Gene technology and ethics in the plant and foods area

- towards an international convention

An abridged version of a report to the
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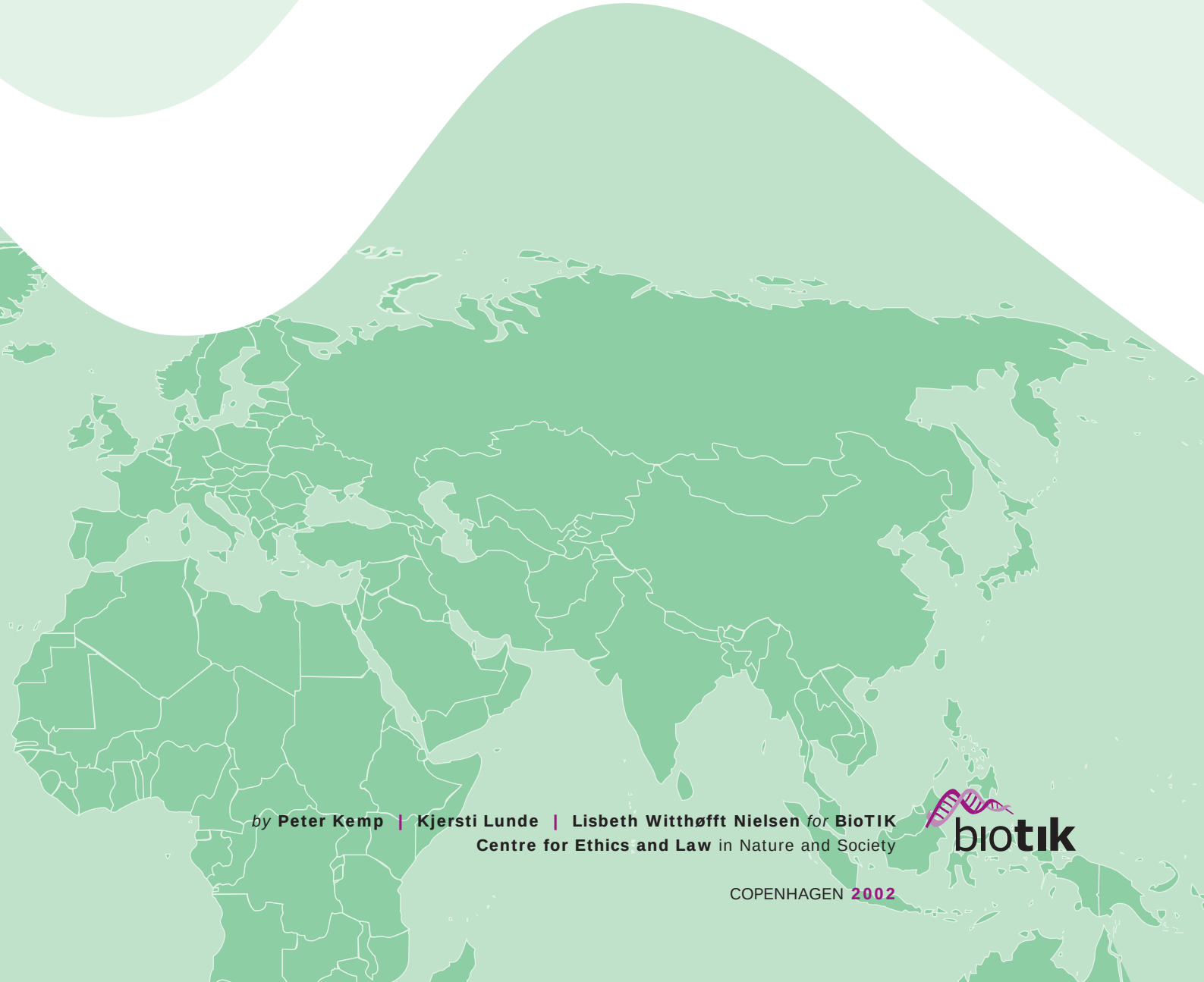

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Centre for Ethics and Law in Nature and Society

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About BioTIK

In 2001 the Danish Parliament launched the BioTIK-project. It is a four-year project focusing on both the possibilities that gene technology offers, and the ethical principles that are to be considered in order to make the right decisions. BioTIK is a Danish abbreviation of biotechnology and ethics.

Hence nine Danish Ministries have joined a Task Force with the purpose to incorporate ethical principles in regulation of biotechnology, in decision making processes and as a basis for public perception and information. Read more about the BioTIK-project at www.biotik.dk.

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Contents

Foreword

This document is an abridged version of a two-part, 180-page report on ethics and genetic engineering. The report was prepared by the Centre for Ethics and Law for the Danish National Consumer Agency, which is part of the Danish Ministry of Economic and Business Affairs. The complete report is intended to contribute to the government's work on a new Council of Europe convention which will lay the foundation of ethical principles for the development and use of genetic engineering in the plant and foods area.

The first part of the report, from March 2001, entitled *Gene technology and ethics in the plant and foods area: Conventions and declarations (Genteknologi og etik: konventioner),* investigates the ethics of existing conventions and declarations that concern the plant and foods area. The report concludes that there is a need for a new international convention that involves ethical principles as the basis for the development and use of genetic engineering in the plant and foods area.

The conclusion of the report's first part is followed up in the second part, from April 2002, *Gene technology and ethics in the plant and foods area: Regulation and national visions (Genteknologi og etik: national ret),* whose general objective is to sketch the main outlines for a new convention. This outline is based on the ethical considerations that were set forth in the BioTIK Group's report *An ethical foundation for genetic engineering choices (De genteknologiske valg),* which was prepared for the Ministry of Trade and Industry in 1999. These ethical considerations can be summarised as follows:

- Economic benefits that can be made compatible with qualitative benefits
- Respect for autonomy, dignity, integrity and vulnerability
- Just distribution of benefits and burdens
- Co-determination and openness

These ethical considerations lay the foundation for the report's investigation of the role of ethics in selected European countries' regulations and public debates concerning the use of genetic engineering in the plant and foods area. These countries are Germany, France, the United Kingdom, and, to a limited extent, Sweden and Norway.

The first part of the report, *Gene technology and ethics in the plant and foods area: Conventions and declarations,* was written by Peter Kemp and Kjersti Lunde. The second part, *Gene technology and ethics in the plant and foods area: Regulation and national visions,* was written by Peter Kemp, Kjersti Lunde and Lisbeth Witthøfft Nielsen. Both reports, as well as an overview of literature cited, can be found at www.biotik.dk and can also be requested from the Centre for Ethics and Law on telephone +45 3369 1616 or by e-mail at centre.for@ethiclaw.dk. We stress that the authors alone are responsible for the positions and evaluations in the reports.

The authors wish to thank everyone who contributed to the preparation of the reports.[1]

[1] *We wish to give special thanks to Brigitta Purschel Christensen, L.L.M.; Hannah Mia Hendriksen, language secretary; Peter Høilund, Ph.D.; Veit Koester, L.L.M.; and Charlotta Zetterberg, L.L.D.*

Introduction

This document, *Gene technology and ethics in the plant and foods area - towards an international convention,* contains the main points of the two parts of the complete report: *Gene technology and ethics in the plant and foods area: Conventions and declarations and Gene technology and ethics in the plant and foods area: Regulation and national visions.* The conclusions of the two reports are a recommendation for a new convention and a proposal for the framework of such a convention concerning the development and use of genetic engineering in the plant and foods area.

