



GMO regulation in Norway

Bjarte Rambjør Heide, Head of Section - VKM/EFSA symposium, 26.10.2017



Outline



The Norwegian Gene Technology Act



Independent risk assessments



Risk management



Norwegian GMO decisions

The Gene Technology Act

Norwegian legislation related to genetic modification



Gene Technology
Act



Food Act

Gene Technology Act



GMO: *“Microorganisms, plants or animals where the genetic composition is changed through the application of gene- or cell technology”*

Research/trials
and commercial
applications

Labelling and
transport/import
requirements

Control and
monitoring

Contained use



Overview GMO regulation in Norway



- Gene Technology Act



- Directive 2001/18/EC



- Cartagena protocol on Biosafety

Gene Technology Act

§10:

“Approval is not required for the placing on the market of a product that has been approved for placing on the market in another EEA state pursuant to the rules laid down in Annex XX, paragraph 25, of the EEA Agreement (Council Directive 90/220/EEC)”.

“The competent authorities under the present Act may nevertheless prohibit or limit such placing on the market if in their view it involves a risk to health or the environment or if placing on the market is otherwise in conflict with the purpose of this Act”.

Gene Technology Act

§1:

“The purpose of this Act is to ensure that the production and use of genetically modified organisms and the production of cloned animals take place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on health and the environment”

The Norwegian assessment criteria

Benefit to
society

Ethics

Sustainable
development

Health

Environment

Independent risk assessments

Independent GMO assessments

The logo for VKM consists of the letters 'VKM' in a bold, green, sans-serif font. The letters are closely spaced and have a slight shadow effect.

Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety



Bioteknologirådet

Independent GMO assessments



Risk assessments on health and environment.

Mission on ERA from the NEA since 2007.

Norwegian link to EFSA.



Assessments of sustainability, benefit to society and ethics.

Role established in § 26 of the Act.

Assessments should build on EFSA and VKM assessments.

Independent GMO assessments

	Carnations	Maize line 1507	Oilseed rape lines Ms8/Rf3/Ms8xRf3
VKM	No increased health risk. Does not represent an environmental risk in Norway.		
NBAB	Not necessary to prohibit as there is no risk to health or environment.		
Public	«OK»		

Independent GMO assessments

	Carnations	Maize line 1507	Oilseed rape lines Ms8/Rf3/Ms8xRf3
VKM	No increased health risk. Does not represent an environmental risk in Norway.	Essentially identical to unmodified maize except for the inserted traits.	
NBAB	Not necessary to prohibit as there is no risk to health or environment.	Majority recommended that Norway prohibit maize line 1507.	
Public	«OK»	Overall negative	

Independent GMO assessments

	Carnations	Maize line 1507	Oilseed rape lines Ms8/Rf3/Ms8xRf3
VKM	No increased health risk. Does not represent an environmental risk in Norway.	Essentially identical to unmodified maize except for the inserted traits.	No toxic, allergenic or nutritionally altered traits. Likelihood of spread to relatives very low.
NBAB	Not necessary to prohibit as there is no risk to health or environment.	Majority recommended that Norway prohibit maize line 1507.	Majority advised the authorities to prohibit the oilseed rape lines.
Public	«OK»	Overall negative	Overall negative

Independent GMO assessments

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Public	«OK»	Overall negative	Overall negative

Risk management

Risk management agencies



Coordinating agency for all applications.
Environmental risk management.
Overall assessment and advice to the government.



Health risk management.
Agronomic assessment.

The opinions of risk management agencies

	Carnations	Maize line 1507	Oilseed rape lines Ms8/Rf3/Ms8xRf3
NFSA	NR		
NEA	Recommended that the carnations should not be prohibited		

The opinions of risk management agencies

	Carnations	Maize line 1507	Oilseed rape lines Ms8/Rf3/Ms8xRf3
NFSA	NR	Supports the VKM assessment	
NEA	Recommended that the carnations should not be prohibited	Recommended that maize line 1507 should not be prohibited	

The opinions of risk management agencies

	Carnations	Maize line 1507	Oilseed rape lines Ms8/Rf3/Ms8xRf3
NFSA	NR	Supports the VKM assessment	Unless more restrictive measures are implemented, there is a degree of risk of undesirable seed spillage.
NEA	Recommended that the carnations should not be prohibited	Recommended that maize line 1507 should not be prohibited	Recommend that the oilseed rapes should be prohibited.

The opinions of risk management agencies

	Carnations	Maize line 1507	Oilseed rape lines Ms8/Rf3/Ms8xRf3
NFSA	NR	Supports the VKM assessment	Unless more restrictive measures are implemented, there is a degree of risk of undesirable seed spillage.
NEA	Recommended that the carnations should not be prohibited	Recommended that maize line 1507 should not be prohibited	Recommend that the oilseed rapes should be prohibited.

Norwegian GMO decisions

Norwegian GMO decisions

- Decisions not to prohibit EU-approved GMOs are considered to be administrative decisions.
- Decisions to prohibit EU-approved GMOs are subjects to royal decrees.



Norwegian Ministry
of Climate and Environment



Norwegian Ministry
of Health and Care Services



Norwegian Ministry
of Foreign Affairs



Norwegian Ministry
of Agriculture and Food



Nærings- og
fiskeridepartementet

Norwegian GMO decisions

Carnations

- No risk to environment or health identified
- No negative impact on sustainability, benefit to society or ethics identified

Maize line 1507

- Negative assessment of ethics

Oilseed rape lines Ms8, Rf3 and Ms8xRf3

- Low, but not negligible, risk to the environment identified

PROHIBITED

PROHIBITED

Norway

“...must continue to pursue a restrictive GMO policy.”

(the Parliament's Standing Committee on Business and Industry 6 April 2017).



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