Chapter 24
Sustainability, social and ethical considerations in regulations

JAN HUSBY
NORWEGIAN INSTITUTE OF GENE ECOLOGY (GENØK), TROMSØ, NORWAY

1. Introduction

The issue of sustainability, social and ethical dimensions of gene technologies and the use of GMOs, is often a part of the national and international debate. Some countries consider some of these elements in their regulations. In the Cartagena Protocol on Biosafety we find, for example, in Article 26, the issue of how socio-economic considerations can be a part of decisions at the national level, and how the parties to the protocol are encouraged to cooperate in this regard.

In this chapter I will use the Norwegian Gene Technology Act as an example of how the issues of sustainability, social and ethical considerations can be addressed within GMO regulations.

The Norwegian Gene Technology Act has some unusual elements compared to the legislation of many other countries. Section One of the Act states:

> *The purpose of this Act is to ensure that production and use of genetically modified organisms, and production of cloned animals, takes place in an ethical and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment.*

This is further elaborated in paragraph two of Section 10 of the Act, where it is stated:

> *Deliberate release of GMOs may only be approved when there is no risk of detrimental effects on health or the environment. In deciding whether or not to grant the application, significant emphasis shall also be placed on whether the deliberate release represents a benefit to the community and a contribution to sustainable development.*

Norway is not a member of the EU, but has implemented some of the EU biosafety regulations due to the Agreement on the European Economic Area (EEA), to which Norway is a Party. An adaptation in the EEA agreement, secures the right to apply these elements when considering whether or not to approve deliberate release of GMOs.

2. The Precautionary Principle

The Precautionary Principle is not written down in the Norwegian Gene Technology Act itself, as we, for example, find it in Article 1 – objective – of the EU Directive 2001/18/EC. In Proposition No. 8, 1992-93, to the Norwegian Odelsting, where we find the legal interpretation of the Act and its consequences, it is stated that the Precautionary Principle shall be a basis for evaluation of safety and risks.

This is further elaborated in Appendix 4 of the newly revised Regulations on Impact Assessments under the Gene Technology Act. The details and questions listed in Appendix 4 of the Norwegian Impact Assessment Regulation are attached at the end of this chapter. There it is stated that the Precautionary Principle shall be used when evaluating possible hazards and damage for animal and human health and the environment. It is also emphasized that ethical considerations shall be ascribed importance in decisions taken in accordance with the Act (see separate sections on the Precautionary Principle in Chapters 7 and 17).

3. Impact assessment or risk assessment

The term ‘Impact Assessment’ is also something that is different from many other modern biotechnology regulations, where we usually find the term ‘Risk Assessment’. Some of the

differences in terminology usage and its consequences will be explained later in this section.

One of the intentions of the applications and approval procedures for deliberate release is to clarify uncertainty and to have appropriate and relevant risk related information. Pursuant to Section 11 of the Act, which states that an application 'shall contain an impact assessment setting out the risk of detrimental effects on health and the environment and other consequences of the release', no GMOs can be released for experimental or commercial purposes without a thorough impact assessment as a prerequisite.

'Other consequences of the release' is usually interpreted to refer to the purpose of the Act regarding ethics, social justification and the principle of sustainability.
The revised Regulations on Impact Assessment entered into force in January 2006 and include in Appendix 4 a comprehensive list of issues and questions regarding ethics, sustainability and social justification that shall be a part of the Impact Assessment. Appendix 4 may, if appropriate and correct information is made available, to a certain degree fulfil the purpose of the Act in relation to the assessments of ethics, sustainability and social justification. An important question is: Who will be responsible for providing this information, the applicants or the authorities?

In Directive 2001/18/EC, we can find elements of the Norwegian approach, since it is stated that in the regular reports from the European Commission to the European Parliament and the member countries, socio-economic implications shall be included. The Commission shall also every year report about ethical issues if they have been raised. This is, however, of no help to the Norwegian authorities that need this type of information linked to the specific case-by-case Impact Assessments.
Another way of presenting the aim and intention of the Norwegian Gene Technology Act and its Impact Assessment Regulation is reflected in Figure 24.1.