In the following pages, we first present a detailed summary of the BioTIK Group's ethical guidelines and interpret their possible meaning for the plant and foods area. This includes an outline of the relation between the human and non-human areas from an ethical perspective. Finally, we give definitions of the central concepts as they are used in the report.

Later, we present the recommendation for a new convention and the proposal for the framework of such a convention. We give a short presentation of selected conventions, declarations and resolutions and then a summary of our interpretation of their ethical evaluations. Next, we compare the major points of the latter with the BioTIK Group's ethical guidelines. On this basis, we sketch the general relation between national law and EU legislation. This is done according to the question of whether ethics is brought into consideration in joint regulations and what possibilities there are for separate rules in national regulations. The central ethical principles and considerations that prevail in Germany, the United Kingdom, France and, to a limited extent, in Norway and Sweden in connection with the debate on and regulation of genetic engineering in the plant and foods area are outlined in an ethical profile of each country. Finally, we present a comparison between the four ethical considerations and the countries' ethical profiles.

Ethics for genetic engineering

In 1997, the Danish Ministry of Trade and Industry appointed the so-called BioTIK Group (BioTIK-gruppe), whose mandate was to contribute to the complex debate on the use of biotechnology and genetic engineering. The BioTIK Group's work resulted in the report *An ethical foundation for genetic engineering choices - a position paper prepared by the BioTIK Group (De genteknologiske valg - et debatoplæg udarbejdet af BioTIK-gruppen),* Ministry of Trade and Industry, 1999.[2] The four ethical considerations set out below are a summary of the ethical guidelines that the BioTIK Group recommended as a starting point for an evaluation of the development and use of genetic engineering: The ethical considerations are (1) the relation between economic and qualitative benefits; (2) autonomy, dignity, integrity and vulnerability; (3) just distribution of both the benefits and the burdens; and (4) co-determination and openness. The report elaborates on these points as follows:

The relation between economic and qualitative benefits

If genetic engineering is to be accepted, it will have to be developed and used for the benefit of human beings, society and living organisms, provided that one prioritizes the quality of life benefits rather than the purely quantitative benefits and hence only strives for quantitative benefits that are consistent with quality of life. Quantitative benefits for individual manufacturers and dealers are not considered to compensate for qualitative damage to human beings and/or animals.

Autonomy, dignity, integrity and vulnerability

If genetic engineering is to be accepted, it will have to be used with respect for human autonomy and dignity and for the integrity and vulnerability of life.

Just distribution of benefits and burdens

If genetic engineering is to be accepted, it must promote justice (equity) in the way that benefits and burdens (e.g. foods and commonly acceptable risks, respectively), are distributed among people.

Co-determination and openness

If genetic engineering is to be accepted, it shall be based on openness to all viewpoints before every decision.

The BioTIK Group's proposal of ethical considerations in the development and use of genetic engineering is based on the perspectives of three ethical traditions: utilitarianism, the ethics of integrity and discourse ethics.[3]

The distinctive feature of biotechnology is that it is a technology that undertakes intervention in living organisms. The core of the ethical guidelines that the BioTIK Group outlines is therefore the moral status that is attributed to everything living. Genetic engineering must be developed and used with respect for human autonomy and dignity and for the vulnerability and integrity of everything living. The BioTIK Group has presented an operational application of what respect for living organisms means in the biotechnological field. This operational application outlines the possible scope and limits on the basis of balancing three ethical traditions: utilitarianism, the ethics of integrity and discourse ethics.

Ethics in the plant and foods area: the non-human and the human spheres

Biotechnology today entails intervention in all life. We can manipulate living organisms in a radically new way that may have unforeseeable consequences in both space and time. It is therefore important to clarify mankind's responsibility for itself and for all life. Biotechnology will be used in areas where we find it beneficial, and there shall be limits on the use of biotechnology out of respect for both ourselves and all living organisms. Where we draw these boundaries must be determined on the basis of ethics.

Ethics is a vision of the good life that entails considerations about our actions, about what is good and evil, right and wrong. Fundamental to this undertaking is a view of life, that is, an understanding of what life embodies and the values we consider valid. This involves a vision of what constitutes the good life for the individual, for society and for nature. Ethics and a view of life are thus crucial in determining how we understand both the choices we face and the responsibility we have for our actions.

The plant and foods area makes clear that the human and the non-human spheres must be understood in a single context. Human

[2] The BioTIK Group's position paper can be found at www.biotik.dk.

[3] An ethical foundation for genetic engineering choices, 44 - 48.

beings are both social and natural creatures. As a body, the human being is a living organism with functions and needs that resemble animals', and it lives in a purposeful realisation of its nature, as does a seed that can realise its potential by becoming a plant. As a natural creature, human beings are a part of and are dependent on surrounding nature. Two prominent philosophers of the 20th century, Maurice Merleau-Ponty and Hans Jonas, write on the existential coherence between human beings and their natural surroundings. Merleau-Ponty points out that the conquest of nature is a form of intervention in human beings' own nature. Jonas holds that human beings exist in a continuity with nature through their bodily metabolism.[4] These two perspectives are central to ethics in relation to the plant and foods area.

What does this mean for the way in which we treat both non-human nature, and ourselves as a part of nature? In outlining an ethics for the plant and foods area, it is appropriate to start with the moral status of all life. Moral status, one might say, defines the value that something has as an end in itself, its inherent value. This is the value that something has in itself apart from its value as a means of obtaining something else.

The ethical considerations include a recognition that everything living has a moral status. About this, the BioTIK Group writes:

Autonomy, dignity, integrity and vulnerability

> If genetic engineering is to be accepted, it will have to be used with respect for human beings' autonomy and dignity and for the integrity and vulnerability of life *(An ethical foundation, 1999).*

What does this mean in the plant and foods area? First, that human beings have a responsibility for plant life out of respect for the integrity and vulnerability of nature and out of respect for present and future generations, for whom plant life constitutes a vital necessity. Second, that human beings have a responsibility for food products out of respect for each human being's inherent value, that is, out of respect for other people in both the present and the future, as our actions have consequences for other peoples' vital necessities. This also implies a responsibility for ourselves as a part of nature. We might refer to this as anthropocentrifugal ethics. In contrast to anthropocentric ethics, which in the final analysis take into consideration only human beings for their own sake, an anthropocentrifugal ethics concerns the relation between human beings and everything living.[5] In the parts of our actions that concern the plant and foods area, we must consider how we can respect the ethical principles that in a certain sense apply to all life - integrity and vulnerability - as distinct from the ethical principles that can be attributed only to human beings - autonomy and dignity.[6]

What is the philosophical content of these principles then, and what is their practical significance concerning the use of biotechnology in the plant and foods area? These are complex and wide-ranging questions. We will point out some central and very simplified meanings of these principles.[7]

The Latin meaning of the word "integrity", *integrare*, comes from *tangere* (to touch) and *in*, which is a privative. Integrity thus means the "untouchable", which can be harmed but must be protected. In the ethical guidelines, it is described as follows: "the individual human being's integrity is understood as his or her life story, which defines his or her life coherency". In other words, a violation is a "touching" that threatens this vulnerable coherency. Kemp and Rendtorff write this about integrity: it "defines those parts of human life which make up its personal identity and should not be manipulated or destroyed."[8]

Respect for a *human being's integrity* might be respect for the coherency that constitutes a personal history and identity. This implies respecting what is personal, including a respect for the individual's understanding of his own life and identity. This might mean, for example, that respect for a human being's integrity is also respect for the demands that the individu-

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4 See Kemp, Lebech, and Rendtorff, Den bioetiske vending (Copenhagen: Spektrum, 1997) 109.

