Bioteknologirådet
The Norwegian Biotechnology Advisory Board

Summary:

The Gene Technology Act – Invitation to Public Debate



Gene technology is developing at an unprecedented pace. In this statement the Norwegian Biotechnology Advisory Board proposes a new way forward for regulating GMO, and invites a renewed public debate and dialogue.

Deadline for comments: 15th of May 2018

Genetically modified organisms (GMOs) is a term that engages across many different societal groups. For some, it represents the possibility of making plants and animals that can contribute to more efficient and sustainable food production. For others, it is associated with a risk of negative environmental impact and concentration of power at large international corporations. In light of rapid technological development in the field of genetic research and engineering, this is a good time to discuss whether to renew the Gene Technology Act, which is more than 24 years old.

The Norwegian Biotechnology Advisory Board has followed developments closely. We hereby invite a broad public debate and dialogue about the regulation of GMO by presenting a proposal for new 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.

Technological development presents new opportunities and challenges

Genetic engineering of plants, animals and microorganisms has been possible for more than 30 years, and GMO-plants have been cultivated for more than 20 years. Recently, there has been a rapid and substantial development in gene technology. New techniques are easier and cheaper to use than first generation genetic engineering technology, and give many more opportunities for changing DNA than ever before. Especially genome editing, CRISPR being the prime example, is now being employed by researchers all over the world at an unprecedented pace. The technique allows for 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 with traits that could potentially become beneficial, sustainable and ethically sound products. Examples are plants and animals that are more resistant to disease, and crops with a higher yield per area. 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, such a powerful technology can also bring 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 in community labs outside government control (DIY-biology), makes it difficult to enforce regulations.

We have to discuss how GMOs are regulated

Current GMO regulatory frameworks, both in Norway, the EU and elsewhere, were developed when genetic engineering was still in its infancy. At the time, the divide between gene technology and conventional breeding techniques was clear. Today, with new technologies giving a much larger 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 can or do 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 both about the interpretation of current legal definitions, especially in the EU, and about whether regulatory systems are sufficiently suitable for the development of the products of tomorrow.

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, social benefit and ethics is also performed. Additionally, there are requirements for labelling and traceability of a GMO.

The Norwegian Biotechnology Advisory Board invites to a public debate and dialogue

The Board has a special mandate for public dissemination of information and debate about all aspects of biotechnology. With this statement, we invite to a broad public debate and dialogue about the regulation of GMOs. The aim is to develop appropriate and robust regulatory frameworks that facilitate the harnessing of the potential of gene technology, while also avoiding harm to health and the environment, and promoting sustainability, societal benefit and ethics. These proposals are preliminary, and can be subject to change before the statement is finalised. We welcome views, comments and suggestions from all stakeholders, and will facilitate dialogue in different forums.

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

- **What should be regulated by the Gene Technology Act?**
- **How should these organisms be regulated?**
- **What are appropriate requirements for labelling and traceability?**
- **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 proposals will have to be thoroughly reviewed and specified by other authorities. The Board has not considered which legislative changes to Norwegian or other international regulations are necessary for the adoption of the proposals.

In this particular case, the Board has deviated from normal practice, allowing all 20 members and deputy members to vote. The issues have been discussed over many meetings, and all members know them well. Furthermore, the Board wants all viewpoints to be sufficiently represented in this principally important case.

SUMMARY OF THE NORWEGIAN BIOTECHNOLOGY BOARD RECOMMENDATIONS

As is often the case in issues discussed by the Board, the members are divided in their opinion. Nevertheless, some prevailing directions has emerged.

How should organisms covered by the Gene Technology Act be regulated?

