



Sustainability, Benefit to the Community and Ethics

in the Assessment of Genetically Modified Organisms:
Implementation of the Concepts set out in Sections 1
and 10 of the Norwegian Gene Technology Act

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Layout: The Norwegian Biotechnology Advisory Board

The Norwegian Biotechnology Advisory Board is an independent body appointed by the Norwegian government and was established in 1991. The Board is founded in the Act relating to the application of biotechnology in medicine and the Act relating to the production and use of genetically modified organisms.

The main tasks of the Norwegian Biotechnology Advisory Board are to identify and examine the ethical questions raised by applications of modern biotechnology on humans, animals, plants and microorganisms, provide advice that can assist policy-making and stimulate public debates on the issues.

Preface

In its contribution to the 1998 National Budget, the Norwegian Ministry of the Environment requested the Norwegian Biotechnology Advisory Board to provide an opinion on how to implement the concepts of “sustainable development” and “benefit to the community” set out in the Norwegian Gene Technology Act.

On 1 September 1998, the Biotechnology Advisory Board set up an ad hoc committee consisting of Andreas Føllesdal, Karl Georg Høyer, Hilde Kruse and Marte Rostvåg Ulltveit-Moe, with Jens Plahte as secretary and Guri Tveito from the Ministry of the

Environment as observer. The committee was assigned the task of preparing the Board’s own discussions on the implementation of these concepts. Andreas Føllesdal and Karl Georg Høyer have led the work of the committee which eventually resulted in the production of this document.

In this report, discussed at a meeting on 4 November 1999, the Biotechnology Advisory Board presents its opinion on the implementation of the concepts of “sustainable development”, “benefit to the community” and “ethical and social considerations”.

Torleiv Ole Rognum

Chairman

Sissel Rogne

Director

Preface to revised edition

The Norwegian Ministry of the Environment has recently updated the regulations for consequence analysis following the Norwegian Gene Technology Act (the new regulations are valid from 01.01.2006). The regulations have been updated with an attachment containing parts of the Advisory Board’s implementations of the concepts of “sustainable development”, “benefit to the community” and “ethical and social considerations”.

In connection with the updates the Ministry of the Environment has done to the regulations, The Norwegian Biotechnology Advisory Board wishes to revise the document describing the implementation of the concepts in the

Gene Technology Act mentioned above. This document was finalized by the Advisory Board in 1999 (see Preface, above).

An ad hoc committee consisting of members from the Biotechnology Advisory Board has been responsible for revising this document. These members are Bjørn Erikson, Karl Georg Høyer, Siri Mathiesen and Marte Rostvåg Ulltveit-Moe in cooperation with the secretariat.

The general structure of the document has not been significantly changed. There are a few general changes and some rewrites in Chapter 4 concerning the “precautionary principle”.

Lars Ødegård

Chairman

Sissel Rogne

Director

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Introduction

The Norwegian Act relating to the production and use of genetically modified organisms¹ strongly emphasizes that the deliberate release of such organisms should have no detrimental effects on either health or the environment. This emphasis is fully in line with the legislation of other nations concerning the regulation of genetically modified organisms (GMOs). In the Act's preparatory work², several references are made to the concept of risk. One of these references emphasizes that the wording "*without detrimental effects on health and the environment*" in the purpose statement of the Act should not be interpreted

literally – but rather that the expression "without detrimental effects" has been used to emphasize the aim of carrying out a prior assessment of the risk to health and the environment and avoiding possible detrimental effects, and that this should be underpinned by the precautionary principle. It is further stated that "*a strict assessment of risk to health and the environment is in line with the views of the Government and the Parliament*"³ (These concepts will be discussed further in Chapter 3).

As distinct from the regulations of 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 Norwegian Gene Technology Act.

The EU has since established new GMO-directives⁴ that move towards the Norwegian legislation. However, there are still differences in the emphasis on ethics and benefit to the community as the Norwegian laws demand an assessment of the GMO's contribution to sustainable development.

However, it is not self-evident how "sustainability" and "benefit to the community" should be considered in terms of the practical application of the Act. In the light of the preparatory work, consultative statements and the political debate on the Gene Technology Act, it is not clear whether the provisions contained in Section 10 relating to "benefit to the community" and "sustainable development" are to be considered as additional requirements or as a softening-up of the requirement for no detrimental effects on either health or the environment. "Sustainable development" and "benefit to the community" can be understood as either:

The Gene Technology Act, Section 10, excerpt:

"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."

