**TITLE: A novel governance framework for GMO**

**SUBTITLE:**

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New breeding techniques, in particular gene editing technologies such as CRISPR, have great potential to transform agri- and aquaculture. However, realising this potential depends in large part on the regulation of genetically engineered products. Given the rapid technological progress in molecular biology, and the widely diverging interests of stakeholders, there is an urgent need for novel approaches regarding the governance of genetically engineered crops and animals along with a restart of the public dialogue. Importantly, regulation should stimulate technological development while simultaneously maintaining governmental oversight and control; however, the EU’s current regulatory regime for genetically modified organisms (GMO) is not necessarily conducive for stimulating development of new products.

We therefore propose a differentiated regulatory framework that would considerably lower the regulatory hurdles for certain uses of genetic engineering, stimulate innovation and development to the benefit of society, while allowing flexibility in terms of risk assessment. We further call upon relevant authorities and governments to advance policy development and facilitate a goal-oriented and inclusive public dialogue. The aim is to harness the potential of gene technologies in a safe, beneficial, sustainable and ethically justifiable manner while maintaining public trust.

**SUBHEADER: The current situation**

In July 2018, after years of regulatory uncertainty in the EU, the European Court of Justice decided that all gene edited organisms are subject to the approval requirements that currently apply to the deliberate release of GMO under EU directive 2001/18/EC [*1*]. The court’s decision has been criticized by many European scientists [*2-5*], who assert that it jeopardizes the future of agriculture and food-related research and development in the EU. In particular, many critics highlight that the current regulatory landscape will prevent the use of gene editing to rapidly develop novel agricultural products in order to deal with the impact of climate change and human population growth. In fact, the recent IPCC climate report highlighted CRISPR gene editing as one of the enabling technologies for swift adaptation of food crops to a changing climate [*6*].

Other actors, in particular environmental non-governmental organisations (NGOs), welcomed the decision to keep all genetically engineered organisms within the scope of the GMO directive. Indeed, there is still fierce resistance to GMOs and polarization of the debate in Europe and elsewhere. It further illustrates the essential need to balance food security with protecting ecosystems and maintaining public trust in a time of technological disruption. Regulation is a key instrument to maintain control and steer technological development and application in directions that benefit society.

The past decade has seen a remarkable technological development in genetic engineering: new technologies are cheaper, more accessible, more precise, and enable an increasing range of applications and products. This is also driving a diversification of the stakeholder landscape as research and development are increasingly shifting from big industry towards academia and small and medium-sized enterprises. Furthermore, there are similar changes in regard to consumer attitudes towards the use of genetic engineering. A recent survey conducted by UK The Royal Society showed that a majority of respondents – 71% – were positive towards the use of genetic engineering to improve animal health, compared to 33% when the main purpose of genetic engineering is to increase profits [*7]*. Thus, both a one-size-fits-all regulatory approach to GMO as well as the notion of a black-and-white public debate are both outdated. These developments call for a reframing of the public debate and for innovation in governance, which was expressed, for example, in a recent white paper by the World Economic Forum [8] and a statement from the German Bioeconomy Council [9].

**SUBHEADER: Differentiated governance**

In line with this approach, the Norwegian Biotechnology Advisory Board, with a majority vote, proposes a novel, differentiated regulatory framework that would allow for technological development, by significantly lowering the regulatory hurdles for certain uses of genetic engineering, while simultaneously maintaining governmental oversight and control.

Briefly, the proposal involves a three-tiered regulatory framework for deliberate release of GMOs (**Fig 1**). The lowest tier only requires a notification to the authorities with confirmation of criteria being fulfilled. It would apply to GMOs with genetic changes that can also be obtained by conventional methods, including substitution of an allele with another one that already exists within the species, or mutations that can arise naturally or by mutagenesis. Basically, all GMOs on this level are comparable to products that are exempted from regulation based on a history of safe use. If the genetic changes are more extensive but do not involve crossing species boundaries (transgenes) or inserting synthetic (artificial) genetic sequences, an expedited assessment may be appropriate under tier 2. This may involve less stringent requirements for field trials or toxicity testing, for example. Transgenic or synthetic organisms, which might pose additional or unknown risks, would be subject to current risk assessments under tier 3. Organisms with temporary, non-heritable genetic changes such as DNA vaccinated animals should be exempted from GMO regulation.

Health and environmental risk, sustainability, societal benefit and ethical considerations, which already form part of the risk assessment of GMOs in Norway, should nevertheless be decisive criteria at all levels. In addition, sponsors must provide sufficient and appropriate documentation to determine whether the GMO meets the criteria for a specific tier; for instance, data showing both on- and off-target genetic changes and information about expected phenotypic effects. In cases where traits or other case-specific factors warrant a more thorough assessment, organisms can be transferred to another tier. Generally, as it is not possible to firmly draw conclusions about the absolute or comparative safety of techniques or products, risk can only realistically be determined on a case-by-case basis [10].

A tiered system would also allow a more nuanced requirement for labelling and traceability of products on the market. More detailed information not only on the technology that has been used in the making of a product, but also about the product itself, will enable consumers to make better informed choices based on their preferences. Requirements for traceability, detection and monitoring can also be tailored to feasibility. This may solve one of the major contemporary challenges for regulatory authorities: that enforcing current provisions may prove difficult or even impossible when many genetically engineered products are indistinguishable from other products.