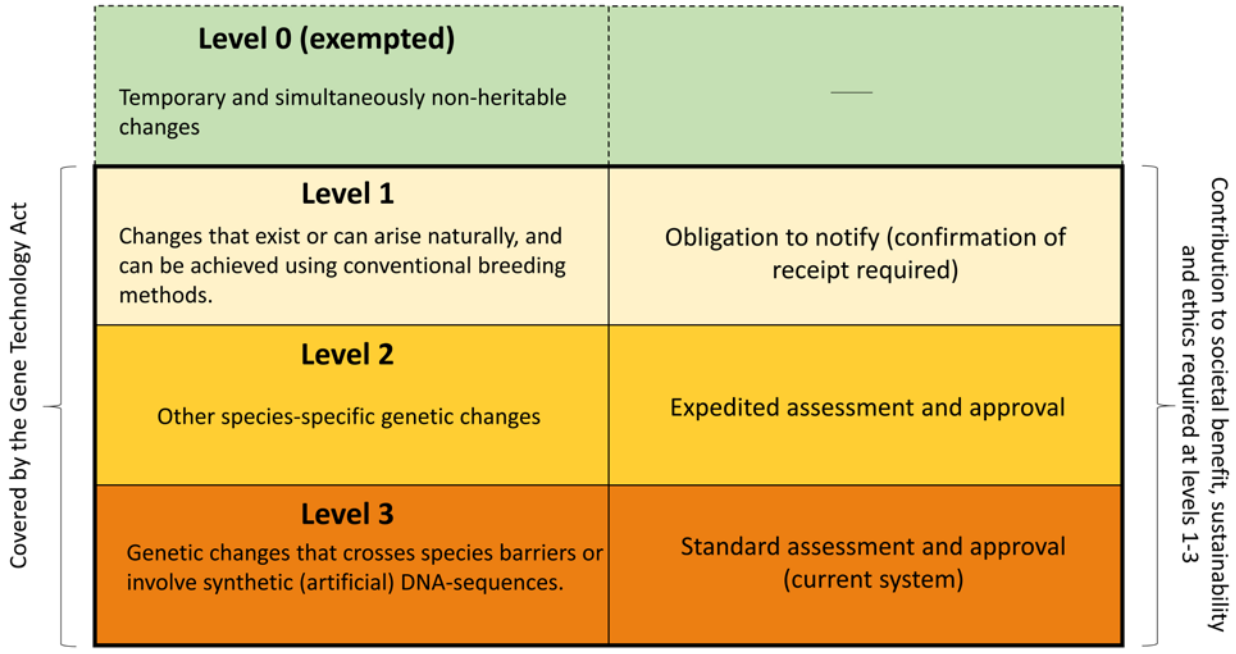
One of the most central questions in the debate is whether all GMOs should be regulated equally, as under the current system, given the large variety of end products that can be obtained with respect to trait, type of genetic change, purpose, etc. The Board has therefore discussed two alternative approval systems.

A majority of 18 out of 20 members believe the requirements for risk assessment and approval should be differentiated into different levels.

Levels based on genetic change:

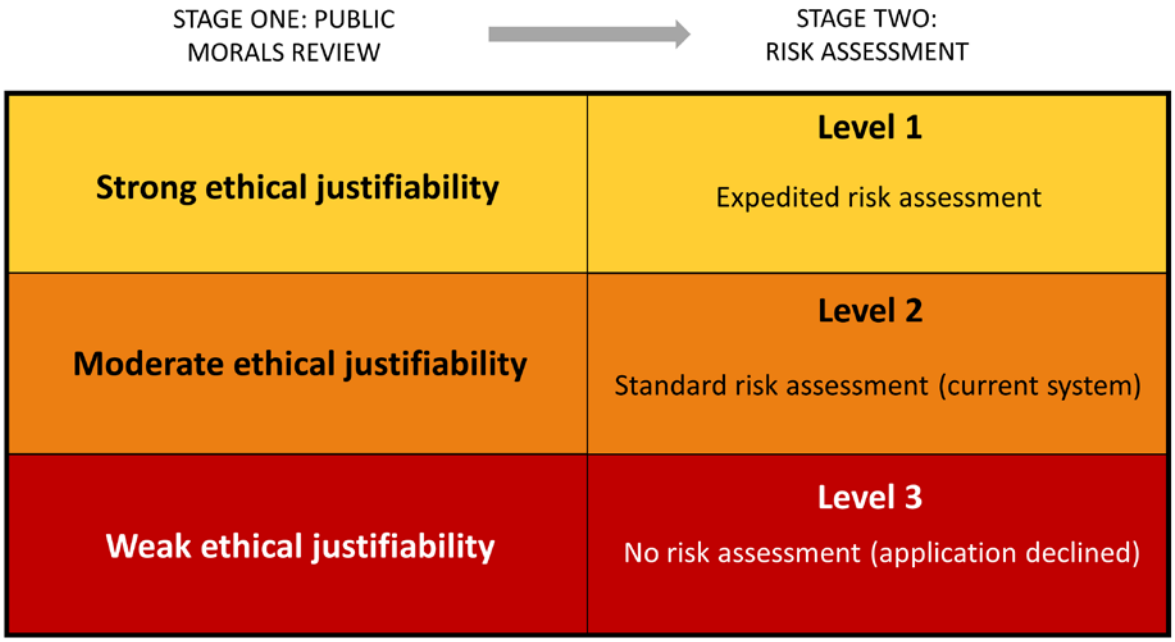
Seventeen of these members argue that organisms can be divided into different levels based on the genetic change that has been made, according to general principles. For example, relevant criteria can be whether or not the change is permanent and heritable, whether or not the change can also be made 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 different risk assessment and approval requirements.



