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Bioteknologirådet
The Norwegian Biotechnology Advisory Board

A forward-looking regulatory framework for GMO



Gene technology is developing at an unprecedented pace. Here, The Norwegian Biotechnology Advisory Board presents its final recommendations for how genetically modified organisms (GMO) should be regulated.

- Gene editing and other gene technologies can contribute to more sustainable agri- and aquaculture
- Competitiveness on the international markets is crucial for Norwegian businesses
- We have a responsibility to protect nature and the environment
- Consumer trust is key

These were some of the central views we received during the five-month public consultation period after the Norwegian Biotechnology Advisory Board published a number of proposals for regulation of release of GMO. Here, the Board presents its final recommendations for how the GMO regulatory framework can be shaped to accommodate and safeguard different considerations and interests.

Technological development presents new opportunities and challenges

Genetic engineering of plants, animals and microorganisms has been performed for more than 30 years, and GMO-plants have been cultivated for more than 20 years. Recently, gene technologies have developed rapidly and profoundly. New technologies are easier and cheaper to use than first generation genetic engineering, and significantly expand the possibilities for rewriting DNA in living organisms. Especially gene editing technologies such as CRISPR have been employed by researchers all over the world at an unprecedented pace. The technology allows targeted genetic alterations such as deleting, substituting or adding DNA, or switching genes on or off without making any changes to the genetic sequence.

This has led to an increase in research and development of organisms that could potentially become beneficial, sustainable and ethically justifiable products. Examples are plants and animals that are more resistant to disease, and higher yielding crops. Food with a potential health advantage, such as gluten-reduced wheat and plant oils with lower levels of saturated fats, are examples of products being developed that can directly benefit consumers.

However, this powerful technology can also present several challenges. It can, for instance, be used to develop organisms that behave very differently from existing organisms when introduced into the environment. This can be microorganisms with fully synthetic genes, or gene drives that are designed to spread genetic changes to entire populations of wild plants or animals. The increasing accessibility of the technology, for example as a tool to use at home or at community labs outside government control (DIY-biology), may render it difficult to enforce regulations.

Need for a forward-looking regulatory framework

The principles for regulation of GMO, both in Norway, the European Union and elsewhere, were developed in the 1990s when genetic engineering was at its infancy. At the time, the divide between gene technology and conventional breeding techniques was clear. Today, with

new technologies presenting a much wider range of possibilities, these lines are becoming increasingly blurred. For example, gene editing can be used to make genetic changes that are equivalent to those that exist or may arise naturally, or can be obtained using conventional breeding techniques.

Therefore, the debate about how genetically modified organisms are and should be regulated is intensifying. There is disagreement about whether current regulations are suitable for research and development of tomorrow`s products. The GMO debate has not become less polarized after the EU Court of Justice in July 2018 decided that gene edited organisms are also to be considered GMO, including where no foreign DNA has been added. Gene edited organisms will therefore be regulated under the current GMO regulatory framework. Now, a reframing of the public debate and innovation in governance is increasingly being called for.

FACTS

Current requirements for approval of a GMO

Before a GMO can be approved, it is subjected to health and environmental risk assessment. This is mandatory in both Norway and the EU. In Norway, an evaluation of sustainability, societal benefit and ethics is also performed for GMO that are regulated by the Gene Technology Act. Additionally, there are requirements for labelling and traceability of a GMO.

On our own initiative, the Norwegian Biotechnology Advisory Board has developed a proposal for a frameworks that can pave the way for harnessing the potential of gene technology, while at the same time safeguarding our health and the environment, and promoting societal benefit, sustainability and ethics.

In this statement, the Board specifically addresses regulation of deliberate release of GMO, focusing on a few select principal aspects:

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

The Norwegian Biotechnology Advisory Board has discussed these questions on a principal level without going into detail, since the proposal will have to be thoroughly reviewed and specified by competent authorities. The Board has not considered which legislative changes to Norwegian or other international regulations are necessary for the adoption of the proposal.