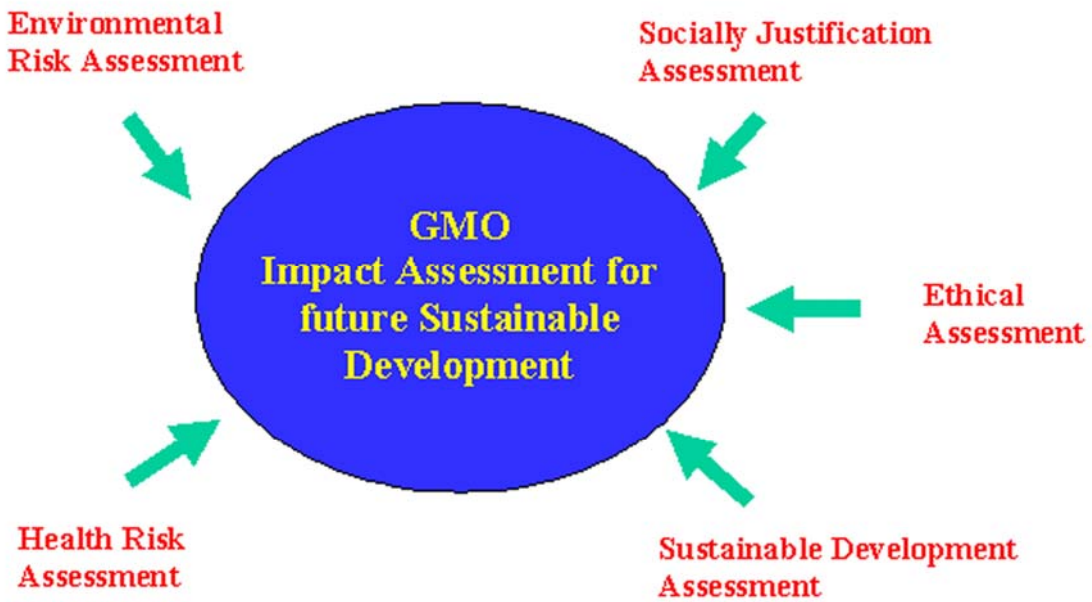

Figure 24.1. The aim and intention of the Norwegian Gene Technology Act.

On the left side of Figure 24.1 we find the traditional 'natural science' risk assessment issues and on the right side, what can be referred to as the 'social science' assessment issues, although sustainability issues in many cases also involve inputs from natural sciences. The intention of this procedure is that if appropriate and relevant knowledge is made available for

both the left and the right side, an overall or 'holistic' evaluation of the GMO in question is possible. An overall evaluation of risks for health or the environment, benefit for the community, and whether the GMO is ethically and socially acceptable, should therefore be possible to carry out. The figure is a simplified model, since experience has shown that it is difficult to operate this system in practical management. There is a need for broad collaboration with authorities in other countries, but also the applicant, in order to receive all necessary information for the assessment. Sustainability linked to GMOs is, in many respects, an international issue and should therefore be seen in a global context.

It could therefore, in addition to the national level, be appropriate to handle this issue under the Cartagena Protocol on Biosafety. In the Protocol, under Article 26 on socio-economic considerations, it is stated that Parties can take into account socio-economic considerations arising from the impact of LMOs, especially on the value of biological diversity to indigenous and local communities. Further, it is stated that Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts.

It is also important to note that in accordance with Article 10 of the Norwegian Gene Technology Act 'a product may not be approved for placing on the market until it has been satisfactorily tested in natural environments that will be affected by the intended use'. This is important, and is usually found in most countries' environmental GMO regulations. Risk assessments on the left side of Figure 24.1 should therefore always be closely linked to both general and specific environmental and ecological knowledge as a basis. The information on environmental and ecological conditions at the national level thereby becomes central for when to use the Precautionary Principle, especially when appropriate or important knowledge is lacking or omitted in applications for deliberate release.

