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The Norwegian Gene Technology Act and socio-economic considerations

The Norwegian Gene Technology Act establishes that the socio-economic criteria sustainability, benefit to society and ethics are important criteria in the impact assessment of living genetically modified organisms prior to cultivation, import and use as food or feed in Norway.

The Norwegian Act relating to the use and production of genetically modified organisms (GMOs) emphasises that the deliberate release of such organisms should not have detrimental effects on health or the environment. This emphasis is fully in line with the legislation of other nations concerning the regulation of GMOs.

Unlike the regulations of most other nations, however, the Norwegian Gene Technology Act also stresses that the deliberate release of such organisms should represent a "benefit to the community" and enable "sustainable development". These concepts are used in Sections 1 and 10 of the Act.

Sustainable development

Integrating the sustainability concept with a basic needs-based version of the development concept was what originally gave rise to the World Commission understanding of the concept. In the report "Our common future" (1987), the term "sustainable" was given a far broader meaning than had previously been the case in the field of conventional nature conservation. According to the World Commission, sustainable development is "development that meets the needs of the present without compromising the ability of future generations to meet their own needs". Following the World Commission's definition assessments of sustainability of GMOs apply globally and in a longer time span (generations). This means that sustainability assessments should not only be performed for domestic cultivation, but also for products imported for food and feed. The assessments should include ecological, economic and social sustainability issues.

Section 1 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".

Section 10 of the Act

" (...) 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".

Relevant questions in an assessment of impact on sustainability include:

- Is biodiversity affected on a global scale?
- Is the fulfillment of basic human needs like food, shelter, health affected?
- Are emissions of greenhouse gasses affected?
- Is the distribution of benefits or burdens between generations affected?
- Is the distribution of benefits or burdens between rich and poor countries affected?



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Benefit to society

The Act sets out that the benefit to society must be assessed prior to an approval. Assessments of benefit to society has domestic focus. Benefit to society is a complex concept, for which neither the Act itself nor its legislative history provides any clear guidance as to how it should be interpreted. However, it is clear that the assessment should go beyond the benefits of the individual manufacturer or consumer. It is also a matter of third party considerations.

Relevant questions in an assessment of benefit to society include:

- Is there a need for the product in terms of demand or otherwise?
- Will the product solve or possibly contribute to solving a societal problem?
- Is the product significantly better than equivalent products already on the market?
- Does the product create problems for existing production which should be preserved?

Ethics

The Act contains issues both relating to ethical norms and values associated with humans and environmental ethical considerations. Focus is *inter alia* on indigenous populations and on species barriers.

The Biotechnology Advisory Board

Section 26 of the Act establishes the role of the Norwegian Biotechnology Advisory Board (NBAB). The NBAB is an advisory body for Norwegian authorities for issues relating to modern biotechnology. The NBAB has a central role in the implementation of the concepts of sustainability, benefit to society and ethics in the Norwegian legislation. Furthermore, in the context of applications for the marketing of GMOs, the NBAB has an important role in the assessment of the specific product's impact on sustainability, benefit to society and ethics.

Socio-economics and decision making

On the basis of the European Economic Area Agreement, Norway participate in the processing of GMO applications under Directive 2001/18. An adaption to the Directive gives Norway the possibility of prohibiting marketing on the basis of national legislation, including assessments of sustainability, benefit to society and ethics.

Norway has prohibited release of some GMOs approved in the EU, based on a combination of arguments, *inter alia* socio-economic issues. However,



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socio-economic factors have so far not been given *decisive* weight in Norwegian decisions regarding release of GMOs .

Ongoing efforts

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.

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The Norwegian Directorate for Nature Management has central, national tasks and responsibilities in managing the natural environment of Norway. These entail preserving biodiversity and paving way for outdoor recreation and the use of resources provided by nature. The Directorate is an advisory and executive agency under the Norwegian Ministry of the Environment. We are authorised to manage natural resources through various Acts and Regulations adopted by the Norwegian Parliament. In addition to tasks fixed by law, the Directorate for Nature Management is also responsible for identifying, preventing and solving environmental problems.