

Proposed revisions of the Norwegian Gene Technology Act

- As a result of the challenges from
 - new breeding technologies

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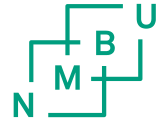
Genetically modified purple carnations are the only GMO approved in Norway



Background

- Norwegian Gene Technology Act
- Norwegian Biotechnology Advisory Board
- New breeding technologies
- Proposed novel regime
- What implications may this have on a given case?
- Conclusions



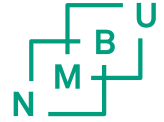


The Norwegian Gene Technology Act

- Act of April 2 1993 no 28 on production and use of genetically modified organisms (GMO)
- Came into force on Sept 1st 1993



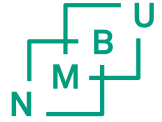
International guidelines and legal framework



- OECD Guidelines 1986
- EU directives built upon OECD Guidelines
 - (90/219/EEC) on contained use
 - (90/220/EEC) on deliberate release

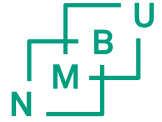


Aims of the Norwegian Gene Technology Act



- Secure that production and use of GMO happens in an **ethical way** and is **beneficial to society**, in accordance with the principle of **sustainable development** and **without adverse effects on health and environment**
- EU Legislation has two of these aims: without adverse effects on health and environment

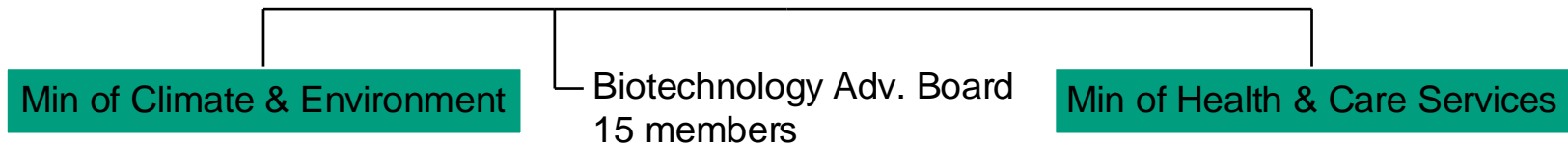




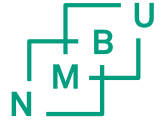
Biotechnology Advisory Board

Gives advice on two laws:

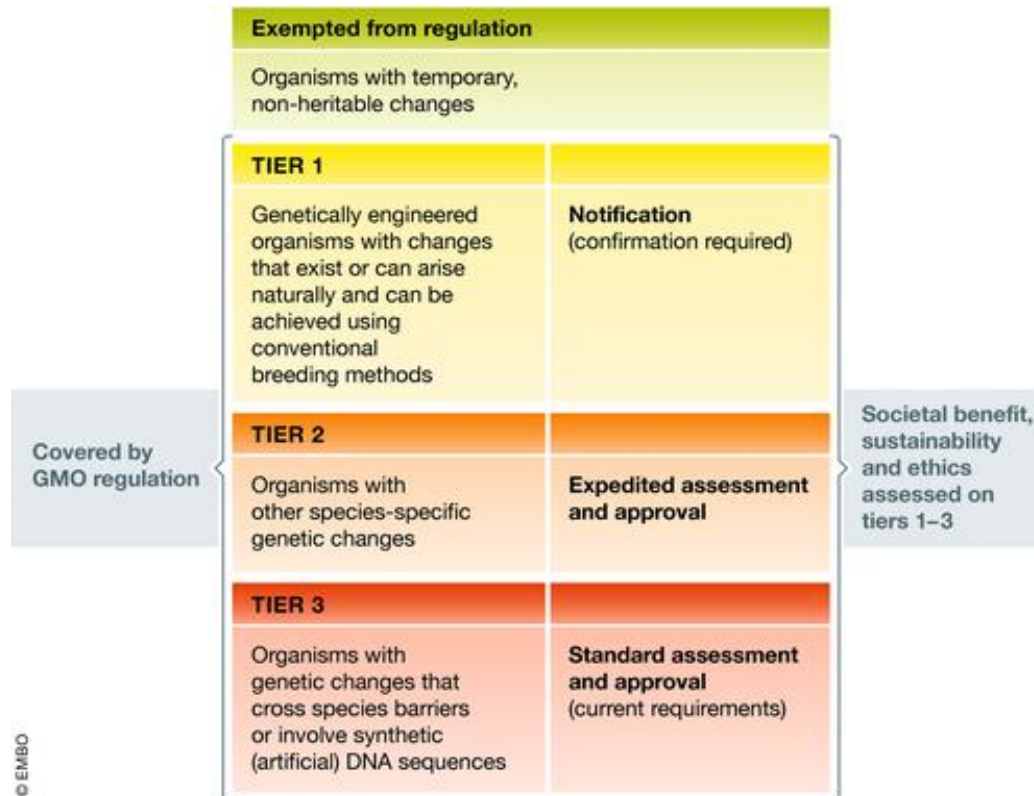
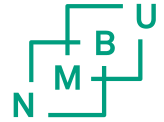
The Gene Technology Act and The Biotechnology Act



