Latour 1987) on the different interpretations of societal benefit, sustainability and ethics means that the public engagement initiative was lacking in some respects. The lack of acknowledgement of the diverse interpretations and responsiveness to the concerns for the broader perspectives indicate that the Board was not fully willing to engage with the public's comments, thus hampering the quality of public engagement as a learning exercise as posed by the RRI framework. Also, its willingness to assign

the public's support to its final statement leaves the initiative looking like an instrumental act orchestrated with the purpose of fulfilling the Board's mandate to give advice and have its statement tested and found valid by the public. Determining the level of power held by the public in this process using Arnsteins' ´ladder of participatioń, I argue that the Boards' process is a form of consultation which Arnstein determines as tokenism:

> When they are proffered by powerholders as the total extent of participation, citizens may indeed hear and be heard. But under these conditions they lack the power to ensure that their views will be heeded by the powerful, When participation is restricted to these levels, there is no followthrough, no 'muscle,' hence no assurance of changing the status quo' (1969).

Conclusions

In November 2020 The Norwegian Government appointed a committee to discuss and consider 'gene technology, new techniques and regulation of gene modified organisms' (Klima- og miljødepartementet 2020) as part of traditional proceedings. It will not be possible to see how the ambiguity reflected in the comments made by members of the public concerning the three assessment terms (societal benefit, sustainability and ethics) will be dealt with and what actors are given power to define them until the question of a revision of the Gene Technology Act is handled within the parliamentary political system. As demonstrated by the proposal-formulation process, public participation served well in terms of bringing different actors 'out of the trenches' and creating a nuanced debate about the regulation of new gene editing technology. Debate and discussion are in themselves a desirable measure and purpose, and the opportunity to include a multitude of voices that would like to be heard on the topic can in its own right be a part of a more 'responsible governance' of gene editing technology. However, the way in which organizers accommodate and use such voices is an equally important measure, and an important question often raised by researchers within the field of public engagement and RRI is how public engagement initiatives can avoid the 'slippage to a reductive rendering of engagement as the right thing to do or as a way to secure public acceptance' (Hartley et al. 2019, 3). While raising debate and allowing voices to be heard is a democratic exercise, the Norwegian Biotechnology Advisory Board's failure to engage with the multitude of meanings of the boundary objects, as well as its eagerness to claim support from the public, suggest that the public engagement initiative was founded more upon instrumental and normative motivations, namely both to support its suggested regulatory framework (instrumental) and because public inclusion is 'the right thing to do' (normative reasons) compared with substantive rationales, as public engagement will lead to better decision-making and more socially robust science (Calvert 2014). The Board succeeded in opening up the debate to such an extent that it has left a proposal developed on the basis of politically charged terms with a multitude of meanings in need of considerable definition before they can function as assessment criteria in a differentiated regulatory framework. In other words, the 'boundary objects' do serve well for the purpose of creating debate for democratic reasons. However, the chosen format of the proposal-formulation process fostered an instrumental and normative rational: the choice to gather written comments and define the scope of the questions narrowly made it more difficult

to adhere to the diversity of opinions and the broader scope of concerns. A laypersons' conference, such as the Board has held in the past, could have served the purpose of fostering such debates better, as it has granted the public more power to set the agenda and allowed for a two-way communication between various actors.

In line with the claims of Smith et al. (2021), I argue that the Board lacked institutional reflexivity concerning the rich dynamics that shape public engagement. This leads me to conclude that the Board's formatting of the proposal-formulation process and its lack of engagement with the knowledge and opinions of the public is problematic in at least two respects: it leaves a weak proposal or even weak regulatory framework, and it suggests that public engagement initiatives are still to some extent 'top down' and instrumentally motivated. In this particular process, the Board has at least partly neglected its mission, i.e. a broader ethical and social analysis or at least discussion. The Board proved reluctant to actually open up for debate, perhaps because opening up for debate also means opening up for criticism. As we have seen, the criticism that did reach the Board was not considered relevant and not discussed in any noteworthy capacity.