Summary of the Norwegian Biotechnology Board recommendations:

A joint Board believes it is important to have a forward-looking GMO regulatory framework that allows for technological development and flexibility while simultaneously maintaining governmental oversight and control. This is particularly important since the total – the accumulated impact of many genetic changes – can be greater than the sum of its parts, especially when the development of new products happens at a rapid pace. The Board therefore recommends not to exempt any genetically engineered organisms with permanent, heritable changes from regulation. However, all Board members believe that requirements for assessment and approval should be differentiated to a larger extent than it is today.

A joint Board recommends that authorities clarify and utilise existing flexibility for differentiated impact assessment of GMOs within the current regulatory framework as soon as possible.

A joint Board recommends that the Norwegian government should appoint a committee to review proposals for amendments to the regulation of deliberate release of genetically modified organisms in the Gene Technology Act.

Other recommendations of the Norwegian Biotechnology Advisory board are as follows:

How should organisms covered by GMO regulations be assessed?

One of the most central questions in the debate is whether or not all GMOs should be regulated equally, as under the current system, given the large variety of end products that can be obtained with respect to trait, type of genetic change, purpose etc. The Board has therefore discussed two alternative approval systems.

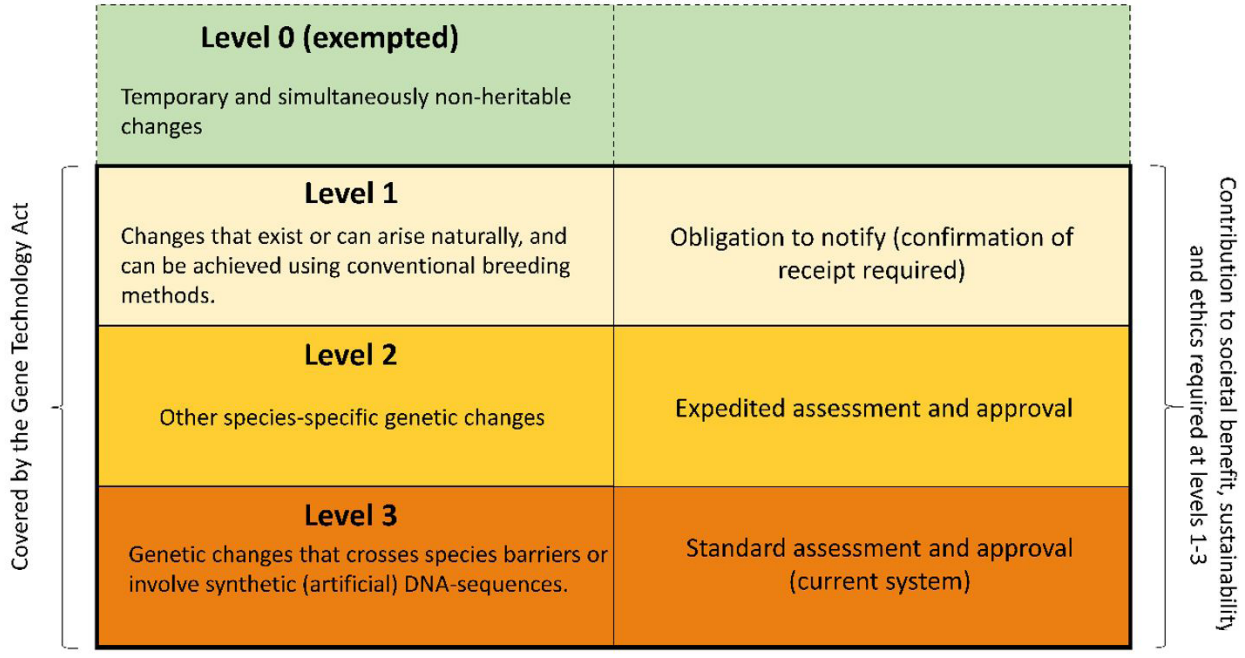
A majority of 11 out of 14 members believe the requirements for risk assessment and approval should be differentiated in a tiered system based on the genetic change that has been made. Relevant criteria can be whether or not the change is permanent and heritable, whether or not the change can also be made using conventional breeding techniques, and whether or not the change crosses species boundaries. At the lowest level, a notification to the authorities (receipt required before the organism can be released) may be sufficient. At higher levels, organisms would require approval before release is authorised, but may be subject to differentiated risk assessment and approval requirements. In cases where a trait or other case-specific factors warrant a more thorough assessment, the application can be transferred to a higher level. These members argue that such a system might be appropriate to reflect the different risk levels that can reasonably be expected for various types of genetic changes, and at the same time allowing for an even more suitable and nuanced assessment of sustainability, societal benefits and ethics.