Sustainable development

The World Commission defined sustainable development in the report "Our Common Future" (1987) as

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

The concept of "sustainable development" is included in the Gene Technology Act in two ways, both as part of the purpose statement of the Act and as an explicit criteria for approval (Section 10, second paragraph, see above).

1. For the Gene Technology Act, see www.lovdato.no

2. Ot. prp. nr.8 (1992-93)

3. Stortinget: The Norwegian Parliament

4. Most importantly the deliberate release directive 2001/18/EC which in 2002 replaced directive 90/220

- additional requirements to the absence of detrimental effects on health and the environment; or
- a softening-up of the requirement of non-detrimental effects; or
- an additional requirement that alone could be sufficient grounds for refusing approval or for a softening-up of the requirement of non-detriment.

According to the first alternative, the requirement would be that, in addition to having no detrimental effects on health and the environment, the *“deliberate release represents a benefit to the community and a contribution to sustainable development”*. If the deliberate release fails to fulfil this requirement, the recommendation would be to reject an application for approval. Under this alternative, any softening-up of the requirement of non-detriment would be impossible.

The second alternative does allow for the approval of deliberate releases even when the possibility of detrimental effects on health and the environment have been established, if it can be demonstrated or argued that the *“deliberate release represents a benefit to the community and a contribution to sustainable development”*. Consequently, the requirements of “sustainable development” and “benefit to the community” are being used as an opportunity for softening up or counterbalancing the requirement of non-detriment, but may not be applied as an additional requirement that alone could be sufficient grounds for rejecting an application for approval. Support for this view is to be found on page 6 of the Proposition to the Odelsting⁵ Ot. prp⁶. 8, where it is stated that

“The greater the risk, the greater the emphasis that must be placed on what the purpose of the measure is”.

In the third alternative, the requirement of “benefit to the community” and/or “sustainable development” could constitute independent grounds for rejecting an application for approval. Support for this interpretation is to be found in the wording of Section 10, second paragraph, stating that “significant emphasis shall also be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development”. Furthermore, “sustainable development” and “benefit to the community” can be used to soften up the requirement of non-detriment. This could be considered as a combination of the first two alternatives and is the alternative the Biotechnology Advisory Board judges to be the best interpretation of the Act.

Furthermore, the Biotechnology Advisory Board has felt the need to determine what is meant by the term “ethically and socially justifiable” (see Section 1 of the Gene Technology Act), as well as which conclusions the Board might attribute to such considerations in its assessments and guidelines for the way in which genetically modified organisms should be regulated. In addition, the Board has considered how the precautionary principle may be applied in regulating genetically modified organisms. The precautionary principle is not mentioned in the Norwegian Gene Technology Act, but appears as an important concept in its preparatory work, as well as in international environmental conventions and agreements.

5. Odelsting: One division of The Norwegian Parliament

6. Ot.prp: Proposition to the Odelsting

Opinion of the Norwegian Biotechnology Advisory Board

1. Decision-making structure

In the opinion of the Norwegian Biotechnology Advisory Board, Section 10 of the Gene Technology Act should be interpreted to mean that the requirements of “sustainable development”, “benefit to the community” and other “ethical and social considerations” represent prerequisites that alone could carry decisive weight against granting an application, but that should also be considered in relation to, and weighed against the risk of detrimental effects, when such risk is low.

Hence, an assessment of the individual application will have the following structure:

- 1) Danger of detrimental effects on health and the environment:
 - a) what are the possible negative consequences?
 - b) what is the likelihood of such consequences occurring?
- 2) The precautionary principle:
 - a) is the risk assessment associated with justified uncertainty?
 - b) is there a possibility of substantial or irreversible harm?
- 3) Is it:
 - a) in compliance with the principle of “sustainable development”?
 - b) of “benefit to the community”?
 - c) “ethically and socially justifiable”?

If there is a demonstrable yet minor risk of detrimental effects under item 1) and the precautionary principle is not applicable according to item 2), then the contribution to “sustainable development” and “benefit to the community” may be seen as significant enough to warrant that the application nevertheless may be recommended (the application is in other respects ethically and socially defensible).

The Biotechnology Advisory Board is an

advisory body and should in all cases consider “sustainable development”, “benefit to the community” and other “ethical and social considerations”, even though it believes there may be a serious risk of detrimental effects involved. In the event that the opinions of the decision-making authority, the Ministry of the Environment, were to differ from that of the Biotechnology Advisory Board on the risk of the detrimental effects of an application, it is important that assessments of the other criteria stipulated in the Act should be made.