Regarding the social science issues on the right side of Figure 24.1, the Norwegian Ministry of Environment requested in 1998 the assistance of the Norwegian Biotechnology Advisory Board (NBAB) in operationalizing the concepts of ethics, sustainable development and social justification in the Gene Technology Act. Their discussion document was the basis for Appendix 4 to the aforementioned Impact Assessment Regulation (NBAB 2000).

The Norwegian Biotechnology Advisory Board (NBAB) is appointed by the Norwegian Government and its mandate is to give advice to the regulatory authorities, Parliament and Government. It includes representatives from different stakeholders, e.g. non-governmental organizations, and scientists from relevant institutions and fields of research. In November 1999, the NBAB published their statement regarding how to interpret, in a practical way, sustainable development, social justification, and ethical and social considerations connected to applications for marketing of GMOs (see the report 'Sustainability, benefit to the community and ethics in the assessment of genetically modified organisms', which is currently available on the NBAB's homepage: www.bion.no).

The NBAB provided an interpretation of the Gene Technology Act, to establish the basis for their further work with the report:

> *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 weighted against the risk of detrimental effects, when such risk is low.*

With this understanding as a starting point, the NBAB developed a decision structure where evaluation of each GMO application should be based on the following general questions:

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?

The first point is connected to the left side of Figure 24.1, and usually has broad coverage in most countries' GMO regulations. Point two, the Precautionary Principle, is now a part of the objective in the revised EU directive (2001/18/EC). We find the principle (or approach) as a basis for the Cartagena Protocol on Biosafety, where it also has gained practical interpretation in Articles 10(6) and 11(8), and in the risk assessment Annex III (point 4).

The NBAB stated that a common understanding is that the Precautionary Principle is one of many principles of the concept of sustainable development. In the international context we find the concept of sustainable development in the Rio Declaration and the Convention on Biodiversity (CBD), which was adopted at the UN's Earth Summit (UNCED) on sustainable development in 1992. The NBAB further states that sustainable development is building on a set of ideas connected to the following:

– 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 growth.

These six points serve as a structure for evaluating whether marketing of a GMO is in accordance with the demand for sustainable development. Many of the points are recognized as important issues in the global discussion regarding acceptance of GMOs in developing countries, and they are closely linked to the need for technology transfer and capacity building.

The NBAB explains that it is necessary to clarify the relationship between biological diversity (i.e. the diversity of genes, species and ecosystems) and ecological sustainability. Effects on biological diversity are a type of environmental risk that implies that assessment primarily should be done in relation to possible effects regarding health, environment and the Precautionary Principle. When these issues are brought into the discussion about sustainable development, it implies a change of focus in time and space. The NBAB was of the opinion that questions related to negative effects on health and environment, and the employment of the Precautionary Principle, apply primarily to local, national and regional relations. Assessments connected to sustainable development apply globally and also, to an extent, over a longer time scale (generations).

In connection with ethical considerations, the NBAB found it appropriate to distinguish between ethical norms and values associated with humans and those associated with environmental ethics ('the integrity of nature'). Based on a set of values, the procedure proposed by the NBAB outlined ethical reflections which aim to enable us to undertake assessments of what is right or wrong, in a more systematic and justifiable way. Further, the NBAB stated that ethical reflections in connection with moral dilemmas are often based on an intuitive experience of the situation as problematic, without actually being able to pinpoint

what is alarming. In many respects, this is the situation when dealing with the scientific knowledge regarding safety aspects of GMOs. Scientists working within different, but relevant, research fields often tend to interpret data connected to risk assessments differently, and make value judgements with a basis in their own research traditions and experiences. This makes it difficult for authorities when receiving advice in connection with decision making, because the emphasis on risks of possible negative effects will vary depending on whom you ask and their professional background, integrity and personal standpoint. The worst-case scenario may, of course, happen, even if the probability is low. It can therefore be easy for authorities to 'hide behind' the Precautionary Principle. Appropriate research and scientific knowledge about possible hazards are therefore of utmost importance also when dealing with ethical dilemmas connected with risks assessments. It is therefore the duty of the authorities to ensure that appropriate and required biosafety research is carried out as a basis for risk assessments.
Knowledge about the public opinion and values regarding these issues is important if this type of assessment is to reflect reality. It is therefore necessary to have meeting points for debate and discussions between politicians, authorities, scientists, the biotech industry, and the public. Debate and meeting points will enhance the authorities' knowledge of the different opinions within the society.