A minority of three board members recommend that in principle, the current requirements for approval and impact assessment should apply to all organisms covered by the Gene Technology Act. However, differentiation through custom guidance documents should be more actively utilised.

What should be covered by GMO regulation?
Whether or not the scope of GMO regulatory frameworks should be reconsidered in light of technological development and increased knowledge, is another important question. Are there reasons to assume a higher level of risk for organisms made using gene technology, for example in terms of unintended effects, than for organisms with similar changes made with conventional breeding techniques? Should some organisms made with gene technology be exempted from GMO regulations? Should organisms made with certain conventional breeding techniques be regulated similarly to organisms made with gene technology?

On the issue of scope, all Board members agree that organisms with temporary, non-heritable changes, such as RNA and DNA vaccines, should be exempted from GMO regulations. A majority of nine members argue that for pragmatic reasons, we should otherwise keep the current divide between organisms made with genetic engineering and organisms produced using conventional breeding techniques. A minority of five members argue that organisms made using certain conventional breeding techniques (e.g. mutagenesis and triploidization) should be included in the GMO regulation. These members justify their position with the principle of equality.

Example of principles for differentiation based on genetic change: a three-tiered system



What are appropriate requirements for labelling, traceability and monitoring?
According to both Norwegian and EU legislation, food and feed containing GMO must be labelled. There is also a requirement for traceability in the form of document-based information, and methods for detection and monitoring. With such a wide range of types of genetically modified organisms that can now be made, what information is relevant to the consumer? When a GMO is indistinguishable from other organisms, complying with detection requirements may also be difficult without introducing additional genetic modifications. What requirements are most appropriate?

On the question of labelling, a joint Board recommends that the requirements should be differentiated to reflect relevant differences between organisms and their traits. This way, consumers will receive more relevant information that provides an even better basis for choosing. However, opinions differ about which organisms should be subject to labelling. Eight members believe all organisms covered by the Gene Technology Act should be labelled according to a differentiated system. Six members argue that organisms at level 1 should be exempted from the labelling requirements.

A joint Board recommends that traceability, which is a prerequisite for enforcing requirements for la-belling, should be reviewed. Document-based traceability, for example identity-assured raw materials, should apply to all organisms covered by GMO regulation. Requirements for detection should be dif-ferentiated according to feasibility. Differentiation of requirements for monitoring should also be re-viewed with the aim of establishing requirements that are feasible for organisms with different genetic changes.

How should contribution to societal benefit, sustainability and ethics be weighted?
Today, societal benefit, sustainability and ethical justifiability form part of the assessment criteria for approval of GMO under the Norwegian Gene Technology Act. Should these criteria remain, and if so, how should they be weighted, given that similar requirements do not apply to products made with other technologies?

Regardless of the scope of GMO regulations and how organisms are assessed, the Board members unanimously argue that societal benefit, sustainability and ethics should form part of the assessment. However, there is disagreement about how these requirements should be weighted.

Seven members recommend that all organisms covered by the Gene Technology Act should be required to contribute positively to societal benefit, sustainability and ethics. They argue that this is an important tool for steering the technological development in a desired direction.