Levels based on an initial assessment of "public morals":
One of the members argues that different levels of risk assessment of organisms should rather be based on an initial assessment of "public morals", including an assessment of foundational ethical requirements and ethical defensibility, and that explicit approval should be a requirement on all levels.

Keep current system:
Two of the board members argue that all organisms regulated by the Gene Technology Act should be subjected to the same level of risk assessment and approval, according to the current system. However, differentiation through custom guidance documents should be more actively utilised.



What should be regulated by the Gene Technology Act?

Whether or not the scope of the Gene Technology Act 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 or that arise naturally? Should some organisms made with gene technology be exempted from the Gene Technology Act? Should organisms made with certain conventional breeding techniques be regulated similarly to organisms made with gene technology?

On the issue of what should be regulated by the Gene Technology Act, all board members agree that no organisms made using gene technology should be exempted, except those with temporary, non-heritable changes such as DNA vaccines.

There is more disagreement on other aspects. A majority of 13 board members argue that organisms made using certain conventional breeding techniques (e.g. mutagenesis, triploidisation and cell fusion) should be regulated in the same way as GMOs with similar genetic changes. These members justify their position with the principle of equality; such techniques can, in the same way as gene technology, be used to make genetic changes that cannot, in practical terms, occur naturally. Moreover, conventional breeding techniques also involve an unknown degree of health and environmental risk, for instance through unintended/off-target effects. Level-based would however be a prerequisite for regulating conventional breeding techniques.

A minority of 7 board members argue that for pragmatic reasons, we should keep the current distinction, where organisms produced using conventional breeding techniques are kept outside the scope of the Gene Technology Act.

What are appropriate requirements for labelling and traceability?

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 surveillance. With such a wide range of types of genetically modified organisms that can now be produced, 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 and traceability, the board members are divided into two groups. A majority of 17 members argue that labelling should be differentiated into different levels, so that consumers will have an even better basis for choosing than today. Five of these 17 members argue that organisms on the lowest level (with genetic changes that can also arise naturally or be made using conventional breeding techniques) should be exempt from the labelling requirements, while the others argue that all organisms covered by the Gene Technology Act should be labelled. This majority of 17 members also argue that requirements for traceability should be further reviewed, and that it may be reasonable to differentiate these based on feasibility.

A minority of 3 members think that current requirements for labelling and traceability for all GMOs should be kept as they are. This, they argue, will ensure consumer choice, while also being in accordance with international requirements.

How should contribution to societal benefit, sustainability and ethics be weighted?

According to the Gene Technology Act, a GMO must be ethically sound, beneficial to society and contribute to sustainable development in order to be approved. Is the requirement for a positive contribution still warranted when the same does not apply to products made with other technologies?

Regardless of the scope of the Gene Technology Act and how the organisms it covers are regulated, the board members unanimously argue that societal benefit, sustainability and ethics should be assessed as part of the approval process. However, there is disagreement about how these requirements should be weighted.

A majority of 13 members argue that all organisms under the Gene Technology Act should be required to contribute positively to social benefit, sustainability and ethics.

A minority of 7 members argue that the requirements should be differentiated according to the level-based system, where the absence of negative impact on society, sustainability and ethics should be sufficient for organisms with genetic changes that do not cross species boundaries or involve the use of synthetic (unnatural) DNA sequences.

Research and competence building

When it comes to research, the board members are in agreement – they believe 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

Genetic engineering of plants and animals is a complex topic, and there are many different opinions about what regulatory frameworks are most appropriate. The recommendations presented here also raise many questions. The Norwegian Biotechnology Advisory Board therefore invites to a public debate and dialogue to get comments and thoughts from all relevant stakeholders, as further basis for discussion before the statement is finalised.

To facilitate this, we plan to hold open meetings and talks in all of the biggest Norwegian cities over the next months. More information will follow online at www.bioteknologiradet.no/genteknologiloven.

The Board hopes this statement will contribute to knowledge building and fruitful discussions about this important topic. Our ambition is that the statement will also be a constructive contribution to the international debate about how organisms produced with gene technology should be regulated.

Bioteknologirådet

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Views and comments are sent to post@bioteknologiradet.no

Deadline for comments: 15th of May 2018

Comments will be posted at www.bioteknologiradet.no/genteknologiloven