Furthermore, the proposal-formulation process indicates that the institutional focus on RRI and on the inclusion of social and ethical issues in the governance of innovation leaves room for new actors, such as ethical boards, to play a larger and more independent role in the governance process. This in turn would allow for a shift in how governance takes place, as governance institutions such as the Board perform what traditionally is known as formal parliamentarian government processes such as gathering hearing statements. Additionally, while the Norwegian Biotechnology Advisory Board has long been regarded as a strict ethical watchdog over biotechnology and gene technology, it may seem as if, through its new formatting of proposal-formulation processes, it has become an actor for driving innovation forward.

Notes

1. This is an unpublished manuscript, and should not be quoted, referenced or cited.
2. The author of this article is responsible for translating the quotations from Norwegian publications into English.
3. The proposed moratorium concerns germline modification, not with regard to plants or animals (Baltimore et al. 2015).
4. https://www.bioteknologiradet.no/2018/12/genteknologiloven/
5. The stated purpose of the Gene Technology Act of 1993 is to ensure that GMOs are developed and used in an 'ethically justifiable and societally acceptable manner, in accordance with the principle of sustainable development' (Government.no n.d., §1).

Acknowledgements

A special thanks to Class 2018 of the Master's program in Science and Technology Studies for their contributions and gathering empirical data used in this article.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

This work was supported by Norges Teknisk-Naturvitenskapelige Universitet.

Notes on contributor

Marit Svingen is a PhD candidate at the Centre for Science and Society in The Norwegian University of Science and Technology (NTNU). She holds an MA in Science and Technology Studies and a BA in Journalism. Her main research interests are the political dimensions of science-society relations, focusing on the governance of knowledge production and innovations within Bio- and Gene Technology.

ORCID

Marit Svingen http://orcid.org/0000-0003-2688-7853

References

Antonsen, Marie Auensen. 2017. (U)Mulige medborgere: Engasjement, etikk og emosjoner i styring av human bioteknologi i Norge. PhD thesis. Doctoral theses at NTNU;2017:261. Norwegian University of Science and Technology.

Antonsen, Marie, and Nora Levold. 2014. "Bioteknologinemda og Jakten på Hybride Praksiser." In *Biopolitikk: Kropp, Kunnskap og Teknologi*, edited by Nora Levold, 97–128. Bergen: Fagbokforlaget.

Arnstein, R. Sherry. 1969. "A Ladder Of Citizen Participation". *Journal of the American Planning Association* 35 (4): 216–224. doi:10.1080/01944366908977225

Asdal, Kristin. 2015. "What Is the Issue? The Transformative Capacity of Documents." *Distinktion* 16 (1): 74–90.

Baltimore, David, Paul Berg, Michael Botchan, Dana Carroll, R. Alta Charo, George Church, Jacob E. Corn, et al. 2015. "A Prudent Path Forward for Genomic Engineering and Germline Gene Modification." *Science* 348 (6230): 36–38.

Bioteknologirådet. 2017. Genteknologiloven – invitasjon til offentlig debatt. https://www.bioteknologiradet.no/filarkiv/2017/12/Genteknologiloven-uttalelse-invitasjon-til-offentlig-debatt-web.pdf.

Bratlie, Sigrid, Kristin Halvorsen, Bjørn K. Myskja, Hilde Mellegård, Cathrine Bjorvatn, Petter Frost, Gunnar Heiene, et al. 2019. "A Novel Governance Framework for GMO. A Tiered, More Flexible Regulation for GMOs Would Help to Stimulate Innovation and Public Debate." *EMBO Reports* 20 (5): e47812. https://www.embopress.org/doi/full/10.15252embr.201947812.

Braverman, Irus. 2019. "Editing the Environment: Emerging Issues in Genetics and the Law." In *Gene Editing, Law, And the Environment*, edited by Irus Braverman, 1–17. Abingdon: Routledge.