**SUBHEADER: Public dialogue at the heart**

Importantly, The Norwegian Biotechnology Advisory Board has a special mandate for public dissemination of information and for facilitating broad debate about biotechnology. During our discussions, we therefore placed public dialogue at the heart of the process. Through public consultation – a series of open meetings and an open invitation to submit views and comments in writing – we got feedback from a wide range of Norwegian stakeholders: scientists, academic institutions, industry, industry organisations, consumer organisations, NGOs, farmer organisations, policy sector, and members of the public.

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 as not only 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 authorization. They argued that such a system would lower the threshold for using genetic engineering significantly, enabling wider and more equitable access to the technology, increasing willingness to invest in R&D, and providing more predictability in the approval process.

The proposal to lower the requirements for impact assessment was also met with resistance, in particular from farmer organisations and environmental NGOs who argued in favour of a precautionary approach in line with current provisions. Uncertainty about effects on ecosystems, in particular if new organisms are introduced at a rapid pace, was their primary concern. Moreover, the fact that gene editing is a technology with which we do not have a long history of safe use was a central argument for keeping with current regulations. However, their comments were constructive and goal-oriented, many recognising the potential of gene editing to contribute positively to food production in the future. And, importantly, there was agreement across stakeholder groups about the value of regulatory oversight, and that societal benefit, sustainability and ethics should be assessment criteria.

The public consultation also highlighted a range of shared views and concerns that are key to the future of genetic engineering in Europe and elsewhere. Among these were the view that gene editing and other technologies can contribute to more sustainable agri- and aquaculture; that competitiveness on the international market is crucial; and that there should be consideration and concern for the environment. In addition, they maintained that transparency and information is key to public trust and that exempting gene editing from regulation may undermine trust and transparency.

**SUBHEADER: Aligning policies**

We believe our proposal can contribute to paving the way for a more holistic and forward-looking approach to governing emerging technologies that have the potential to transform society. Our public consultation also demonstrates how to facilitate an inclusive, proactive and reciprocal dialogue.

To move forward, we therefore urge EU authorities to clarify the existing possibilities for a differentiated approval regime for GMOs. The deliberate release directive (Directive 2001/18/EC) allows for derogation from standard procedures for both field trials (Article 7 of Part B) and marketing (Article 16 of Part C). Differentiation and derogation from requirements may be granted for a single GMO or groups of GMOs, and any requirement can in theory be omitted. However, there is no precedent since a derogation of this kind has not, to our knowledge, been requested by the European Commission or any Member State. Furthermore, since the directive specifies an approval requirement for all GMOs, there may be insufficient scope for introducing a notification system. All GMOs must also be labelled under current regulations.

Should there be insufficient scope to implement our proposal, we urge the Commission to initiate a review of the regulations. Although not a part of the EU, Norway is bound by EU regulations through the EEA agreement. Thus, the scope for making adaptations to the Norwegian Gene Technology Act relating to our proposal, as currently evaluated by Norwegian authorities, will depend on EU GMO regulations.

We also call upon all relevant bodies in the EU and beyond to establish a dedicated international policy forum for further deliberations and collaboration in shaping tomorrow’s GMO governance framework and advancing the public dialogue.

Getting it wrong by failing to adapt legislation to a rapidly changing technology can entail significant opportunity costs. Maintaining an exceedingly prohibitive regulation could also cause lack of transparency in technological development and application – especially when new forms of genetic engineering can go undetected – and ultimately lead to capitulation to the demand for deregulation. At the same time, blindly adapting legislation to technology may hamper perspective and control in order to assure benefit and safety. Getting it right is important for society to harness the potential of genetic engineering in a safe, sustainable, societally beneficial and ethically justifiable manner while maintaining public trust.

*The full report (in English), can be found at: http://www.bioteknologiradet.no/a-forward-looking-regulatory-framework-for-gmo/*

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FIGURE LEGENDS

**Fig 1 | Proposed differentiated regulatory framework for GMO**

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**Authors contributions:**

**Sigrid Bratlie: Developed the main contents of the proposal/model for a novel regulatory framework, lead the work on the public consultation and evaluated the results, wrote the report/statement on which the manuscript is based, and wrote the manuscript.**

**Kristin Halvorsen: Contributed significantly to the development of recommendations for regulation, writing of the full report, the public consultation and contributed to writing the manuscript.**

**Bjørn K. Myskja: Partook in developing recommendations for regulation and writing of the full report, contributed significantly to meetings during the public consultation, and contributed to writing the manuscript.**

**Hilde Mellegård: Contributed significantly to the consultation and evaluation of the results, wrote the report/statement on which the manuscript is based, and contributed to writing the manuscript.**

**Cathrine Bjorvatn: Partook in developing recommendations for regulation and writing of the full report.**

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**Competing interests: P.Frost is the General Manager and Director of Research Science at MSD Animal Health Innovation Norway that develops DNA vaccines for the aquaculture industry. Otherwise, the authors declare no competing interests.**

**Supplementary Materials:**

**Full report and comments from the public consultation are available at:** *http://www.bioteknologiradet.no/a-forward-looking-regulatory-framework-for-gmo/*