In Norway, as in many other European countries, all new applications for marketing release of GMOs are subjected to public hearings where different opinions may come forward. For many years, the NBAB has also arranged public meetings and consensus conferences where important biosafety related topics have been the main focus. This type of activity increases public knowledge about biosafety and GMOs, and the authorities and politicians gain important feedback related to the aforementioned outlined topics. Issues related to safety and use of GMOs have also been discussed at open conferences organized by the NBAB. These types of conferences take place in many countries, and usually involve different stakeholders and the general public, and commonly draw a large audience.

The procedures for addressing biosafety issues in accordance with the principles of sustainable development, ethical and social elements, as proposed by the NBAB, have not yet fully been applied in practical management, but will be applied in the near future due to the newly implemented Impact Assessment Regulation. It will therefore be interesting to see how this regulation will be used in the future management of GMO applications in Norway. It will also be interesting to see how the use of this regulation will influence public debate and further development of GMO regulations in Europe and other parts of the world.

The debate about acceptance of GMOs is not only an issue of natural science and risk assessment, but involves many cross-cutting research fields, ethics and socio-economic issues at both a national and a global scale. It is therefore important to engage in an open discussion regarding the types of issues that have been raised through the Norwegian approach towards GMO regulations.

Literature

Aarhus Convention, 1998. Convention on Access to Information, Public Participation in Decision Making and Access to justice in Environmental Matters. Aarhus Denmark, 25th June 1998.

Berg, Paul; David Baltimore; Herbert Boyer, et al. (1974). «Potential Biohazards of Recombinant DNA Molecules.» *Science* 185: 303.

Berg. P, Baltimore D, Sydney B, Roblin R.O, and Singer M.F. 1975. Summary statement of the Asilomar Conference on Recombinant DNA Molecules. Proc. Nat. Acad. Sci. USA. Vol. 72, No 6, pp. 1981-1984.

Danish Act, from 1986.

EC 2001. Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and

repealing Council Directive 90/220/EEC. Official Journal of the European Union, L 106, 17.4.2001.

EC 2002. Council Decision 2002/811/EC of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Official Journal of the European Union, L 280, 18.10.2002, p. 27.

EC 2003. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Official Journal of the European Union, L 268, 18.10.2003.

EC 2003. Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming.

EC 2003. Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Official Journal of the European Union, L 268, 18.10.2003.

EC 2003. REGULATION (EC) No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 July 2003 on transboundary movements of genetically modified organisms. Official Journal of the European Union, L 287, 5.11.2003.

EC 2004. REGULATION (EC) No 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. Official Journal of the European Union, L 136, 30.4.2004.

EEC 1990. COUNCIL DIRECTIVE of 23 April 1990 on the contained use of genetically modified micro-organisms (90/219/EEC**).** Official Journal of the European Union, L 117, 8.5.1990.

EEC 1993. COUNCIL REGULATION (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products. Official Journal of the European Union, L 214, 24.08.1993.

Impacts of Applied Genetics: Micro-organisms, Plants and Animals, US Congress, Office of Technology Assessment, Washington, D.C., 1981.

OECD 1996. Recombinant DNA safety consideration. OECD, Paris.

Proposition No 8, to the Odelsting (1992-93). Concerning the Act relating to the production and use of genetically modified organisms (The Gene Technology Act), The Norwegian Ministry of Environment.

The Danish Gene Technology Act (1986) Act no 288 of 4 June 1986

The Norwegian Biotechnology Advisory Board.(2000) Sustainability, benefit to the community and ethics in the assessment of genetically modified organisms; Implementation of the concept set out in section 1 and 10 in the Norwegian Gene Technology Act 2000. Printed in English December 2003, ISBN 82-91683-21-2.