Six members recommends that the requirements should be differentiated according to the tiered system, where the absence of negative impact on society, sustainability and ethics should be sufficient for organisms on level 1 and 2 (organisms with genetic changes that do not cross species barriers or involve the use of synthetic DNA sequences). They argue that genetic engineering is not inherently more problematic than other technologies if the products have similar traits and do not deviate too much from nature.

One member recommends that societal benefit, sustainability and ethics should still form part of the assessment of all GMOs, but that absence of a negative impact is sufficient for approval at all levels.

Research and competence building
When it comes to research, all Board members agree that it is important to facilitate the gathering of knowledge about technical and safety aspects of gene technologies, and to build competence in Norwegian research environments.

Public dialogue

The Norwegian Biotechnology Advisory Board has a special mandate for public dissemination of information and debate about all aspects of biotechnology. Following the release of our preliminary proposal for GMO regulations, we held a broad public consultation to gather input for further discussions before finalising our recommendations. Between December 2017 and May 2018 we hosted seven open meetings at different locations, and invited anyone to send us their views and comments.

We received 50 comments from a wide range of stakeholders. Of these, 34 were from organisations and businesses, while 16 were from independent scientists or members of the general public. Comments (in Norwegian) can be

found on our website www.bioteknologiradet.no/gentek-nologiloven. Here is a summary of the most important aspects:

- Almost all commented on the importance and timeliness of the initiative and the debate about regulation of GMO. Many emphasised that gene technologies such as gene editing can contribute positively to society, for instance through development of products that can give more sustainable agri- and aquaculture. At the same time, many stressed the importance of a precautionary approach, and emphasised that we need more knowledge about and experience with the use of gene editing technology.

- We received a range of questions, comments and suggestions about GMO regulation in general, and our proposal in particular. Comments from industry and industry organisations (especially in agri- and aquaculture) expressed concern about future competitiveness for Norwegian businesses if Norway and the EU maintain a non-differentiated regulatory framework, especially if regulations differ from other countries. Other topics included the relationship to EU legislation, definitions and terms, risk assessment and uses of genetic engineering that had not been addressed in the Board`s preliminary proposal.

- There was broad agreement about many aspects of GMO regulation. In particular, the need for a timely and forward-looking regulatory framework that can be adapted when technologies and knowledge develop, while still safeguarding important considerations. There was also broad support for the purpose of the Norwegian Gene Technology Act; to ensure that the production and use of GMO is ethically sound, beneficial to society, consistent with the principle of sustainable development, and does not pose a threat to health and the environment.

- There was broad agreement about the importance of public trust and consumer choice, and almost all supported labelling of GMO in general. A few argued against differentiation of labelling. However, most were in favour of differentiation based on the type of genetic change and/or the organism's traits. Justifications were that the consumer will get more relevant information, and that labelling is not useful if products cannot be traced in an effective way.

- 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.

- Many comments, in particular those from industry and academic research, supported a tiered regulatory system where assessments are differentiated according to the genetic change. This way, risk assessments will be more proportional to the risk and more predictable, they argued. Several stressed that GMO regulations will be a significant barrier to using new technologies if approval requirements are not lowered.

- Many other comments, especially those from farmer`s organisations and environmental organisations, argued that adapting current GMO regulations through guidance documents will give sufficient flexibility. They believed we have limited experience using new gene technologies, and were worried that an expedited assessment or notification is not sufficient to uncover risks.

- A number of independent scientists and members of the general public supported a revision of the GMO regulations, but argued that there should be a system based purely on the traits of the product, in line with Canadian regulations.

The Norwegian Biotechnology Advisory Board hopes this approach has contributed to and will continue to contribute to knowledge building and constructive dialogue about a very important topic. Our ambition is also that these recommendations will be an important contribution to the international debate about how genetically engineered organisms should be regulated.

With this statement, the Norwegian Biotechnology Advisory Board hopes to provide a good basis for shaping a GMO regulatory framework that better allows us to handle the rapid technological development that we are facing.

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