2. System limits

An essential question is to understand the limits of the system relating to the cases for consideration. It is particularly important not to define the system limits for “sustainable development”, “benefit to the community” and other “ethical and social considerations” too narrowly. The Gene Technology Act uses the terms “production” and “use” to express this broader approach. This means that assessments should not only apply to the genetically modified product itself, but also to the production system in a broader sense, which includes the production line – from development and pilot production to processing in a production facility – and thereafter the marketing, sales and distribution of the finished product. But it also covers the properties of the product itself. The Biotechnology Advisory Board feels, therefore, that it might be useful to distinguish between three different concepts that jointly determine system limits:

- product characteristics
- production
- use

This distinction applies primarily to the assessments of “sustainable development”, “benefit to the community” and “other ethical and social considerations”.

3. Danger of detrimental effects on health and the environment

Section 10, second paragraph, of the Gene Technology Act uses the wording “*danger of detrimental effects on health or the environment*”. The term “risk” is not directly used in Section 1 of the Act (purpose statement) nor in Section 10, second paragraph. However, Section 10, fifth paragraph, contains the following wording: “*The authorities responsible under the present Act, however, may still prohibit or limit such placing on the market if in their opinion it involves a risk to health or the environment or if the placing on the market is otherwise in conflict with the purpose of this Act*”. Section 11 of the Act also uses the term “risk”: “*Applications for approval of deliberate release pursuant to section 10 shall contain an impact assessment setting out the risk of detrimental effects on health and the environment and other consequences of the release*”.

In the Act’s preparatory work, several references are made to the concept of risk. It is, for instance, emphasized that the wording “*without detrimental effects on health and the environment*” in the purpose statement of the Act should not be interpreted literally – but rather that the expression “without detrimental effects” has been used to emphasize the aim of carrying out a prior assessment of the risk to health and the environment and avoiding possible detrimental effects, and that this should be underpinned by the precautionary principle⁷. It is further stated that “*a strict assessment of risk to health and the environment is in line with the views of the Government and the Storting*”³.

Assessment

When evaluating cases pursuant to the provisions of the Gene Technology Act, the Biotechnology Advisory Board therefore considers the two concepts of “danger” and “risk” to be synonymous. When it is stated in Section 10, second paragraph, that a deliberate release of genetically modified organisms may only be approved when there

is no danger of detrimental effects on health or the environment, this must be understood as a declaration of intent to apply the provisions of the Act in a restrictive manner. In consequence, the deliberate release of genetically modified organisms may only be approved when the risk of detrimental effects on health and the environment is low.

Risk is per se a complex concept. The Biotechnology Advisory Board applies the commonly accepted scientific and technical understanding of the term as a function of two factors – consequence and probability – recognizing, nevertheless, that the product of these two factors does not provide an adequate understanding of risk in a decision-making context. In such a context, the risk involved may in fact be minor, even though the negative consequences may be very substantial. Hence, the Board concludes that approving a deliberate release in such an instance would be incompatible with the intentions of the Act, even when there is a reasonably secure basis for probability assessments.

It might be useful to introduce the concept of “perceived risk”, i.e. the manner in which risk is perceived by individuals or society as a whole. Perceived risk is, moreover, a commonly applied concept in recent developments in the field of risk research – even in narrower scientific and technical contexts. Something that has serious negative consequences generally entails greater perceived risk, even if the probability of such consequences occurring is low. If so, it would not be acceptable to implement the measure or the deliberate release. This calls for an additional prerequisite linked to the requirement of low risk, namely that the deliberate release of genetically modified organisms may only be approved when the possible detrimental effects on health and the environment are minor.

In general, every application for a deliberate release should be assessed in the light of the risk with which the specific release applied for may be associated, i.e. on a case-by-case basis. However, a number of serious consequences may arise as the cumulative effects of several releases, even if the effects of the individual releases are minor. The term “cumulative effects” is relevant in such contexts. It

7. Ot. prp. nr. 8 (1992-93) p 67

underlines the need for a further additional prerequisite: that the deliberate release of genetically modified organisms may only be approved when the cumulative detrimental effects on health and the environment of several releases are minor.

There is a connection between these prerequisites for deliberate release and the application of the precautionary principle. The recommended prerequisites apply only when the knowledge base is reasonably or totally secure. This applies to knowledge of the consequences, as well as of the probabilities, including those related to cumulative effects. It also expresses another additional prerequisite – if there is a reasonable degree of doubt about the knowledge acquired through impact assessments and the related risk assessments, then the precautionary principle will (under certain conditions) apply. In this respect, we refer to the assessment of the conditions for the application of this principle under the Gene Technology Act that follows below.