The Norwegian Ministry of Environment. (1993) The Act relating to the production and use of genetically modified organisms (Gene Technology Act), Act No. 38 of 2 April 1993.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Secretariat of the Convention on Biological Diversity (ISBN: 91-807-1924-6) Montreal, 2000.

US Congress, Office of Technology Assessment (OTA) April 1981. Impacts of Applied Genetics: Micro-organisms, Plants, and Animals.

Appendix 4 to the Norwegian Impact Assessment Regulation:

EVALUATION OF ETHICAL CONSIDERATIONS, SUSTAINABILITY AND BENEFIT TO SOCIETY, CF SECTION 17 OF THE REGULATIONS

INTRODUCTION

This appendix explains what should be included in an account of other consequences of the production and use of genetically modified organisms pursuant to Section 17 of the regulations. To the extent necessary, such an account should as far as possible include all the elements listed in the Appendix. However, the Appendix is not exhaustive, and not all the elements will be relevant in every case.

The purpose of the Gene Technology Act, as set out in its section 1, 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 to health and the environment. Section 10, second paragraph, of the Act lays down that the deliberate release of genetically modified organisms may only be approved when there is no risk of adverse effects on health or the environment, and that considerable weight is to be given to whether the deliberate release of genetically modified organisms will be of benefit to society and is likely to promote sustainable development. The comments on the objects clause of the Act in Proposition No. 8 (1992 to 1993) to the Odelsting make it clear that the precautionary principle is to be used as a basis in evaluating potential adverse effects on human and animal health and the environment, and that ethical considerations must be given considerable weight when making decisions on applications for approval pursuant to the Act. The comments on Section 10, second paragraph, make it clear that when applications for deliberate release pursuant to the Act are considered, any benefits to society and contributions to sustainable development are to be used both as independent criteria for the evaluation of applications and as criteria that may result in less strict application of the requirement that the release of genetically modified organisms must not have adverse effects on health or the environment. An evaluation of benefits to society and contribution to sustainable development should be based on the principles of cost-benefit analysis.

I PROCEDURE FOR THE EVALUATION

The evaluation should be 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 project
   a) tend to promote or hinder sustainable development?
   b) have favourable or unfavourable social consequences
   c) be ethically justifiable?

In assessing the questions in item 3, it can be useful to distinguish between the following three elements:

– the characteristics of the product
– its production
– its use.

II RISK OF ADVERSE EFFECTS ON HUMAN AND ANIMAL HEALTH AND THE ENVIRONMENT

A. Checklist

1. Does the application provide sufficient documentation for evaluating possible adverse effects?
2. Is it reasonable to assume that there will be a major or significant risk to health or the environment?
3. Is it reasonable to assume that there will be major or significant adverse effects on health or the environment?
4. Is it reasonable to assume that there will be major or significant adverse cumulative effects on health or the environment?

B. Comments

If the answer to question 1 is no, the application shall be evaluated in relation to the precautionary principle. If the answer to one or more of questions 2–4 is 'yes', the application shall be refused. If the answer to all of questions 2–4 is 'no', the application shall be evaluated in relation to the precautionary principle.

III THE PRECAUTIONARY PRINCIPLE

A. Checklist

- Is there a reasonable degree of doubt about existing risk assessments, and is there a danger that the risk may be higher than these assessments indicate?
- Is there a reasonable degree of doubt about existing probability assessments, and is there a danger that the probability of adverse effects is higher than these assessments indicate?
- Is there a reasonable degree of doubt about existing impact assessments and is there a danger of even more serious effects on health and the environment than these assessments indicate?
- Is there a reasonable degree of doubt about possible serious cumulative effects on health or the environment?
- Is there a reasonable degree of doubt as to whether proposed mitigating measures and instruments will function as intended?

B. Comment

If the answer to one or more of these questions is 'yes', this indicates that the application can be refused with reference to the precautionary principle.