5 The word "anthropocentric" is intended here to express a view of nature that places human beings in the centre. A consideration of nature is evaluated according to what is good for human beings. An anthropocentric ethics is thus an ethics that not only places the human being in the centre but uses the human being as the measure for the ethical evaluation.

6 This is based on the BioTIK Group's formulation. Some will also attribute dignity to animals or to all of creation.

7 For a detailed examination of these ethical principles, see Kemp & Rendtorff, Basic Ethical Principles in European Bioethics and Biolaw, a report to the EU Commission (Barcelona & Copenhagen: 2000).

8 Peter Kemp, "Four Ethical Principles in Biolaw", in Kemp, Rendtorff & Mattson Johansen, eds., Bioethics and Biolaw (Copenhagen: Rhodos and Centre for Ethics and Law, 2000) II, 38.

al makes regarding the type of food he will consume and the type he will give others, for example his children. It is well known that a number of perceptions of food that are closely linked to human beings' identity are determined by culture and religion. It also seems fair to respect people's - perhaps emotional - resistance to genetically modified food on these grounds.

About the *integrity of nature*, the BioTIK Group writes the following:

> Respect for the integrity of animals or plants or nature as a whole is respect for the organic-spatial and natural historical (narrative) coherency of life they comprise or are part of. Lack of respect here consists of viewing nature quite simply as raw materials or pure capital for exploitation and production. In a way, we can accord animals, plants and the coherency of living nature the same integrity that we accord ourselves as purely organic or temporal beings.[9]

In its set of ethical guidelines regarding biotechnology, the BioTIK Group writes that, if genetic engineering is to be accepted, it "will have to be developed and used with respect for the integrity of life, provided that (. . .) all the living organisms, both individuals and especially species, with which we can coexist (for example plant species) are accorded an integrity of their own, which might be understood as their splendour value."[10] This might mean, for example, that respect for the integrity of plants could consist of protecting the stability of ecosystems and thus the foundation of the life of plant species. Kemp and Rendtorff write more precisely that respect for the integrity of nature is also respect for the teleology of nature.[11] That is, that the life coherency of plants, for example, must be considered in relation to the opportunity plants have to realise their nature. In other words, integrity can consist of having a life similar to the conditions of a seed that has not been manipulated by human beings.

Regarding *vulnerability*, the BioTIK Group's ethical guidelines include these considerations: "with respect for the vulnerability of life, provided that (a) this vulnerability is not just considered as a fact, but also as an appeal for care and consideration and (b) impoverishment and impairment of nature are avoided."[12] Vulnerability in this view refers to the irreplaceability of living organisms, to that which can be irrevocably lost. The reduction of biological diversity has clearly shown the vulnerability of nature to human beings' intervention. The demand for nutrient-rich and fresh food is also made out of consideration for the vulnerability of human beings. Genetically modified food may not pose a risk to the health of human beings. Regarding the responsibility of human beings for nature as a whole, it might be said in summary that human beings have a responsibility both out of respect for nature's vulnerability and integrity and out of respect for the inherent value of existing and forthcoming human generations.

Autonomy (self-determination/freedom) and *dignity* have a central place in both moral philosophy and the self-understanding of political democracies. They are concepts that have a prominent place in a number of international agreements that seek to protect human beings, both in the United Nations' Human Rights Declaration and the Bioethics Convention (the Oviedo Convention). The meaning of the word "autonomy" in ancient Greek is "self-governing", and this concept is closely linked to the modern idea of freedom.[13] As Kemp points out, "autonomy" has several meanings in European philosophy, and thus several sources of the concept can illuminate the bioethical dilemma of our time.[14] For John Locke, autonomy is freedom for the individual to determine when no other authority than his own nature need be recognised.[15] For Immanuel Kant, autonomy is also a positive ability to be morally self-governing in the sense that one can act in a morally responsible manner and thereby help to create a good society.[16] Autonomy is thus more than freedom for the individual; in self-government, there is also an acknowledgement of moral responsibility towards others.

In our context, autonomy concerns choice in relation to food products - the opportunity to

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9 *An ethical foundation for genetic engineering choices, 46.*
10 *Ibid. 115.*
11 *Kemp & Rendtorff, Basic Ethical Principles in European Bioethics and Biolaw, I, 140.*
12 *An ethical foundation for genetic engineering choices, 57.*
13 *Kemp, "Four Ethical Principles in Biolaw" 15.*
14 *Ibid. 15.*
15 *John Locke (1632-1704) is one of the founders of liberalism and a central figure in our culture's political thinking. In the liberal tradition, autonomy has been perceived to a great degree as freedom for the individual.*
16 *Immanuel Kant (1724-1804) created an ethics based on duty and respect for the dignity of the individual.*

make a responsible choice. A choice assumes that there are multiple possibilities, that it is possible to choose either to consume genetically modified foods or not to consume them - at a price that makes the choice realistic. An informed choice of food products assumes information about production, transparent product conditions and confidence in both the producer and the food control measures of the authorities. Consumers' autonomy is not unlimited freedom, but also includes an aspect of moral responsibility for others or for what is other. Through their choice of food products, human beings thus express a moral position. In order to make an informed and responsible choice, the consumer must know whether the product is a threat to nature, whether it involves unacceptable pollution or unacceptable socio-economic conditions for the producer. This aspect of the concept of autonomy can be linked to human dignity, and we will return to this point later. But in the food product area, ethics do not concern consumers' autonomy alone. The producer must also have autonomy, but it is an autonomy that is bound by moral responsibility towards nature's vulnerability and integrity and towards the quality of food products for the consumer (including respect for the consumers' moral status).

Consideration for the consumer can almost be summed up in the concept of *dignity*. Dignity requires that we respect the humanity of each person. For Kant, it means that a person can never be made into a pure means for others' objectives, but must always be treated as an end in himself. This might mean, for example, that people may not be subjected to food products that pose a risk to health, although they provide economic benefits for someone else. Food products must be of a quality that is healthy for people. Kemp and Rendtorff also emphasise another aspect of dignity, namely that it is a virtue the individual can develop.[17] As a virtue, dignity can mean managing one's moral responsibility towards oneself as both a social and a natural being, towards other people (in the present and the future) and towards nature. In other words, out of consideration for one's own dignity, a human being may demonstrate responsibility.

Definition of concepts

Ethical considerations, values and principles: The foundation of ethics is a vision of the good life, more precisely designated as the good life for the individual as well as society and nature. Associated with the ethical vision are various values that characterise society's or the individual's perception of the good life. These values might vary greatly. In Western ethics one thus speaks of human beings' having a value in themselves, that means every human life must be considered irreplaceable. Human freedom is also considered a value that must be preserved if it is to be possible to practise the values associated with the vision of the good life. A value can also be attributed to nature - either because of its significance for people's own lives or because of the source of wealth it represents for all life. These values are expressed in the ethical debate and regulations by means of a number of principles.

The four ethical considerations are based on respect for the autonomy and dignity of human beings and for the integrity and vulnerability of everything living. These principles are the foundation for ethical considerations of the irreplaceability of the individual person and nature. In this regard, the principles reflect a view of man and nature. The principles can thus be used as a guide for determining the actions and considerations that are appropriate or inappropriate in relation to the ethical vision. The principles function as a connecting component between the abstract values that delineate the ethical vision precisely and the concrete ethical issues that must be taken into consideration in specific situations. As an example of ethical considerations that may be associated with the four ethical principles, we might mention the consideration of the individual's autonomy and dignity expressed through protection of the consumer's free and informed choice and the patient's demand for an opportunity to give informed consent.