Callon, Michel. 1999. ""The Role of Lay People in the Production and Dissemination of Scientific Knowledge." *Science, Technology and Society* 4 (1): 81–94.

Calvert, Jane. 2014. "Governing in the Context of Uncertainty." *Hastings Center Report* 44 (6): S31–S33. doi:10.1002/hast.395.

Charmaz, Kathy. 2006. *"Constructing Grounded Theory: A Practical Guide Through Qualitative Analysis"*. London: Sage Publications.

Chilvers, James, and Matthew Kearnes. 2020. "Remaking Participation in Science and Democracy." *Science, Technology, & Human Values* 45 (3): 347–380.

Delgado, Ana, Kamilla Lein Kjølberg, and Fern Wickson. 2011. "Public Engagement Coming of Age: From Theory to Practice in STS Encounters with Nanotechnology." *Public Understanding of Science* 20 (6): 826–845.

European Commission n.d. "Responsible Research & Innovation." https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation.
GenØk-Senter for biosikkerhet. 2018. Innspill til Bioteknologirådets forslag om endring av genteknologiloven." https://www.bioteknologiradet.no/filarkiv/2018/04/Gen%C3%98k.pdf.
Hartley, Sarah. 2016. "The Treatment of Social and Ethical Concerns in Regulatory Responses to Agricultural Biotechnology: An historical analysis". In *Innovation in agricultural genomics: Overcoming complexities in the intellectual property–regulatory complex*, edited by Emily Marden, R. Nelson Godfrey, and Rachael Manion, 42–67. Vancouver: University of British Columbia Press.
Hartley, Sarah, Delphine Thizy, Katie Ledingham, Mamadou Coulibaly, Abdoulaye Diabaté, Bakara Dicko, Samba Diop, et al. 2019. "Knowledge Engagement in Gene Drive Research for Malaria Control." *PLoS Neglected Tropical Diseases* 13 (4): e0007233. doi:10.1371/journal.pntd.0007233.
Havforsknings institutt. 2018. "Uttalelse fra Havforskningsinstituttet angående debattinspill fra Bioteknologirådet om endringer i Genteknologiloven." [Submission dated 15 May 2018] https://www.bioteknologiradet.no/filarkiv/2018/04/Havforskningsinstituttet.pdf.
Hilgartner, Stephen. 2019. "Governing Gene Editing: A Constitutional Conversation." In *Gene Editing, Law, and the Environment*, edited by Irus Braverman, 187–193. Abingdon: Routledge.
Horst, Maja. 2007. ""Public Expectations of Gene Therapy Scientific Futures and Their Performative Effects on Scientific Citizenship." *Science, Technology & Human Values* 32 (2): 150–171.
Hurlbut, J., Krishanu Saha Benjamin, and Sheila Jasanoff. 2015. "CRISPR Democracy: Gene Editing and the Need for Inclusive Deliberation." *Issues in Science and Technology* 32: 266–271.
Irwin, Alan. 2001. "Constructing the Scientific Citizen: Science and Democracy in the Biosciences." *Public Understanding of Science* 10 (1): 1–18.
Irwin, Alan. 2006. "The Politics of Talk Coming to Terms with the 'New' Scientific Governance." *Social Studies of Science* 36 (2): 299–320.
Irwin, Alan. 2008. *"STS Perspectives on Scientific Governance." In The Handbook of Science and Technology Studies, Edited by Edward J. Hackett, Olga Amsterdamska, Michael E. Lynch, and Judy Wajcman, 583–608*. 3rd ed. Cambridge, MA: MIT Press.
Jasanoff, Sheila. 2004. *States of Knowledge: The Co-Production of Science and the Social Order*. London: Routledge.
Jasanoff, Sheila. 2005. *Designs on Nature: Science and Democracy in Europe and the United States*. Princeton, NJ: Princeton University Press.
Jasanoff, Sheila. 2019. *Can Science Make Sense of Life?* Cambridge: Polity Press.
Justesen, Lise. 2005. "Dokumenter i Netværk." In *Kvalitative Metoder i et Interaktionistisk Perspektiv*, edited by Margaretha Järvinen, and Nanna Mik-Meyer, 215–234. København: Hans Reitzels forlag.
Kjeldaas, Sigfrid, Trine Antonsen, Sarah Hartley, and Anne Ingeborg Dyhr. 2021. "Public Consultation on Proposed Revisions to Norway's Gene Technology Act: An Analysis of the Consultation Framing, Stakeholder Concerns, and the Integration of Non-Safety Considerations." *Sustainability* 13 (14): 7643. doi:10.3390/su13147643.
Klima- og miljødepartementet. 2020. "Oppnemning av eit offentleg utval som skal greie ut om genteknologi, nye teknikkar og reguleringa av genmodifiserte organismar." https://www.regjeringen.no/no/dokumenter/oppnemning-av-eit-offentleg-utval-som-skal-greie-ut-om-genteknologi-nye-teknikkar-og-reguleringa-av-genmodifiserte-organismar/id2785259/.
Kuiken, Todd. 2017. "«Vigilante Environmentalism: Are Gene Drives Changing How We Value and Govern Ecosystems?" In *Gene Editing, Law, and the Environment: Life Beyond the Human (1st ed.)*, edited by John Patterson, Julian Webb, and Irus Braverman, 95–111. New York: Routledge.
Latour, Bruno. 1987. *Science in Action: How to Follow Scientists and Engineers Through Society*. Milton Keynes: Open University Press.
Latour, Bruno. 1996. *Vi har Aldri Vært Moderne*. Oslo: Spartacus Forlag.
Legemeiddelindustrien. 2018. "Innspill Genteknologiloven." [Submission dated 14 May 2018] https://www.bioteknologiradet.no/filarkiv/2018/04/Legemiddelindustrien.pdf.