Checklist questions

1. Does the application provide adequate documentation for assessing possible detrimental effects?
2. Is it reasonable to assume that major or significant risk to health or the environment is involved?
3. Is it reasonable to assume that major or significant negative consequences for health or the environment are involved?
4. Is it reasonable to assume that major or significant negative cumulative consequences for health or the environment are involved?

Comment

If the answer to question 1 is “no”, the case will be assessed in the light of the precautionary principle. If the answer to one or more of questions 2 through 4 is “yes”, the application will be rejected. If the answer to all questions from 2 to 4 is “no”, the application will be subject to further consideration in the light of the precautionary principle.

4. Precautionary principle

The precautionary principle is not mentioned in the wording of the Gene Technology Act itself. However, reference is made to this principle in the Act's legislative history. Several references are to be found in Ot. Prp.⁶ No. 8. It is stated that the precautionary principle also applies in relation to the ethical assessment of consequences, in addition to the relevant impact assessments⁸.

The precautionary principle is also mentioned in the discussion of the Act's requirement of being "without detrimental effects". It is stated that the term is used to underscore the aim of carrying out a prior assessment of the risk to health and the environment while avoiding possible detrimental effects and that this should be underpinned by the precautionary principle⁹. Moreover, the statutory proposition to the Storting outlines the manner in which the precautionary principle is to be interpreted¹⁰:

"The Ministry emphasizes that the precautionary principle does not mean that all use of gene technology should be automatically considered hazardous, but in instances where a concrete assessment indicates that there may be reasonable doubt about the risk, this directs against such use."

Today, there is a general understanding that the precautionary principle represents one of several principles embodied in the concept of "sustainable development". The fact that the concept is emphasized in the statutory text itself further underlines that the precautionary principle must be taken into account when considering cases under the Gene Technology Act. Within the framework of the international processes related to "sustainable development", the precautionary principle is laid down in the so-called Rio Declaration and in the UN Convention on Biological Diversity – both adopted at the UN Earth Summit (UNCED)

on sustainable development in Rio in 1992. A further confirmation and more specific formulation of its content and importance are to be found in the White Paper to the Storting¹¹ on "sustainable development". There, the precautionary principle is given a central role as an instrument to develop an environmental policy allowing sustainable development. This is defined as follows¹²:

"If there is danger of serious or irreversible harm, any lack of complete scientific certainty shall not be used as grounds for carrying out encroachments on nature or for deferring environmental policy measures. Great importance must be attached to the possible detrimental effects when setting objectives."



8. Ot. prp. 8 (1992-93) p 45.

9. Ot. prp. 8 (1992-93) p 67.

10. Ot. prp. 8 (1992-93) p 46.

11. St. meld. No. 58 (1996-97)

12. St. meld. No. 58 (1996-97) concerning sustainable development, p. 13

Assessment

Consequently, the precautionary principle regulates actions associated with doubt or uncertainty. This constitutes the most central dimension of the principle. Are we absolutely certain – or even just reasonably certain – of the consequences and/or the probabilities, then the principle will not apply. However, in the event of reasonable doubt, the precautionary principle alone constitutes sufficient grounds for acting in nature's best interests, i.e. it is sufficient grounds for refraining from carrying out the encroachment on nature that is the subject of the application, e.g. the deliberate release of a genetically modified organism. This latter aspect also embodies the precautionary principle's other central dimension – that nature is to have the benefit of the doubt. The position of the Biotechnology

Advisory Board is that mankind in this context, is to be perceived as a part of nature, which means that the principle also applies in those instances where there is uncertainty about the consequences for human health.

What then can give cause for doubt? The principle does not apply to doubt about all types of consequences for health and the environment. It would have to involve potentially serious detriment. The definition uses the terms serious or irreversible harm. The principle is, in this respect, based on a discussion of how we must act in order to avoid unintentional, irreversible environmental consequences.

Cumulative effects represent a crucial element of this discussion – meaning that the principle should also apply when there is reasonable doubt about serious cumulative effects, even if there may be no doubt about the serious consequences associated with the individual encroachment or release.

So, in which contexts could such doubt exist? The following elements might serve as a guide:

- doubt about fundamental cause-effect relationships
- doubt about probability assessments
- doubt about impact assessments
- doubt about cumulative consequences and/or
- doubt as to whether moderating and regulatory measures and policy instruments are functioning as intended.

