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Socio-economic considerations in decision-making on LMOs: experiences from Norway

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Outline

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

LMOs in Norway

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- No LMOs approved for cultivation in the environment, food or feed.
- Eight LMOs have been prohibited in Norway
  - vaccines, oilseed rape, maize, chickory salad , test kit for antibiotics in milk
- 12 LMOs have been approved in Norway
  - Mainly carnations
- Four applications for LMOs are pending in the Ministries
  - One oilseed rape, two maize and one potato

The Norwegian Gene Technology Act

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- § 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

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- § 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*.

The Norwegian Gene Technology Act

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- Five assessment criteria:
  - Health
  - Environment
  - Ethics
  - Sustainable development
  - Benefit to society
- The Norwegian Biotechnology Advisory Board (NBAB).

Regulation relating to impact assessment pursuant to the GTA Appendix 4

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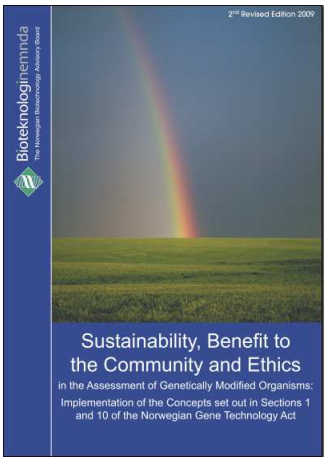
- Opinion of the NBAB on how to implement the concepts sustainability, benefit to community and ethics.
- Based on
  - GTA & preparatory docs
  - Official Norwegian policy on sustainable development and precautionary principle



Assessment of benefit to society

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Relevant questions in the assessment of a LMO product 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 opportunites?
- Does it cause problems for existing production?

Sustainable development

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Definition:

"*Development that meets the needs of the present without compromising the ability of future generations to meet their own needs*".

World Commission on Environment and Development (Brundtland Commission) 1987

Assessment of contribution to sustainable development

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Categories of questions and examples relevant questions:

- **Global impacts**
  - global impacts on biodiversity?
- **Ecological limits**
  - impact on the efficiency of energy use?
- **Basic human needs**
  - impact on the degree to which basic human needs are met?
- **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?
- **Economic growth**
  - impact on the global/transnational environmental impacts of economic growth?

Norwegian processing of applications before decision in the EU

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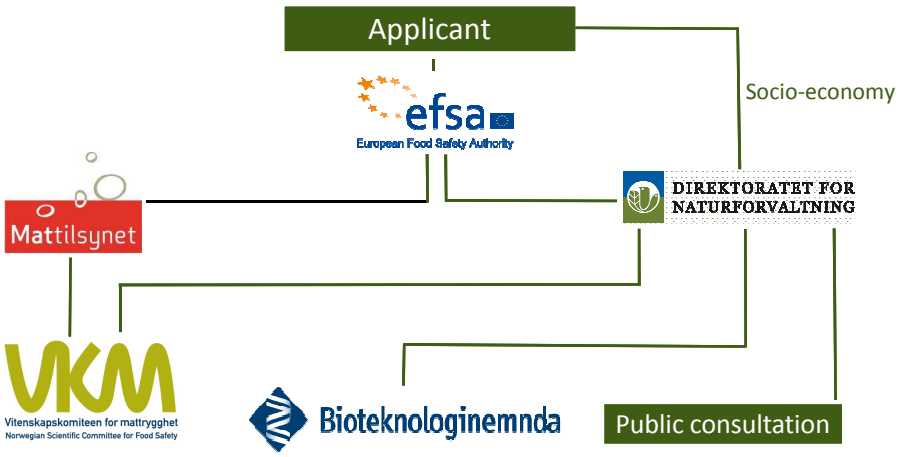

Challenges for advisory bodies, regulators and decision makers

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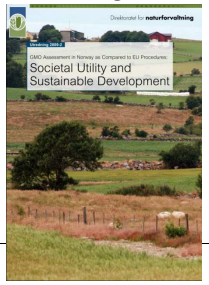
GMO Assessment in Norway as Compared to EU Procedures

- Evaluation of sustainable development, elements ”global impact” and ”ecological limits”.
  - RA of Notifier of high relevance.
- Evaluation of sustainable development, remaining elements
  - no information in the Notifications.
- Evaluation of social utility.
  - information scarce and not substantiated.



12

Challenges for advisory bodies, regulators and decision makers

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- **Information contained in the GMO notifications in the EU**
  - Relevance for an assessment of sustainability and benefit to the society?
- **Retrieving supplementary information from Notifiers**
  - General information regarding socio-economics to the EFSAnet
  - Direct requests to the applicants
- **Retrieving information from other sources**
  - Peer review litterature
  - National reports
  - International reports
- **Retrieving information from stakeholders**

13

Case 1 Carnation Moonlite

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- 11 carnations have been approved in Norway
- Last assessment by the NBAB regarding carnations from 2008:
  - Carnation Moonlite – not yet approved

Case 1 Carnation Moonlite

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The NBAB (2008)

- All members concluded that Moonlite was not particularly beneficial to society nor that it contributed to a more sustainable development
- However, the majority (11/17) were of the opinion that the interests of sustainability and benefit to society could not be given decisive impact in the negative direction.
- The majority emphasized that the proposed use of Moonlite did not involve health or environmental risk.
- Therefore, the majority recommended the Norwegian authorities to approve the application regarding imports of cut flowers of carnation line Moonlite.

Case 2
Gluphosinate-ammonium tolerant maize T25

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Background

- Norwegian Scientific Comittee for Food Safety:
  - *The Committe cannot identify documentation that the maize [T25] after 10 years of cultivation and use as food and feed is less safe than conventional maize with regards to health*.
  - *The Commitee finds that it is not likely that use of maize T25 will result in altered risk for the environment as compared to conventional maize*.

Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Case 2
Gluphosinate-ammonium tolerant maize T25

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Background

- The Norwegian Biotechnology Advisory Board

  14 of 15 members recommended a ban on T25 to be issued, based on:
  - use of gluphosinate-ammonium is worrying in terms of sustainability issues, and risk to health and the environment.
  - the documentation regarding sustainability, benefit to society and ethics should be more comprehensive
  - lack of documentation of the vitamin content in T25

Bioteknologinemnda

Case 2
Gluphosinate-ammonium tolerant maize T25

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Background

- Public consultation
  - Three consultation bodies were opposed to the approval of the product.
  - Two consultation bodies were in favour of approval of the product.
  - One consultation body considered the information contained in the Notification incomplete.

Case 2
Gluphosinate-ammonium tolerant maize T25

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Report from the regulatory authorities to the MoE

- Cultivation: **No**
  - The recommendation was based primarely on burden to society.
- Import, food and feed: **Yes**
  - The recommendation was primarely based on the assessment of risk to health and the environment by the commitee.

Ongoing work

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- The Norwegian Directorate for Nature Management is currently, in cooperation with the NBAB, considering how to develop trait-specific guidelines for assessment of sustainability and benefit to society.

Conclusions

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- The Norwegian Gene Technology Act requires a broad approach to GMO assessment - increased complexity.
- Norway has developed a framework for the assessment of socio-economic, but has not finalized detailed guidelines as to how the socio-economic criteria should be assessed or weighed
- Norway has not used the socio-economic criteria to any large extent in decision-making on LMOs.
- Implementing criteria requires continuous efforts and considerations.