



A novel tiered governance framework for GMO

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Bioteknologirådet
The Norwegian Biotechnology Advisory Board

The Norwegian Biotechnology Advisory Board (NBAB)

- Evaluate and discuss **social** and **ethical consequences** of modern biotechnology
- **Advice** the authorities
- **Inform** the public and promote **debate**





Wide range of genetic changes possible with genetic engineering:



**Potential uses for genetic technologies:
dialogue and engagement research
conducted on behalf of the
Royal Society**



**Findings Report
December 2017**

Report Authors:

Anita van Mil, Henrietta Hopkins, Suzannah Kinsella

Figure 37: To what extent is using genetic technologies in animals for food is a positive or negative development for society when this is done to increase profitability (e.g. genome edited cattle that grow larger)

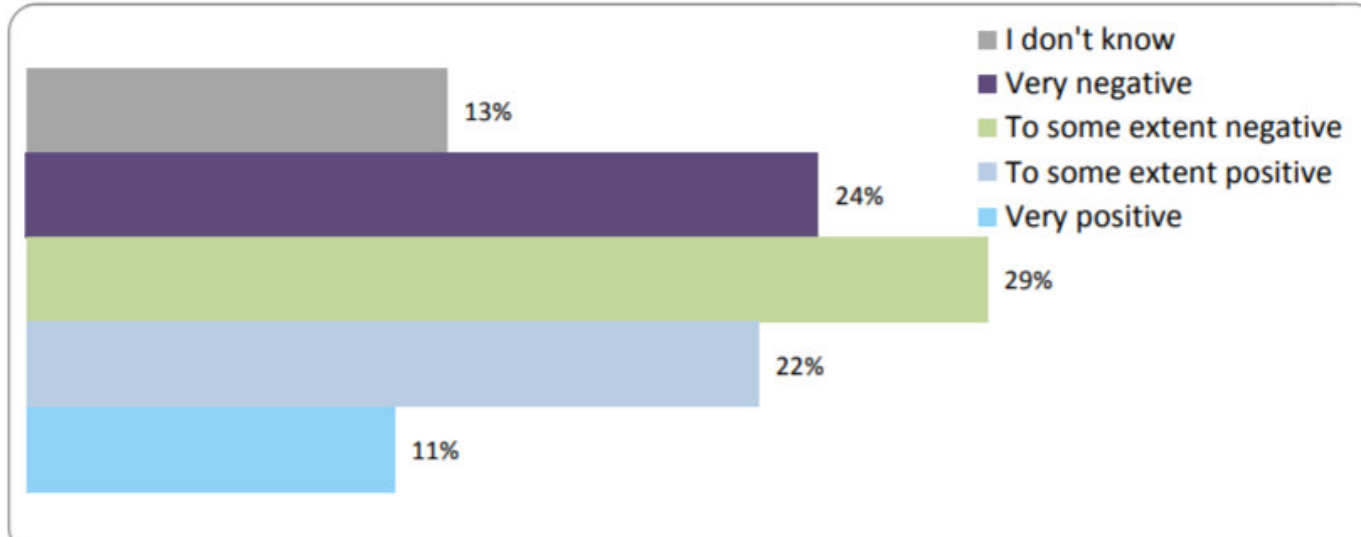
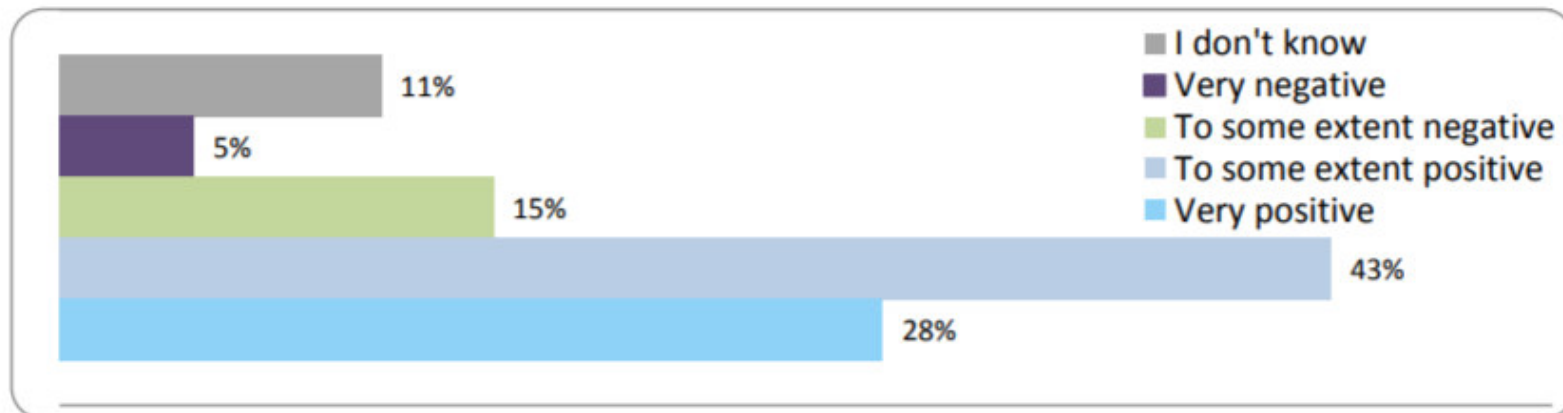


Figure 38: The extent to which using genetic technologies in animals for food is a positive or negative development for society when this is done to prevent disease