Often, there will also be considerable uncertainty and insufficient knowledge about the effects of a deliberate release of genetically modified organisms in relation to “sustainable development” and “benefit to the community”. It could be queried whether the precautionary principle might not also apply in the face of this type of uncertainty as well. Uncertainty about the negative consequences for society might, for instance, be perceived as a decisive argument for opposing the deliberate release of a genetically modified organism. The Biotechnology Advisory Board is of the opinion that the precautionary principle does not



apply in this type of context, on the grounds that it has been given a precise meaning in the context of environmental and health issues. The application of the precautionary principle in other areas might easily lead to a watering down of the concept, resulting in its loss of significance and impact.

Thus far, the question has been what criteria should be used for applying the precautionary principle. It is important that we separate this from the question of what strategies and measures may then be used to deal with this uncertainty. In the Act's preparatory work it is stated that application of the principle implies that approval will not be given to the release of the GMO in question. In many cases this will be the case. But at the same time it is also important to stress that the application of the precautionary principle does not necessarily lead to only one kind of action. There may, in principle, be many strategies and measures available. Among such strategies, the following can be mentioned (see, for instance: NOU 2001: 18):

1. Permanent ban.
2. Moratorium (time-based, temporary ban).
3. Step-by-step strategy (with well-defined milestones that must be reached for each step).
4. Take-it-slow strategy (where limited activity is followed up by targeted follow-up programs, in research, for instance).
5. Surveillance strategy (where more extensive activities are followed up with specific surveillance programs and reporting systems, while preserving the principle of reversibility).

The choice of strategy must be done on the basis of a case-by-case assessment.

Checklist questions

- Is there a reasonable degree of doubt about existing risk assessments and is there danger of even greater risk being involved?
- Is there a reasonable degree of doubt about existing probability assessments and is there danger of an even greater probability of detrimental effects being involved?
- Is there a reasonable degree of doubt about existing impact assessments and is there danger of even more serious consequences for health and the environment being involved?
- Is there a reasonable degree of doubt about possible serious, cumulative consequences for health and the environment?
- Is there a reasonable degree of doubt as to whether the proposed moderating measures and policy instruments are functioning as intended?

Comment

An affirmative answer to one or more of these questions indicates that the precautionary principle should be used. In such cases further assessments of which strategies and measures should be used to deal with the relevant uncertainty should be made.

5. Sustainable development

The concept of “sustainable development” is embodied in the Gene Technology Act in two different contexts – in the purpose statement (Section 1 of the Act) and as an explicit criterion for the approval of applications (Section 10, second paragraph).

Integrating the sustainability concept with a basic needs-based version of the development concept was what originally gave rise to the World Commission’s understanding of this concept. In the report “Our common future” (1987), the term “sustainable” is given a far broader meaning than had previously been the case in the fields of conventional nature conservation and environmental protection. 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*”.

The Norwegian authorities have found that GMO-applications only to a small degree contain documentation that emphasizes the given GMO’s contribution to sustainable development. The Gene Technology Act grants the option to demand such documentation. Even though Norwegian authorities have asked for this in the consideration of several GMO-applications over the last few years, it seems that applicants limit their documentation to suit the demands of the EU-legislation.

It is the opinion of the Norwegian Biotechnology Advisory Board that it is important for the Norwegian authorities to continue asking for such information so that assessments can be made in line with the Gene Technology Act.

Assessment

“Sustainable development” could be said to build on a series of ideas:

- the idea of the global effects of human activities;
- the idea of ecological limits and that these limits have been exceeded in several areas;
- the idea of meeting basic human needs;

- the idea of just distribution between generations;
- the idea of just distribution between wealthy and poor nations;
- the idea of a new form of economic growth¹³.

The six points listed above can serve as a structure for assessing whether the deliberate release of a genetically modified organism is in compliance with the requirements of “sustainable development”. Assessments concerning the question of “sustainable development” should be global and cover long time periods (generations).

A clarification of the relationship between biodiversity (i.e. diversity of genes, species and ecosystems) and ecological sustainability is needed. Effects on biodiversity is one type of environmental impact, which means that it should primarily be assessed in relation to detrimental effects on health and the environment and the precautionary principle. Introducing this type of assessment in relation to the question of “sustainable development” implies a shift of focus in time and space. An assessment of the possible detrimental effects on health and the environment refers primarily to local, regional and national contexts. An assessment of the issue of “sustainable development” applies globally and also, to a longer time span (generations). When diversity is reduced, humankind’s opportunities of promoting “sustainable development” are reduced accordingly. Preserving biodiversity represents a form of long-term life insurance – for the existence of species, ecosystems and humankind (for a more detailed discussion, see Chapter 7).

Checklist questions

Global effects

- Is biodiversity affected on a global scale?
- Is the functional capacity of ecosystems affected?