The plant area: embraces plants both as species and individual plants, and as a part of living nature. Here we take into consideration both plants that can be genetically modified and surroundings that are not genetically modified. That is, the ecosystem as a whole and the mutual dependency that exists between living organisms.

The food product area: This area assumes that mankind is the measure for ethical evaluation. In this context, it is relevant to speak of consideration for the consumer and producer and of consideration for citizens in general who are affected by food product policies, international trade and so on. Consideration for animals and plants could be brought into the discussion on the basis of respect for non-human nature, but we have chosen to restrict the dis-

[17] *Kemp & Rendtorff, Basic Ethical Principles in European Bioethics and Biolaw, I, 31.*

cussion to consideration for human interests - both current and future. Genetically modified (GM) animal feed might also be considered, however, to the extent that it is relevant in relation to consideration for the consumer. In addition, we should mention that the criteria for the treatment of animals are not without significance for the plant and foods area, because animal products make up a large proportion of food for non-vegetarians.[18]

GMOs (Genetically Modified Organisms). In the report, this designation refers particularly to plants in which the genetic material has been changed in a way that does not occur in natural reproduction, grafting or breeding.[19]

[18] It is also noteworthy that Sweden, for example, encompasses animals in its legislation in this area. It will be fair to protect animals in a framework that is not limited to the food product area or the medical production, however. The same applies to the issues about the use of laboratory animals.

[19] In contrast to traditional breeding, breeding by means of genetic engineering makes it possible in theory to transfer genes from unrelated plants, viruses, bacteria, and so on.

Recommendation for a new convention

On the basis of the study of conventions, resolutions and declarations that comprises the first part of the report on genetic engineering and ethics, we have reached the conclusion that there is a need for a new convention on the use of genetic engineering in the plant and foods area. The ethical considerations that the BioTIK Group has formulated are inadequately covered by existing conventions. This applies to consideration for both living nature in its entirety and for consumers in particular, including the principle of a just distribution of benefits and burdens. Most relevant for the protection of consumers is the Oviedo Convention, because there are many parallels between the medical use of biotechnology and the use of this technology in the foods area. In addition, some of the ethical considerations regarding nature are, under special conditions, covered by existing conventions. Nevertheless, we recommend that all the important ethical considerations be included in a new convention because the ethical guidelines for genetic engineering in the plant and foods area can thus appear together. Moreover, the existing conventions give room for various interpretations, and it will presumably give a higher degree of protection if one explicitly requires that these ethical considerations be respected.

Some of these ethical considerations are partially stated in existing declarations and resolutions. These declarations can be considered as expressing a desire for ethical principles in the plant and foods area. As such they can form part of the argument for including ethical considerations in a new convention on this topic. We recommend that a new convention of this kind, drawn up in accordance with the BioTIK Group's ethical considerations, should define in greater detail what the ethical principles mean for the plant and foods area. And in particular, there should be an enquiry in greater depth into what the ethical principles of respect for integrity and vulnerability mean, in our relation to plants and animals. Vulnerability characterises life coherency as expressed by the concept of integrity. The need to respect the integrity of animals and plants implies the necessity of protection both on aesthetic and ethical grounds, and especially when living organisms are used in food production.

In the relation between producer and consumer, it is a matter of respecting not only integrity and vulnerability, but also autonomy and dignity. This means, not least, a just or fair distribution of both the benefits and the burdens, nationally and internationally.

The main outlines for a new convention

The main outlines are based on the ethics that is described in *An ethical foundation for genetic engineering choices (1999)*. The ethical considerations are supplemented by points of view gathered from debates and regulations in a number of European countries. Finally, the ethical principles and considerations that are acknowledged and expressed in the existing conventions and declarations have also given some direction to the main outlines proposed for a new convention on the use and development of genetic engineering in the plant and foods area.

The preamble should refer to the following:

The United Nations' Human Rights Declaration and the rights and freedoms that are protected in it.

The Council of Europe's Convention on the Protection of Human Rights and Fundamental Freedoms.

The United Nations' resolution the *World Charter for Nature* on the protection and preservation of nature.

The Rio Declaration and the goals for sustainable development; also recognition of the precautionary principle.

The Council of Europe's Bioethics Convention on the protection of human beings as patients.

The Aarhus Convention on the protection of democratic rights in environmental matters.

The Convention on the preservation of biological diversity.

1 The purpose of a new convention

The purpose of a new convention regarding the development and use of genetic engineering in the plant and foods area is to advance quality of life and justice through respect for the autonomy and dignity of human beings and for the integrity and vulnerability of all life.

2 Giving priority to quality of life

Genetic engineering should be developed and used to promote the quality of life, for example, in the form of better foods, a cleaner environment or improved health. The quality of life or qualitative benefits should take priority over quantitative benefits so that one seeks only those quantitative benefits that are consistent with quality of life. Quantitative benefits for manufacturers and dealers cannot be considered as making up for qualitative damage to human beings and animals.

3 Respect for the autonomy and dignity of human beings

Autonomy must be respected, as the individual person must be respected for what he is in himself and not be made into a pure means for other people's technical, scientific and social objectives. People should, for example, have the opportunity to choose nourishment freely by means of labelling of genetically modified food products.

Dignity must be respected, as the individual person is ascribed irreplaceable worth and significance because of what he/she means to others, that is, to the social community. Consequently, the individual should not be excluded from scientific and political society because of critical points of view and activities, nor be violated psychologically or physically (genetically) as an object for scientific and technical manipulation.

4 Respect for the integrity of life

The individual human being's integrity must be protected by respect for the integrity of human beings, that is, the coherency of life in both space and time. All the living organisms, both individuals and species with which mankind lives together, are accorded an integrity of their own, which can be understood as their "splendour value".

Out of respect for the dignity and integrity of human beings, no food products may contain genetically modified organisms from human beings.

5 Respect for the vulnerability of life

The vulnerability of living organisms must be protected on the basis of the view that this vulnerability is not just a fact, but is also an appeal for care and consideration and because an impoverishment and impairment of nature must be avoided.

6 Justice, solidarity and responsibility

Justice, solidarity and responsibility must be

promoted in the distribution of benefits and burdens (respectively, food and commonly acceptable risks, for example). This implies that, over the long term, wealthy population groups may not be favoured at the expense of poor groups.

Technology and science must be developed in a responsible way and with the aim that every person is ensured a minimum of benefits and is not subject to hazards that he has not accepted, but is subject only to dangers that, on the basis of an independent (not commercially determined) scientific evaluation, do not have a high probability of causing permanent damage.

One may not subject others to risks which, as a researcher or producer, one takes measures to avoid oneself.

Oppression and discrimination must be avoided.

The welfare of current generations must not be increased at the expense of the welfare of future generations.

Precautions must be taken for the purpose of ensuring equitable access to healthy food of good quality.

Genetically modified foods may not, through public intervention or monopolistic conditions, become either so expensive that population groups whose resources are not extensive are cut off from receiving the benefit of them, or so inexpensive in relation to other products that such groups are under pressure to use them.

7 Local self-determination

An individual society must have the right to self-determination and freedom of choice, and decisions must respect the population's desires and concerns.