Macnaghten, Phil. and Julia S. Guivant. 2011. "Converging citizens? Nanotechnology and the political imaginary of public engagement in Brazil and the United Kingdom". *Public Understanding of Science* 20 (2), 207–220. doi:10.1177/0963662510379084

Macnaghten, Phil. 2015. "Comparing GM Crops in Mexico, Brazil and India." In *Governing Agricultural Sustainability: Global Lessons from GM Crops*, edited By Phil Macnaghten and Susana Carro-Ripalda, 136–150. New York: Routledge.

Macnaghten, Phil. 2020. "Towards an Anticipatory Public Engagement Methodology: Deliberative Experiments in the Assembly of Possible Worlds Using Focus Groups." *Qualitative Research* 21: 3–19.

Meyer, Morgan. 2022. "Taking responsibility, making irresponsibility: Controversies in human gene editing". *Social Studies of Science* 52(1): 127–143. doi:10.1177/03063127211025631.

Natur og Ungdom. n.d. Innspill til forslag fra Bioteknologirådet om framtidig regulering av genmodifiserte organismer (GMO). https://www.bioteknologiradet.no/filarkiv/2018/04/Natur-og-Ungdom.pdf.

Naturverforbundet. 2018. "Innspill til forslag fra Bioteknologirådet om framtidig regulering av genmodifiserte organismer (GMO)." [Submission dated 14 May 2018] https://www.bioteknologiradet.no/filarkiv/2018/04/Naturvernforbundet.pdf.

Nofima. n.d. "Høringsuttale frå Nofima til forslaget til framtidig GMO-regulering frå Bioteknologirådet." https://www.bioteknologiradet.no/filarkiv/2018/04/Nofima.pdf.

Norges Bondelag. 2018. «Innspill til Bioteknologirådets offentlige debatt om endring av genteknologiloven.» [Submission dated 09 April 2018] https://www.bioteknologiradet.no/filarkiv/2018/04/Norges-Bondelag.pdf.