13. Not only an increase in GNP, but with certain additional indicators, such as the use of material, natural and energy resources.

- Do these effects differ between production and use?

Ecological limits

- Is the efficiency of energy use affected?
- Is the efficiency of other natural resource use affected?
- Is the distribution between the use of renewable and non-renewable natural resources affected?
- Are discharges of pollutants with a global/transboundary range affected?
- Are emissions of greenhouse gases especially affected?
- Do these effects differ between production and use?

Basic human needs

- Is the fulfilment of basic human needs like food, shelter, health and more, affected?
- Do these effects differ between production and use?

Distribution between generations

- Is the distribution of benefits or burdens between generations affected?
- Do these effects differ between production and use?

Distribution between rich and poor

- Is the distribution of benefits or burdens between rich and poor countries affected?
- Do these effects differ between production and use?

Comment

Compliance with the requirements of “sustainable development” will have to be based on an overall assessment and discussion of all these questions. However, not all the questions may be relevant in all cases.

6. Benefit to the community

The concept of “benefit to the community” appears in the Gene Technology Act as one of several criteria for granting an application. It is a complex concept, for which neither the Act itself nor its legislative history provides any clear guidance as to how it should be understood. In the current context, the Biotechnology Advisory Board has opted for a relatively pragmatic approach, aimed at expressing those aspects of the concept on which there appears to be a high level of agreement.

The majority of the Storting’s³ Standing Committee on Municipal Affairs and the Environment underlined that:

*“...permission [for the deliberate release of a GMO] must be contingent on the utility value involved and the ethical, health and ecological issues that the deliberate release raises following prior thorough trials and impact and risk assessments.”*¹⁴

It is assumed that applicants will draw attention to the benefits to society of a new, genetically modified product. On the other hand, the governing bodies and the Biotechnology Advisory Board also have a responsibility to assess the disadvantages to society of a new, genetically modified product. This is all part of the general concept of “benefit to the community”.

The Norwegian authorities’ experience with GMO-applications so far is that they contain (surprisingly) little documentation that could render possible an assessment of a given GMO’s benefit to the community. This is, after all, the one point where the manufacturer can make a case for the positive effects of the product they have developed. It is the opinion of The Norwegian Biotechnology Advisory Board that it is important for Norwegian authorities to continue asking for such information so that assessments can be made in line with the Gene Technology Act.

Assessment

The Board will assess both the positive and

the negative effects the product may have on the community. When new antibiotics are approved in Norway, the Norwegian Medicines Agency (NoMA) performs an assessment of the drug itself – whether it functions satisfactorily and whether its side-effects are acceptable – which is, in many ways, similar to the requirements set out in the Gene Technology Act of avoiding detrimental effects on health and the environment. In addition, a societal assessment is made, which goes beyond the scope of the manufacturer’s wish to sell the product and the patient’s wish to buy it, and which for instance includes an assessment of the risk of developing antibiotic resistance. This societal assessment could focus on the following aspects:

- which problem does the new drug seek to solve?
- which alternatives are available for solving the same problem?
- which problems could arise if the use of the drug leads to increased resistance?

These elements serve as a source of inspiration for how the Biotechnology Advisory Board will implement the requirement of “benefit to the community”.

It should be emphasized that we are considering, in this context, the benefits and disadvantages to society. Hence, it is not only a matter of the benefits that the individual manufacturer, consumer or applicant may achieve. It is also very much a matter of third-party considerations. To the extent in which second-party considerations are involved, e.g. by highlighting the aspect of competition with other manufacturers already on the market, this should also be seen in a broader, societal context.

So, what types of benefits and disadvantages are involved? To start with, we need a negative delimitation. It might involve purely ethical assessments, e.g. in relation to weak parties. But in the context of the Biotechnology Advisory Board’s work, this is covered by the question of “other ethical and social considerations”. What then about geographical space, i.e. what is the spatial extent of what we here call the “community”? This requires, first of all, a positive delimitation. The term

14. Recommendation to the Storting No. 155 (1990-91), p. 8

“community” means primarily Norway. But a negative delimitation is also needed – it does not encompass the whole world. Considerations of this type would largely be covered by aspects related to “sustainable development”. However, the term “primarily” is indication that it might be useful to assess the situation in our part of the world – also outside Norway’s borders. Furthermore, it might be relevant to consider the matter of societal changes over time, e.g. the fact that there will always be changes occurring in what is perceived as a necessity or an inconvenience. This type of assessment may easily develop into something comprehensive and speculative. Other, more fundamental, long-term assessments are covered by the considerations of “sustainable development”. The Biotechnology Advisory Board believes, therefore, that any assessment of “benefit to the community” must primarily be undertaken in the light of the situation prevailing today or of the near future.

