



NORWEGIAN MINISTRY OF
CLIMATE AND ENVIRONMENT



The Norwegian approach:
Socio-economic and sustainability aspects in
the framework of national GMO assessments

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Outline

- **Principles** of the Norwegian Gene Technology Act
- **Experiences** with the implementation of socio-economic aspects and sustainability in the assessment of GMOs
- **Challenges** for advisory bodies, regulators and decision makers

In Norway GMOs are regulated by the Gene Technology Act (1993)

§ 1 Purpose of the Act

*“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 Gene Technology Act

§ 10 Requirements relating to approval

*“The deliberate release of genetically modified organisms may only be approved when there is no risk of adverse effects on health or the environment. In deciding whether or not to grant an application, **considerable weight** shall also be given to whether the deliberate release will be of **benefit to society** and is likely to **promote sustainable development.**”*

Deliberate release of GMOs in Norway:

Always public consultation

- **§ 13 on Public consultation:**
 - Public consultation is to be announced and held before a decision is made.
 - To be carried out in a way that ensures that the general public and interest groups are given access to relevant information

Information flow, public participation

- The Norwegian Environment Agency coordinates public hearings and provides information on its website/through Biosafety Clearing House.
- Around 50 organisations, advisory bodies, research institutions and interest groups are actively invited to participate and submit comments
- Risk/impact assessments from research institutions and advisory committees are published (www).
- National decisions are finally announced/published through Official Governmental Gazette, websites, newspapers.

Norwegian Biotechnology Advisory Board

- Gives advise to the Government, provides information to the public
- Consists of 15 members representing different fields of expertise and interest groups
- Adressess issues related to gene technology and human biotechnology
- Is NOT a traditional expert committee
- Ideally, should reflect Society at large
- Both lay man's perspectives and views from academia are reflected

The Norwegian Gene Technology Act (in summary):

- Broad list of assesment criteria
- Rules for information flow, public hearings and public participation
- The Norwegian Biotechnology Advisory Board

Norwegian GMO policy is restrictive

- Norway has implemented directive 2001/18 and assess/comment on GMO applications as they are processed in the EU.
- Only four plant GMOs have been actively approved so far (carnation lines and a tobacco)
- National bans (main arguments being health and environmental issues):
 - Four oil seed rape lines
 - One maize line (Bt 176)
 - One chickory salad
- National regulation on GM food and feed prohibits products with inserted antibiotic resistance gene markers

GMO assessment structure

The evaluation is organized as follows:

1. **Risk of adverse effects** on human and animal health and the environment:
 - a) what are the possible adverse effects?
 - b) how probable are these effects?
2. **Precautionary principle:**
 - a) is there justified uncertainty associated with the risk assessment?
 - b) is there a possibility of substantial or irreversible harm?
3. Will the GMO
 - a) tend to promote or hinder **sustainable development**?
 - b) have favourable or unfavourable **social consequences**?
 - c) be **ethically justifiable**?

Socio-economy/social utility

Relevant questions in the assessment of a GMO and its **benefit to society**:

- Is there a need or demand for it?
- Can it solve a problem for the society?
- Is it better than corresponding products?
- Are there better alternatives?
- Does it help create new employment opportunities?
- Does it cause problems for existing production?

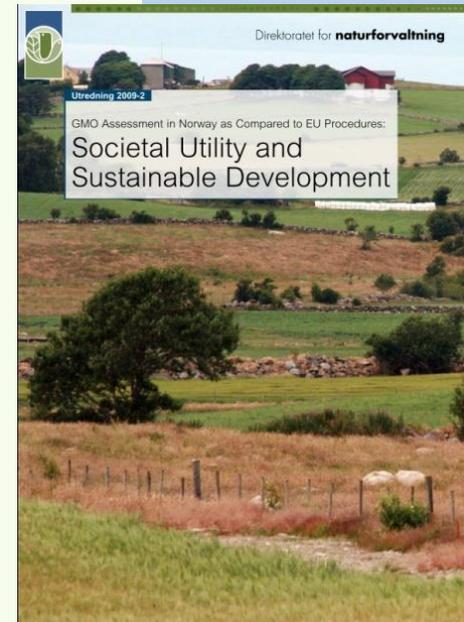
Some parameters for sustainable development

Questions that may be relevant to ask:

- **Global impacts**
 - Is biodiversity affected?
 - Is the functional capacity of ecosystems affected?
- **Ecological limits**
 - Is the distribution between use of renewable and non-renewable natural resources affected?
- **Distribution between generations**
 - impact on the distribution of benefits/burdens between generations?
- **Distribution between rich and poor countries**
 - impact on the distribution of benefits/burdens between rich and poor countries?

Challenges for advisory bodies, regulators and decision makers in Norway

- For our broader national assessments, typically only **limited information** is available on
 - **Sustainable development**
(risk assessment from the notifier is highly relevant)
 - Information regarding **social utility** and **ethics**
(Report on LMO Assessment in Norway as Compared to EU Procedures (2009))



Challenges for advisory bodies, regulators and decision makers in Norway

- **Missing data**
 - Not information available from one or more GMO cultivating regions
 - Not information available for one or more aspects that Norway finds relevant for our overall assessment
- **Contradictory influence**
 - Positive influence on a criterion/parameter in one region – negative influence on the same criterion/parameter in another region
 - Positive influence based on one criterion – negative influence when another criterion is evaluated
- **The difficult task of weighing and balancing**



What do we do?

- **Retrieving supplementary information from Notifiers**
 - Specific questions to the EFSAnet
 - Direct requests to the Notifiers
- **Retrieving information from other sources**
 - Peer review literature
 - National reports
 - International reports
 - Information from stakeholders
- **Several notifications pending**
- **At the moment no “pull” and little “push”**

Conclusions

- **The Norwegian Gene Technology Act requires a broad approach to GMO assessment - increased complexity**
- **Notifications to the EU do not provide sufficient information for us to address our broad assessment criteria**
- **So far, Norway has no ban on a GMO solely based on the assessment criteria ethics, sustainable development and social utility**

Thank you for your attention!

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