8 Protection of plants and ecosystems

Genetic engineering should not harm the environment or reduce ordinary sustainability. Specifically, it should *not* do any of the following:

- affect the ecological balance to an extent that causes damage to health or to nature, over either the short or the long term,
- cause significant damage to non-target organisms
- contribute to the deterioration of biodiversity in nature
- contribute to the deterioration of biological diversity in agriculture (varieties and breeds)
- lead to increased or new problems with pests
- contribute to a change in the nutrient turnover in the soil or in the geochemical processes, or increase soil erosion
- contribute to increased or undesirable use of chemicals in agriculture

9 Protection of vulnerable groups

The producers have a responsibility to consumers that is not limited to labelling products. Labelling is not adequate protection of vulnerable groups, including the illiterate and the seriously ill. Like incapable persons generally, children must be considered especially vulnerable since they cannot make choices themselves. Consequently, foods that are produced for and marketed to children, may not contain genetically modified organisms.

10 Information, labelling and accessibility of food products

The public must have a right to the product information that is necessary for making an informed decision about the use of genetic engineering.

No food products may contain genetically modified organisms from human beings.

All food products that contain or are made by means of genetically modified organisms must be labelled as such. The minimum level of 1% must be reduced as the technology improves.

The labelling of food products as "free from genetically modified organisms" must be monitored and controlled by responsible authorities. Consumers must be ensured access to food products without genetically modified organisms at a price and quality that are competitive in comparison with the equivalent genetically modified food products.

11 Public participation in decisions

The principle of proximity and respect for the individual person's self-determination assume that citizens have a democratic influence on the determination of risk limits. In cases where the principle of proximity does not obviously have to give way to general decisions for the benefit of all, the decision shall be made as close as possible, both geographically and socially, to the people who are affected.

Decisions about the use of genetic engineering must be built on openness towards all points of view, and this calls for regular public hearings and information and objective information about the consequences. There must also be independence of interests driven solely by the prospects of financial gain; impartial communications among researchers, businesses, authorities and the population; and an open scientific discussion among researchers.

In the use of genetic engineering, the assignment of responsibility for decisions and their implementation must be defined clearly. Alternatives must be taken into account; possible harm must be minimised; reversibility and flexibility must be maximised; and dependence on genetic engineering must be limited.

12 The access of the public to the courts

Citizens who are denied information or receive inadequate information about the use of genetic engineering in the plant and foods area must have the right to bring such cases to court.

13 The producers' responsibility

Farmers and producers must be assigned a special responsibility for healthy and sustainable food production, out of consideration for both current and future generations. This implies a responsibility for the protection of all nature and agriculture in particular.

14 Protection of producers

GMO-free agriculture must be protected both now and in the future. This implies that agriculture must be ensured the opportunity to operate without genetically modified organisms.

15 The establishment of an international committee for social justice

An international committee for social justice should have the task of contributing to solutions to ethical dilemmas regarding the use of genetic engineering in the plant and foods area.

16 The establishment of national ethical committees

National ethical committees should have special responsibility for protecting the ethical principles and illuminating the socio-economic consequences of genetic engineering.

17 Ethical rules

Ethical rules for the professions that develop and use genetic engineering in the plant and foods area should be developed and established.

18 A diversity of scientific environments

The existence of several independent scientific environments must be ensured, and the various scientific points of view must be taken into consideration, in decisions regarding the use of genetic engineering.

19 Training in ethics and the philosophy of science

University educational programmes in the life sciences must comprise courses on ethics and the philosophy of science. Committees that evaluate safety and risk must include members with a training in the philosophy of science and ethics and a knowledge of the foundation and limitations of scientific methods.

Existing conventions that concern the plant and foods area

We have selected the international conventions that seem to have significance regarding the use of genetic engineering in the plant and foods area. The basis for this selection is the BioTIK Group's ethical guidelines for the development and use of biotechnology. This implies consideration for nature and consumers, among other things. The guidelines concerning the treatment of animals are not without significance for the plant and foods area because animal products make up a large proportion of the food of non-vegetarians. It would be reasonable, however, to protect animals in a framework, regardless of whether they are used as food products, in medical production or in other ways. In other words, the protection of animals that are used in biotechnology should take place according to a separate convention. The animal area is thus not part of this study, but, to be complete, a convention on the food product area should be supplemented by a convention that protects animals, as the BioTIK Group's ethical considerations include the regulation of biotechnology developed and used in relation to animals.

In addition to the conventions, we have chosen to look at selected UN resolutions and declarations and an international codex on food products. Resolutions and declarations are generally short and universal declarations of principle. They appear to be largely expressions of acknowledgement of a moral responsibility rather than of a concrete political will. Resolutions and declarations do not have the same legal status as a convention, but they can be groundbreaking for conventions as they legitimate a problem as being of an international nature. They can thus be of assistance in the work of developing new conventions. Conventions may also often confirm principles in existing declarations. For example, the Stockholm Declaration of 1972 contributed to the recognition of environmental issues as relevant to the international agenda. It nevertheless took two decades before the protection of nature's biological diversity became obligatory by international agreement: the Biodiversity Convention.

Our method has been to undertake a close reading of selected texts and to comment on those aspects that we believe have ethical relevance. We have compared these aspects with the BioTIK Group's ethical guidelines. The preliminary studies, which lay the groundwork for the individual agreements, can often make important contributions to interpretation. They may give some indication of the degree to which the text was prepared according to ethical considerations. In this part of the project, we have chosen to look at the preliminary studies and other comments to a limited extent only. In addition, we offer a reminder that conventions are compromises. In some cases, the preliminary studies or "authorised" commentaries do not give clarifying comments. The reason for this might be that the parties could not agree on a precise formulation.[20] This gives an opportunity for the parties to agree on the formulation of a convention, then to interpret it in various ways as it is implemented by individual nations. The concrete interpretation of conventions, as it occurs in national legislation, court judgements and administrative practice, is of greater significance.

We have found the following texts relevant and have commented on them in the context of our general project:[21]

- **Codex Alimentarius:** Code of Ethics for International Trade in Foods, WHO/FAO, 1962
- **World Charter for Nature,** UN General Assembly Resolution 37/7 of 28 Oct. 1982
- **Declaration on Environment** and Development, UN's Rio Conference, 1992
- **Convention on Biological Diversity**, UN's Rio Conference, 1992
- **Convention on Human Rights and Biomedicine,** Council of Europe, Oviedo, 1997
- **Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters**, ECE, Aarhus, 1998
- **Cartagena Protocol on Biosafety to the Convention on Biological Diversity,** 2000

[20] This is very clear in the Oviedo Convention, for example, whose "Explanatory Report" contains the following: "it was a generally accepted principle that human dignity and the identity of the human being had to be respected as soon as life began." It remains up to the individual nation to decide when life should be considered as beginning. Directorate of Legal Affairs, Council of Europe (Strasbourg, 1997) 8.

[21] Of the texts that we have not found relevant or significant in this context, we can mention the following: International Plant Protection Convention - regarding pest control (FAO, 1951); the Stockholm Declaration - regarding the environment (UN, 1972); the Bern Convention - regarding protection of specific species of wild fauna and flora (Council of Europe, 1979); the European Charter on the Environment and Health (FAO, 1989); and UN General Assembly Resolution 45/94 - regarding the environment (1990).

The following sections contain presentations of these texts and summaries of our analyses of their ethical significance.

Codex Alimentarius

The Codex Alimentarius (1962) is an international collaboration under the auspices of the WHO and FAO that attempts to set international standards in the food product area. The Codex has 165 member countries. The ”Code of Ethics for International Trade in Foods” is found under the Codex. This is the part of the Codex we examine closely. Its purpose is to protect consumers’ interests by establishing requirements for nutritional and healthy food products as well as to protect against unfair forms of trade. The Code of Ethics is a short and concrete set of rules that sets requirements for the labelling of food products, among other things. In 1999 the Codex Commission commenced work on a project to standardise risk assessment of genetically modified food products.