IV SUSTAINABLE DEVELOPMENT

A. Checklist

1. Global impacts
   - Will there be global impacts on biodiversity?
   - Will there be impacts on ecosystem functioning?
   - Will there be differences between the impacts of production and use in these respects?

2. Ecological limits
   - Will there be any impact on the efficiency of energy use?
   - Will there be any impact on the efficiency of other natural resource use?
   - Will there be any impact on the proportions of renewable and non-renewable resources used?
   - Will there be any impact on emissions of global and transboundary pollutants?
   - Will there be any particular impact on greenhouse gas emissions?
   - Will there be differences between the impacts of production and use in these respects?

3. Basic human needs
   - Will there be any impact on the degree to which basic human needs are met?
   - Will there be differences between the impacts of production and use in these respects?

4. Distribution between generations
   - Will there be any impact on the distribution of benefits between generations?
   - Will there be any impact on the distribution of burdens between generations?
   - Will there be differences between the impacts of production and use in these respects?

5. Distribution between rich and poor countries
   - Will there be any impact on the distribution of benefits between rich and poor countries?
   - Will there be any impact on the distribution of burdens between rich and poor countries?
   - Will there be differences between the impacts of production and use in these respects?

6. Economic growth
   - Will there be any impact on the use of energy and other natural resources for economic growth?
   - Will there be any impact on the global/transnational environmental impacts of economic growth?
   - Will the there be any impact on the distribution of economic growth between rich and poor countries?
   - Will there be differences between the impacts of production and use in these respects?

B. Comment
An evaluation of whether a project is in accordance with the principle of sustainable development must be based on an overall assessment and discussion of all these questions. However, not all the questions will be relevant in all cases.

V FAVOURABLE OR UNFAVOURABLE SOCIAL CONSEQUENCES

A. Checklist
1. Characteristics of the product
   - Is it reasonable to say that there is a demand or a need for the product?
   - Is it reasonable to say that the product will solve or help to solve a social problem?
   - Is it reasonable to say that the product is significantly better than similar products that are already on the market?
   - Is it reasonable to say that there are alternatives that are more suitable than this product for solving or helping to solve the social problem in question?

2. Production and use of the product
   - Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities?
   - Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities, in rural areas in particular?
   - Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities, in other countries?

- Will the product tend to create problems for existing production that should be maintained?
- Will the product tend to create problems for existing production in other countries?

B. Comments
An evaluation of whether a product is of benefit to society must be based on a discussion of the answers to all these questions. However, not all the questions will be relevant in all cases.

VI ETHICAL CONSIDERATIONS

A. General considerations

1. Analysis of the situation
   - What alternatives are there?
   - Which parties are involved? How will they be disadvantaged by, or benefit from, the different alternatives?

2. Ethical reasoning
   - Which norms are applicable?
   - How can any conflict between these norms be resolved?

3. Implementation
   - How can the best alternative be implemented in practice?

B. Checklist

1. Ethical norms and values relating to people
   - Will approval or prohibition of the product and its production and use be in accordance with the moral views of the general population?
   - Will the product or its production and use come into conflict with the ideals of solidarity and equality between people, such as the need to show special consideration for weaker groups?
   - Decisions made by mainstream society can have a serious adverse impact on indigenous peoples, people who live in highly traditional cultures, and weaker groups. Special account should be taken of the need of these groups to be able to control their own processes of social change.
   - Will the marketing and sales, in particular, of the product come into conflict with ethical norms and values relating to people?

2. Eco-ethical considerations
   - Will the product and its production be in conflict with any intrinsic value assigned to animal species?
   - Will the production of the product cause unnecessary suffering to animals?
   - Will the production of the product involve crossing species barriers in ways that are materially different from those otherwise found in cultivation or in the wild, and that must be considered incompatible with the value assigned to the integrity of species?

C. Comment

An evaluation of other ethical and social considerations must be based on a discussion of the answers to all these questions. However, not all the questions will be relevant in all cases.