Statement on

GMO AND ETHICS IN A NEW ERA

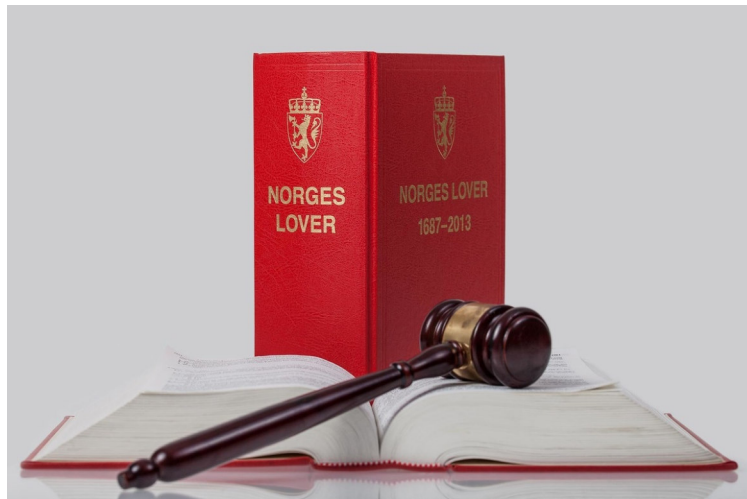


THE DANISH
COUNCIL
ON ETHICS

EU and Norwegian GMO regulation



- Directive 2001/18 (deliberate release) is incorporated into the EEA agreement and implemented into Norwegian law through the Gene Technology Act
- Regulation 1829/2003 (GM Food and Feed) is to be incorporated into the EEA agreement



GMO legislation in Norway

- Gene Technology Act



- Food Act



The Gene Technology Act - assessment criteria



Environment

Sustainability



Ethics

Health



Benefit to society



December 2018

The Norwegian Biotechnology Advisory Board :

Proposal for relaxation of Norwegian regulations for deliberate release of genetically modified organisms (GMO), with applicability also for EU legislation.



www.bioteknologiradet.no/a-forward-looking-regulatory-framework-for-gmo/

We have asked:

How can we utilize the potential of genetic engineering in a safe and ethically sound way, while at the same time promoting sustainability and benefit to society?



Oslo



Hamar



Trondheim



Ås



Tromsø



Bergen

A forward-looking regulatory framework that allows technological development

Safeguard important aspects (health, environment, societal benefit, sustainability and ethics)

Maintain oversight and control

Transparency and public trust

What should be covered by GMO regulation?

- NBAB statement

Three main options:

- Retaining the current distinction
- Including currently exempt organisms/methods
- Exempting certain organisms produced using gene technology



What should be covered by GMO regulation?

- NBAB statement

The Board recommend that no organisms with permanent heritable genetic changes obtained via gene technology should be exempted

Consequences of deregulation of certain genome edited organisms:

- Less oversight and control
- No option to assess risks or other aspects such as sustainability, societal benefit or ethics
- Less consumer choice

How should organisms covered by GMO regulation be assessed?

- NBAB statement

Minority position of the Board

Current requirements for approval/impact assessment should apply to all organisms covered by GMO regulations

More actively differentiation between various types of organisms

- guidance documents



Majority position of the Board

Exempted from regulation	
Organisms with temporary, non-heritable changes	
TIER 1	
Genetically engineered organisms with changes that exist or can arise naturally and can be achieved using conventional breeding methods	Notification (confirmation required)
TIER 2	
Organisms with other species-specific genetic changes	Expedited assessment and approval
TIER 3	
Organisms with genetic changes that cross species barriers or involve synthetic (artificial) DNA sequences	Standard assessment and approval (current requirements)

Labelling and traceability/detection requirements can be tailored to feasibility on each tier

Covered by GMO regulation

Societal benefit, sustainability and ethics assessed on tiers 1–3

A joint Board recommended that societal benefit, sustainability and ethics should still be part of the assessment



Majority position of the Board

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Covered by
GMO regulation

Societal benefit, sustainability and ethics assessed on tiers 1–3

Public dialogue at the heart of the process

7 public meetings, 50 written feedbacks

Many, in particular those from industry and academic research, supported a tiered regulatory system where assessments are differentiated according to the genetic change.

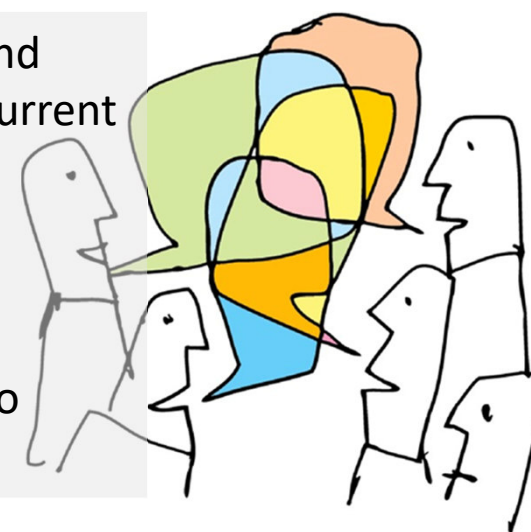
Arguments:

- GMO regulations will be a significant barrier to using new technologies if approval requirements are not relaxed.
- Risk assessments will be more proportional to the risk and more predictable
- Concern about future competitiveness for Norwegian businesses

Several other, especially those from farmer`s organisations and environmental organisations, supported the keeping of the current GMO regulations.

Arguments:

- Guidance documents will give sufficient flexibility
- We have limited experience using new gene technologies
- An expedited assessment or notification is not sufficient to uncover risks



A joint NBAB has recommended that the Norwegian government appoint an official committee to review proposals for amendments to the Gene Technology Act



Thanks!



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