In the opinion of the Biotechnology Advisory Board, it might be useful to divide checklist questions into two groups:

- product characteristics
- production and use of the product

Checklist questions

Product characteristics

- Is it reasonable to say that there is a need for the product in terms of demand or otherwise?
- Is it reasonable to say that the product will solve or possibly contribute to solving a societal problem?
- Is it reasonable to say that the product is significantly better than equivalent products already on the market?
- Is it reasonable to say that there are alternatives that are better than the product in terms of solving or possibly contributing to solving the societal problem in question?

Production and use of the product

Among the relevant aspects to be considered are:

- Does the product contribute to creating new employment opportunities in general and in rural areas in particular?
- Does the product contribute to creating new employment opportunities in other countries?
- Does the product create problems for existing production whose existence should otherwise be preserved?
- Does the product create problems for existing production in other countries?

(This list of questions is not meant to be exhaustive, but primarily to serve as an indication of the type of questions that should be considered).

Comment

Any assessment of benefit to the community must be based on a discussion of the responses as a whole. However, it should be emphasized that every question may not be equally relevant in all instances.

7. Other ethical and social considerations

The Gene Technology Act aims “to ensure that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way...” (Section 1). This brings in the concept of “ethically and socially justifiable”. Section 10 of the Act, which stipulates the criteria for approval, makes no reference to such a concept (other than what is implied by the terms “sustainable development” and “benefit to the community”). Nonetheless, the Biotechnology Advisory Board finds that the reference to “other ethical and social considerations” constitutes an independent criterion that must be considered in all applications for approval. This opinion is further corroborated by the legislative history of the Act. It is, moreover, the type of issue that is specifically emphasized in the Board’s mandate. According to the first paragraph of its mandate, the Biotechnology Advisory Board is “to assess general questions, or questions of principle concerning biotechnological activity, including ethical and social questions”.

Assessment

The preparatory work of the Act provides some guidance on how the term “other ethical and social considerations” is to be understood, i.e. the type of considerations that may be included. In the proposition Ot. prp⁶. No. 8, it is stated that the purpose of the Gene Technology Act is “... to ensure that modern biotechnology is utilized for the common good and in keeping with the ethical values on which our society is founded”. In the White Paper to the Storting No. 25 (1992-93) entitled “Humankind and biotechnology”, it is stated that we must “root our positions in ethical principles that enjoy broad acceptance in Norwegian society”. This is expressed even more precisely in the Recommendation to the Storting³ No. 155 (1990-91):

”The Committee underlines that legislation and guidelines must be founded on fundamental norms that, in the Committee’s view, must form an ethical basis for developments in the field of biotechnology, i.e. on the Christian-

humanistic value base and on respect for the value of human life, humankind’s absolute value, human rights, the principle of equality and solidarity and on respect for ecological balance and the integrity of nature.”

In the light of this, the Biotechnology Advisory Board finds that it might be useful to make a distinction between ethical norms and values associated with humankind and eco-ethical (the integrity of nature) circumstances and assessments. This provides a structure for the grouping of checklist questions. An example of an eco-ethical issue would be the respect for nature’s intrinsic value. In order for a deliberate release of genetically modified organisms to be justifiable in terms of the respect for human equality, it must be likely that sufficient consideration has been given in society as a whole to the interests of any weak parties involved. Moreover, other aspects of an application for approval, than merely the product’s characteristics or its production and use, may also be brought in for consideration. There might, for example, be a question of whether the applicant can prove that the genetic material used has been acquired in an ethically justifiable manner and under which (ethical) conditions the product is to be marketed and distributed.

The aim of any ethical reflection must be to enable us to make an assessment of what is right and wrong, good or evil, in a more systematic and reliable manner. When we ask ourselves how we should act toward one another or how society should be organized, we must also look at the type of rules and guidelines that are commonly followed in everyday life: how do individuals in fact act and how is society organized? These are descriptive questions of what we call morals – our customs and practices, the norms that are known and followed in society and the values that are generally accepted. But we are concerned not only about the way in which people act in reality and the practices that have developed in society. Generally speaking, we see that we are unable to find complete answers to all such “should” questions by simply ascertaining how things really are. In order to answer these questions we cannot be content with knowing which moral

opinions people generally have, although this is an important element. Often, we would like to reach moral beliefs that entail no self-contradictions, that can be defended and that we can stand up for and abide by, either as individuals or as a society. This can be understood as ethics, i.e. the theory of morals, the organization of our norms and values about right and wrong, premises and conclusions in a systematic and clear manner. Hence, ethical reflection consists of starting out on the basis of accepted moral beliefs – in concrete situations, as well as about basic values – and considering whether these norms and values coincide mutually and whether they can be defended against objection.