The Code of Ethics is not directly comparable to the ethical guidelines. It does not treat genetically modified food products in particular, but rather concerns food products in general. Nevertheless, the ethical requirements that the Codex sets for food products also apply to genetically modified food products. One must therefore acknowledge that the Code of Ethics is consistent with the ethical guidelines on several points, although we cannot say that the ethical guidelines are fully covered by the Code of Ethics. This is true of the requirement that genetic engineering must preserve or improve health and promote respect for human autonomy through the labelling of food products, for example.

World Charter for Nature

The World Charter for Nature (1982) is a resolution of the UN General Assembly. The Charter has a strongly ethical character. It sets nature in a central position and ascribes to it a value in itself. Nature must be respected, preserved and protected out of consideration for both nature itself and mankind. More specifically, citizens and states have a moral responsibility towards nature, and clear limits are drawn for the use and exploitation of nature.

The World Charter for Nature does not concern biotechnology directly, but concerns rather the protection and preservation of nature. One can say that, as such, it indirectly sets limits for the use of biotechnology. Like the ethical guidelines, the World Charter ascribes a moral status to nature. That is, mankind has a moral responsibility towards nature, not only out of consideration for nature itself. The World Charter is in line with the ethical guidelines’ respect for animals and the integrity and vulnerability of nature. In addition, the World Charter is also in line with the ethical guidelines’ requirement that biotechnology must not harm the environment or reduce nature’s ordinary sustainability. Finally, the World Charter is in accordance with certain of the ethical guidelines concerning democratic debate and decision-making processes. This is true of the items on public hearings and information, reliable information about possible consequences and the need to define the assignment of responsibility for decisions. Since the World Charter is a resolution, these items are not internationally binding in the same way as a convention is. But perhaps the World Charter can provide support for the inclusion of these ethical guidelines in a text for a convention.

The Rio Declaration

The *Declaration on Environment and Development (1992)* is a UN declaration from the Rio Conference on the environment and development. The Rio Declaration follows up on the Brundtland Commission’s report and sets the concept of sustainable development in the centre of debate. The Declaration attempts to make the desires for economic growth and welfare for current and future generations compatible with the protection of nature. It is a declaration of principles that is very comprehensive in its theme, and formulated in general terms.

The Rio Declaration is a general statement of principles regarding the environment and development. The declaration says nothing directly about biotechnology. But it sets forth a view of the relation between mankind and nature, particularly through the expression ”sustainable development”. The Declaration can be interpreted as being in line with the ethical guidelines on two points. First, in its requirement of biotechnology that it may not be developed and used in such a way that the current generation’s welfare is achieved at the cost of that of future generations. Second, the Rio Declaration states that the integrity of the ecosystem must be preserved, protected and restituted. These points resemble the formulations in the ethical guidelines.

The Biodiversity Convention

The *Convention on Biological Diversity (1992)* is a UN convention that was prepared under the United Nations’ Environment Programme (UNEP). While the Rio Declaration sets forth

general principles for the environment and development, the Biodiversity Convention puts sustainable use and preservation of biological diversity in focus. The objective is to preserve genetic diversity through sustainable use of plants and animals and their habitats. The Convention goes into some detail on intermediate objectives, concept definitions and international collaboration on access to technology and resources.

The Biodiversity Convention attributes an inherent value to biodiversity. This can be interpreted as an acknowledgement of the integrity and vulnerability of species. The Convention's general objective is to preserve biological diversity. This objective places limits on the use of genetic engineering. The ethical guidelines that are relevant for comparison are particularly the requirements that genetic engineering may not harm the environment or reduce nature's ordinary sustainability. To what extent these ethical guidelines are covered by the Convention is a matter of interpretation. In addition, the Convention seeks a just distribution of access to genetic resources, the transfer of technology and the benefits that follow from the use of genetic resources. The Convention seeks fairness on these points in relation to its general objective, namely the preservation of biological diversity. This justice is thus sought within a narrower framework than in the ethical guidelines.

The Oviedo Convention

The *Convention on Human Rights and Biomedicine (1997)* is a convention of the Council of Europe that is also called the Bioethics Convention. Its primary objective is to protect human beings in relation to the use of biotechnology in medical science. The Convention is very clear regarding the ethical principles that are considered fundamental for human moral status. These principles lay the foundation for the guidelines regarding informed consent, private life and the right to information, the human legacy, research, organ donation and commercialisation of the body.

The Oviedo Convention is the first convention prepared specifically to regulate biotechnology. It is limited to the area of medical science and consequently concerns only the human being. The ethical foundations of the Convention and the guidelines are very similar. The Convention, like the ethical guidelines, builds upon human autonomy, dignity and integrity. In addition, human vulnerability may be understood as an underlying motivation for the Convention. These ethical principles will be relevant to apply to the foods area. The Convention's general objective - that biotechnology must be used for the benefit of mankind - also resembles that of the ethical guidelines. The ethical guidelines concerning the human sphere are also covered by the Convention. The Convention has a somewhat weaker formulation, however, regarding the danger to which the individual is subject in comparison with the benefit the individual stands to obtain. This danger is relevant for medical research. A possible interpretation of the Convention is that it acknowledges that, under special circumstances, a person can be subjected to a danger from which the person can only benefit indirectly.

The Aarhus Convention

The *Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (1998).* This is a UN convention signed by the pan-European conference of ministers of the environment "Environment for Europe", which was held under the auspices of the UN's Economic Commission for Europe (ECE). Its purpose is to ensure citizens' rights in the environmental area, and this is treated under the issues that appear in the Convention's title. As such, the Convention can be understood as a step in the process of democratisation.

The Aarhus Convention concerns the role of the public in the environmental area. To the degree to which biotechnology affects the environmental area, the Convention is relevant to the ethical guidelines for democratic debate and the decision-making processes. The Convention applies to genetically modified organisms intended for release into the environment. Whether it applies to other genetically modified organisms (for example, animal feeds) depends on an interpretation of whether or not the individual case is relevant to the environmental area. The Convention is thus narrower in its scope than the ethical guidelines. In general it does not cover the parts of the ethical guidelines that it overlaps. With this limitation, the Convention overlaps the ethical guidelines' requirements for public hearings and information, objective information about possible consequences, citizens' right to democratic influence in the determination of risk limits and, finally, the requirements that the decisions reflect the concerns of the population and that the assignment of responsibility is clearly defined. The provisions in the Convention apply, however, only when the authorities, within the framework of national legislation, find that decisions regarding the release of geneti-

cally modified organisms must be subject to the Convention's provisions.

The Biosafety Protocol

The *Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000)* treats safety in international trade in living genetically modified organisms. Its purpose is to support the Biodiversity Convention's ambition to preserve biological diversity. Consequently, the Protocol's rather detailed rules regarding risk assessment and decision making should be understood in this light.

The Biosafety Protocol applies to safety in international trade in living modified organisms (LMOs) that are intended for release, food, feed or manufacture. As such, the Protocol in its entirety is within the working sphere of the ethical guidelines. But the Protocol applies exclusively to international trade in LMOs; that is, it does not regulate the development of LMOs or their use in the country where the LMOs are developed. The Protocol thus has a narrow and precisely limited application area. Consequently, none of the ethical guidelines are completely "covered" by the Protocol, but some of the ethical guidelines are covered in the area to which the Protocol applies. The Protocol can be said to support the requirement that genetic engineering must advance justice for the purpose of avoiding oppression and discrimination. Further, the Protocol requires consideration for nature's sustainability and biodiversity. To what degree the Protocol - and the Biodiversity Convention - cover the ethical guidelines' specifications in these areas is a matter of interpretation. On one point the Protocol seems to supplement the Aarhus Convention: For all LMOs that the Protocol applies to, it is possible to interpret the Protocol as meaning that the public must be heard and informed, including being informed of possible consequences.