Norges miljø-og biovitenskapelige universitet. 2018. "Innspill til Bioteknologirådets forslag om endring av genteknologiloven." [Submission dated 15 May 2018] https://www.bioteknologiradet.no/filarkiv/2018/04/NMBU-Fakultet-for-Biovitenskap.pdf.

Norsvin, Geno, and Aquagen. 2018. "Innspill til Bioteknologirådet om endring av Genteknologiloven." [Submission dated 15 May 2018] https://www.bioteknologiradet.no/filarkiv/2018/04/Geno-Norsvin-AquaGen.pdf.

Norwegian Biotechnology Advisory Board. 2018. The Gene Technology Act: Invitation to Public Debate. http://www.bioteknologiradet.no/filarkiv/2010/07/genteknologiloven-engelsk-hele-for-web-v-2.pdf.

Norwegian Biotechnology Advisory Board. 2018. Proposal for Relaxation of Norwegian Regulations for Deliberate Release of Genetically Modified Organisms (GMO) with Applicability also for EU Legislation. http://www.bioteknologiradet.no/filarkiv/2019/03/2019-04-16-Genteknologiloven-komplett-ENGELSK.pdf.

Nowotny, Helga, Peter Scott, and Michael Gibbons. 2001. *Re-Thinking Science – Knowledge and the Public in an Age of Uncertainty*. Cambridge: Polity Press.

Oikos. 2018. Innspill fra Økologisk Norge til Bioteknologirådet om fremtidens Genteknologilov." [Submission dated 15 May 2018]. https://www.bioteknologiradet.no/filarkiv/2018/04/Oikos.pdf.

Smith, Robert D. J., Sarah Hartley, Patrick Middleton, and Tracey Jewitt. 2021. "Knowing When to Talk? Plant Genome Editing as a Site for Pre-Engagement Institutional Reflexivity." *Public Understanding of Science* 30 (6): 740–758. doi:10.1177/0963662521999796.

Star, Susan Leigh. 2010. "This Is Not a Boundary Object: Reflections on the Origin of a Concept." *Science, Technology, & Human Values* 35 (5): 601–617.

Statens leggemiddelverk. 2018. "Legemiddelverkets innspill til Genteknologiloven." [Submission dated 29 Mary 2018]. https://www.bioteknologiradet.no/filarkiv/2018/04/Statens-Legemiddelverk.pdf.

Stengers, Isabelle. 1999. *For en Demokratisering av Vitenskapene*. Oslo: Spartacus Forlag.

Stilgoe, Jack, Richard Owen, and Phil Macnaghten. 2013. "Developing a Framework for Responsible Innovation." *Research Policy* 42: 1568–1580.

Stirling, Andy. 2007. "*Opening Up" and "Closing Down*." *Science Technology & Human Values* 33: 262–294.

Tichelkamp, Thomas. n.d. "Del 1 - Generell diskusjon om GMO i landbruket." https://www.bioteknologiradet.no/filarkiv/2018/04/Thomas-Tichelkamp.pdf.

Universitetet i Oslo. 2018. "Høring – fremtidens genteknologilov – utsetting av genmodifiserte organismer." [Submission dated 30 May 2018] https://www.bioteknologiradet.no/filarkiv/2018/04/Universitetet-i-Oslo.pdf.

Wahlberg, Ayo, Christoph Rehmann-Sutter, Margaret Sleeboom-Faulkner, Guangxiu Lu, Ole Döring, Yali Cong, Alicja Laska-Formejster, et al. 2013. "From Global Bioethics to Ethical Governance of Biomedical Research Collaborations." *Social Science and Medicine* 98: 293–300.

Wynne, Brian. 2005. ""Reflexing Complexity: Post-Genomic Knowledge and Reductionist Returns in Public Science." *Theory, Culture & Society* 22 (5): 67–94. doi:10.1177/0263276405057192.