Ethical reflection on moral dilemmas is often based on an intuitive perception of a situation as being problematic, without quite being able to put one's finger on exactly what gives cause for concern. Such reflection aims primarily at identifying and clarifying the ethical conflicts we experience. Often, however, reflection also contributes to raising our awareness of the problems, enabling us to see and perceive new ethical facets of a situation.

Five different questions must be answered in the ethical assessment of the choices facing a person, an organization or a society in order to determine the best alternative – morally and totally. Several of the answers are interdependent and the process therefore often requires that we move back and forth between answers until we reach sufficient clarity about all of the perspectives and issues involved.

Situational analysis

- What are the alternatives?
- Who are the parties involved? How are these parties affected or assisted under the various alternatives?

Ethical reasoning

- Which norms apply?
- How can any conflict of norms be resolved?

Implementation

- How do we implement the best alternative in practice?

A thorough ethical assessment of the issues related to human equality will identify the parties affected and the manner in which they are affected by the practice under consideration, compared with alternative courses of action. Furthermore, the interests at stake for the parties involved must be determined. Different alternatives will have different effects on the various parties; often some will benefit, others will lose. This being the case, it is especially important to clarify how we can weigh the differing interests of the parties, when some will gain and others will suffer from an alternative, for example, in the light of the norm of safeguarding the needs of weaker parties or of securing people's anticipations of profit. Often, such norms will conflict, something that in turn requires assessment of and argument for why the interests of certain individuals are to be favoured at the expense of others.

In the legislative history of the Act, in the preface of the Rio Convention on biological diversity and in other discussions, reference is made to nature's intrinsic value to underline the importance that we, as individuals or as a society, should have regard for animal and plant species and/or ecosystems. This can be understood in several ways.

It can be seen as a reminder that parts of nature have a utility value in ways other than their direct value as expressed through sale or economic production. It can also be understood to mean that many people attribute to parts of nature not only value as tools for achieving something else, but that something of what we value is nature itself, nature experiences and the existence of natural phenomena. We also ascribe to nature an intrinsic value and it is this appreciation that calls for nature to be respected. These two interpretations are still "anthropocentric" in the sense that, in the final analysis, it is only the interests and appreciation of humans in the broadest sense of the term that count. A third interpretation is that the term "nature's intrinsic value" is meant to express a veneration for nature as a general warning to refrain from encroaching on nature in ways that might have unpredictable consequences. A fourth interpretation of "nature's intrinsic value" is that individual animals, species or ecosystems possess an inherent value that goes beyond the value that we as humans

attribute to them, and that such values imply other guiding principles for biotechnology. This means that other parties and interests should be included in the ethical evaluation than just humans – for example, the survival of (higher) animal and plant species and/or ecosystems. The justification for such a position may be of a religious nature – Divine creation – or based on the respect for all living things in general. Some of these views are more controversial than others. For the purpose of the Biotechnology Advisory Board’s work, however, it is worth noting that any disagreement may not necessarily be so serious in practice as to give rise to difficulties when the Board advises whether to authorize or prohibit.

Checklist questions

Ethical norms and values associated with humans

- Does the authorization/prohibition of the product and its production and use comply with the ethical principles of the population at large?
- Does the product or its production and use conflict with ideals of human solidarity and equality, especially in relation to the safeguard of weaker groups of society?
- Indigenous peoples, people with strong traditional cultures and weaker groups of society may be exposed to serious adverse consequences of the decisions of mainstream society. The interests of such groups in being allowed to control their own cultural change should be taken into special consideration.
- Does especially the marketing and sale of the product conflict with such norms and values?

Eco-ethical considerations

- Do the product or its production conflict, by their very nature, with any intrinsic value of animal species?
- Does the production of the product cause unnecessary suffering to animals?
- Does the production of the product result in any transgression of barriers between species in ways that are materially different from what otherwise occurs in cultivated or wild nature and that must be considered incompatible with the value ascribed to the segregation of species?

(This list of questions is not meant to be exhaustive, but primarily to serve as an indication of the type of questions that should be considered).

Comment

An assessment of the regard for such ethical and social circumstances must be based on a discussion of all answers as a whole. Once again it must be emphasised, however, that not all the questions may be equally relevant in all cases.

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