International agreements in relation to the ethical guidelines

The BioTIK Group has formulated a proposal for the operational application of the ethical considerations, called "the ethical guidelines".[22] We present the ethical guidelines here in numerical order and offer some general comments on them in relation to the texts we have analysed. In addition, we will comment briefly on instances in which the international texts' contents are in accordance - wholly or partially - with some of the ethical guidelines.

The ethical guidelines are structured as follows:

- **I General guidelines**
- **II Guidelines concerning the human area**
- **III Guidelines concerning the animal area[23]**
- **IV Guidelines concerning nature and agricultural use**
- **V Guidelines concerning democratic debate and decision-making processes**

A comparison of the texts and the ethical guidelines shows that the ethical guidelines are not completely covered in the existing conventions that concern the plant and foods area. Of special significance, nevertheless, are the Oviedo Convention and the Biodiversity Convention. This is because these conventions recognise ethical principles that are considered fundamental for man and nature's moral status. The ethical principles we find in these texts could constitute the foundation of a new convention on the use of genetic engineering in the plant and foods area.

The Oviedo Convention uses ethical principles as the foundation for the protection of mankind in the area of medical science. These ethical principles are autonomy, dignity, integrity and, indirectly, vulnerability also. These ethical principles are considered fundamental to man's moral status. The Oviedo Convention's recognition of these ethical principles as being fundamental for the protection of human beings as patients is an argument for using the principles in other areas as well. It would hardly be reasonable that there are areas in which human moral status is considered invalid. Consequently, it will be fair to recognise the ethical principles that are central for the protection of human beings as patients, as being valid in the foods area as well. This would strengthen the protection of human beings as producers and consumers. The existence of the Oviedo Convention is thus an important argument for using these ethical principles in a new convention on the foods area.

The Biodiversity Convention recognises the inherent value of biodiversity. It is possible to interpret this as a recognition of the integrity and vulnerability of species. This can be an important argument for protecting the plant area in the use of genetic engineering. The World Charter for Nature and the Rio Declaration express similar ideas but also open the possibility of attributing moral status not only to species but at the level of the individual as well. On this point both the Rio Declaration and the World Charter are imprecise. The World Charter for Nature recognises every *life form* as unique and as possessing inherent value. In addition, it states that *ecosystems* and species have a certain integrity. The emphasis on ecosystems' integrity can be interpreted as a recognition of individuals' mutual dependency. It seems reasonable to understand the World Charter as attributing an integrity and vulnerability to the entire living nature. The Rio Declaration also attributes integrity to the earth's ecosystems. Since the World Charter for Nature and the Rio Declaration are not treaties, but more in the nature of expressions of a shared international moral standpoint, they may serve as a support for incorporating ideas about the integrity and vulnerability of nature in a political and legally binding document such as a convention on the plant and foods area.[24]

The Biodiversity Convention protects biological diversity, which is one aspect of nature. But no convention has as its central objective the protection of living nature in its entirety in relation to the use of biotechnology.

I General guidelines

"If genetic engineering is to be accepted, it - like biotechnology in general - will have to be developed and used. . . (followed by items 1-6, including sub-items):

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22 An ethical foundation for genetic engineering choices, 56-59.

23 In the BioTIK Group's ethical guidelines, genetic engineering used on animals is one of the main areas. The animal area is not covered in this study. See p. 11.

24 In international law, it is not unusual that a joint declaration (such as a UN resolution, a human rights declaration or another declaration) is followed up by a binding convention. Conventions prefer to use the preamble to confirm the principles in declarations and thus clarify the justification of the convention.

(1) to the benefit of human beings, society and living organisms, provided that one

a promotes the quality of life (qualitative benefit) by saving life, preserving or enhancing health as long as possible for human beings and the nature that he or she lives off and in, preventing hunger and material hardship, combating and alleviating pain in human beings and animals, etc., and
b prioritizes the quality of life rather than purely quantitative benefits and hence only strives for quantitative benefits (e.g. enhanced production) that are consistent with quality of life, and that
c quantitative benefits for individual manufacturers and dealers are not considered to offset qualitative damage to human beings and/or animals.

Comment

General: None of the texts sets this kind of ethical requirement regarding the development and use of genetic engineering. But to the extent that the ethical principles of autonomy, dignity, integrity and vulnerability are recognised for mankind and living nature, one might say that these general criteria are a fair interpretation of the principles. Consequently, the texts that recognise the moral status of living nature in these principles can be considered an indirect support for these general guidelines for the development and use of genetic engineering.

Particular: The Codex Alimentarius does not cover genetically modified food products. It can nevertheless be said that the Codex is in accordance with these ethical guidelines - although the ethical guidelines are not covered by the Codex. In addition, one can point out that the Oviedo Convention covers the requirement that biotechnology must be used for the benefit of mankind - but this relates only to medical science.

(2) with respect for the human being's autonomy and dignity, provided that

a autonomy (right to self-determination) is respected when the individual human being is respected for what he or she is in himself or herself, i.e. as an independent and free (autonomous) individual, and consequently is not rendered purely a means for other people's technical, scientific and social purposes, but through such means as the labelling of genetically modified food, etc. is given the possibility to freely select what food he or she eats, and
b dignity is respected when each human being is accorded irreplaceable value and significance by virtue of what he or she means to others, i.e. for the social community, and consequently is neither excluded from the scientific and political society due to critical views and activities, nor violated psychologically and/or physically (genetically) as the object of scientific and technical manipulation, e.g. in medical experiments.

Comment

General: In their entirety, these requirements are not covered by the texts. But the Oviedo Convention makes a requirement of respect for human autonomy and dignity within medical science.

Particular: The Oviedo Convention is in accordance with these criteria, but again, the Convention concerns only medical science. The Codex sets a requirement for labelling food products. That is only one possible interpretation of this point, however.

(3) with respect for the integrity of life, provided that

a the individual human being's integrity is understood as his or her life story, which defines his or her life coherency,
b animals as individuals and especially as species are not just considered and treated as objects that human beings can unrestrainedly manipulate, but as creatures with a life coherency that we accord a value in itself, and
c that all the living organisms, both individuals and especially species, with which we can coexist (for example plant species) are accorded an integrity of their own, which can be understood as their splendour value.

Comment

General: The Oviedo Convention recognises the integrity of human beings, and this is fun-

damental to the Convention's more precise statement of what protection in the area of medical science entails. The Biodiversity Convention attributes an inherent value to biodiversity, and this can be interpreted as a recognition of the integrity of species. The World Charter for Nature and the Rio Declaration also attribute integrity to species, but one can neither affirm nor deny that this also applies at the level of the individual.

Particular: Sub-item 3a is covered by the Oviedo Convention - although only regarding use by medical science. Sub-items 3b and 3c are partially covered by the Biodiversity Convention, and they are supported by the World Charter for Nature and the Rio Declaration.

(4) with respect for the vulnerability of life, provided that

a this vulnerability is not just considered as a fact, but also as an appeal for care and consideration,
b impoverishment and impairment of nature is avoided.