The Biotechnology Advisory Board



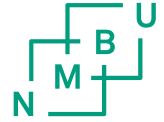
- Took an independent action to revise the Act due to new breeding technologies
- Proposed a novel regimes in Dec 2017
- Public hearing till May 15th 2018
- Revised proposal in Dec 2018 – handed over to the Ministry of Climate and the Environment
 - It is being considered by the Directorate for the Environment at the moment



What will happen next?

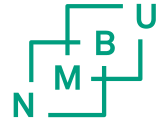
- A government Committee on revisions of the Act?
- What can we do within the current framework from EU?
- Do we need to influence the Competent Authorities in EU and the Commission to revise the Directives?

What implications may this have for CA in Norway?



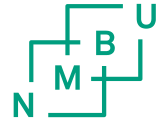
- They will be given an oversight of gene edited plants in the pipeline
 - even if there are no traces left

What implications may this have for plant breeding in Norway?

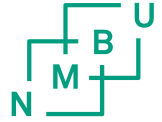


- The reduced request for risk assessment will allow small and medium enterprises to market gene edited plants
- Norwegian plant breeders and universities will be enabled to take on research and become more competitive
 - Benefit to society? More jobs?
- Farmers will have access to improved varieties
 - More sustainable?
- Norwegian consumers may have more healthy produce in the shops

One example – potato resistant to late blight



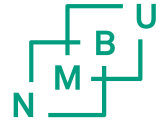
- Alternative 1 – no genes added – just edited existing **genes** to improve resistance
- Alternative 2 – genes for resistance added (stacked)



Late blight in potato

Exempted from GMO regulation Organisms with temporary, non-heritable changes		
Covered by GMO regulation	Tier 1 NO extra DNA added	Notification (confirmation required)
	Tier 2 Genes from close relatives added	Expedited assessment and approval
	Tier 3 Genetically engineered organisms with genetic changes that cross species barriers or involve synthetic (artificial) DNA-sequences.	Standard assessment and approval (current requirements)
		Societal benefit, sustainability and ethics are criteria at levels 1-3

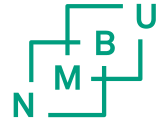
If the potato project succeeds – what then?



- 7 sprays against the fungus is saved on average each year
 - 75 million NOK = 7.5 million EURO
 - The environment is spared from fungicides
 - The potato does not have fungicide residues

Surely, this would benefit the **environment**, people's **health**, would lead to a more **sustainable** agriculture, be **beneficial to society** and is **ethically justifiable**?

Further read



A novel governance framework for GMO

– A tiered, more flexible regulation for GMOs would help to stimulate innovation and public debate

[Bratlie](#), S. et al.,

EMBO Rep (2019)20:e47812

<https://doi.org/10.15252/embr.201947812>