Comment

General: The Oviedo Convention does not state directly that mankind is vulnerable, but in view of the protection that the Convention seeks to give human beings, it recognises mankind's vulnerability. It seems fair to say that the Biodiversity Convention and the World Charter for Nature indirectly attribute vulnerability to living nature.

Particular: Sub-item 4a is covered by the Oviedo Convention - within the area of use by medical science. Sub-item 4b is supported by the Biodiversity Convention and even more strongly by the World Charter for Nature.

(5) in order to promote justice (equity) in the way benefits and burdens (e.g. foods and commonly acceptable risks, respectively), are distributed among humans, always provided that

a technological and scientific development is carried out with a view to ensuring that every human being is guaranteed a minimum of necessary benefits, and is not exposed to dangers that he has not accepted himself, and is only exposed to dangers that according to an independent (noncommercially determined) scientific opinion will probably not lead to lasting damage,

b risks are not something one subjects others to while one as a scientist and/or manufacturer concomitantly protects oneself against running the very same risks,
c some population groups must not be favoured at the expense of others in the long term,
d the welfare of present-day human beings must not be enhanced at the expense of the welfare of future generations,
e public intervention and monopoly-like states must not render genetically modified products and treatments so expensive that less well-off groups are prevented from benefiting from them, nor so cheap relative to other products that such groups are pressured into using them,
f oppression or discrimination is avoided.

Comment

General: None of the texts sets nearly as strong requirements for justice and fairness as the ethical guidelines do, and they do not address justice in relation to biotechnology to any great extent. The Biodiversity Convention makes certain requirements for justice, but they relate to the Convention's objective of preserving biological diversity. That is something different from the ethical guidelines' requirement that genetic engineering must be used to advance justice, including the point that the current generation's welfare must not be improved at the expense of future generations'. The Convention's requirement of justice concerning the use of genetic resources and biotechnology can be fairly compared with economic terms of trade and solidarity in relation to a joint agreement on protecting biodiversity. The ethical guidelines specify justice at a more general level and partly as a necessity in relation to the recognition of autonomy, dignity, integrity and vulnerability. Justice can be understood as a framework for the ethical principles, and justice and the ethical principles will be mutually dependent, if they are to have any meaningful content. If these principles are recognised in a new convention on the plant and foods area, it is reasonable to specify in greater detail what they imply for a society that is attempting to achieve justice.

Particular: Sub-item 5d can be said to be supported by the Rio Declaration. Sub-item 5c is supported to a certain extent by the Biosafety Protocol, but cannot be said to be covered fully by the Protocol.

(6) with respect for the individual society's right to self-determination and freedom of choice, in that decisions should reflect worries and wishes among the population.

Comment

None of the texts has nearly as explicit a requirement regarding the development and use of genetic engineering. In addition, what is stated about the ethical principles and justice under item I:5 also applies.

II Guidelines concerning the human area

"Genetic engineering may not subject human beings to unacceptable risks and depreciate life by . . ." (followed by items 1-6, including sub-items):

(1) changing human beings' genetic constitution in a manner that affects the germ cells,

Comment

Covered by the Oviedo Convention.

(2) being used for the therapeutic treatment of the severely ill at the expense of psychological and social care for the patients' dignity and personal integrity, such that they are just treated as defect machines (the "defect machine model"),

Comment

Covered by the Oviedo Convention.

(3) exposing one or more human beings to a danger out of proportion to the possible benefit that they themselves will be able to gain from the technology.

Comment

Within the field of medical science, the criterion is fairly well covered by the Oviedo Convention, although the Convention has a somewhat weaker formulation. This formulation can also be used in other areas, but is inadequately covered by the other texts. The Biosafety Protocol also stipulates consideration for the health of human beings, but that is within the relatively narrow area to which the Protocol applies.

IV Guidelines concerning nature and agricultural use

"Genetic engineering may not harm the environment or diminish the sustainability of nature by . . ." (followed by items 1-7, including sub-items):

(1) affecting the ecological balance in such a way that there is a danger to health and nature itself,

(2) causing considerable harm to non-target organisms (i.e. organisms not directly involved),

(3) contributing to deterioration of biodiversity in nature,

(4) contributing to deterioration of biological diversity in agriculture (varieties and races),

(5) causing enhanced or new problems with pests,

(6) contributing to changes in nutrient turnover in the soil and the geochemical processes, or enhancing soil erosion,

(7) contributing to enhanced or undesirable use of chemicals in agriculture.

Comment

The Biodiversity Convention is the text that lies closest to these specific provisions on what showing consideration for nature might entail. The Biodiversity Convention and the ethical guidelines are not directly comparable, however. The perspective of the Biodiversity Convention is different from that of the ethical guidelines. The Convention attempts to protect biological diversity, and the ethical guidelines seek to regulate the use of biotechnology. While the Convention has a general requirement on the protection of biodiversity, the ethical guidelines make more concrete demands on the management of biotechnologies in relation

to the environment and nature. The Convention says little about genetic engineering directly, but can perhaps be said to regulate the use of genetic engineering indirectly. To what extent the ethical guidelines are covered by the Convention is a matter of interpretation. It can probably be said with fairness that the Convention aims to cover all the items (with perhaps the exception of item 7), but it does not specify all of these requirements regarding the use of biotechnology. According to the Convention, areas worthy of special preservation must be designated by an individual party, and these areas must be given special protection. Outside these areas, nature does not appear to receive as strong a protection. Consequently, it is unclear to what extent it is a necessary interpretation (and not merely one possible interpretation) of the Convention, to say that it covers these ethical guidelines. Presumably an investigation of the implementation of the Convention regarding the use of LMOs would give a more precise indication of this. On the other hand, the ethical guidelines are not completely clear either. When does one, for example, contribute to a reduction of biological diversity in agriculture? Does one do so by allowing the standardisation of individual farms?

The World Charter can be considered an indirect support for these items, but the Charter does not mention biotechnology in particular.

V Guidelines concerning democratic debate and decision-making processes

”Democratic debate and decisions on the use of genetic engineering shall . . .” (followed by items 1-3, including sub-items):

(1) be based on openness to all viewpoints prior to every decision through

a regular hearings and information of the public,
b objective information on the possible consequences,
c independence of interests driven solely by the prospects of financial gain,
d objective communication between scientists, companies, authorities and the population,
e an open scientific discussion between researchers.

Comment

General: None of the criteria under items V:1-3 is adequately covered by the existing conventions. The criteria can be understood as specifying what respect for the ethical principles - autonomy, dignity, integrity and vulnerability - may mean regarding democratic debate and decision-making processes. The guidelines should therefore be included in their entirety in any new convention on the plant and foods area.

Particular: Sub-items 1a and 1b are covered by the Aarhus Convention to the degree that the development and use of genetic engineering can be considered environmental issues. Sub-item 1d can be said to be supported by the Aarhus Convention. To what extent the Biosafety Protocol covers sub-items 1a and 1b is a matter of interpretation (the Protocol otherwise applies only to the extent that it encompasses biotechnology). Sub-items 1a and 1b are supported by the World Charter.

(2) respect the individual human being’s right to self-determination by

a giving citizens (consumers, patients, etc.) the possibility to choose freely and give or refuse their consent,
b ensuring citizens (consumers, patients, etc.) democratic influence on the stipulation of risk limits,
c respecting the proximity principle to the greatest extent possible such that decisions in cases where the principle does not obviously have to give way to general decisions to the benefit of all are made as close as possible - both geographically and organizationally - to the people they affect.

Comment

Sub-item 2a is covered by the Oviedo Convention. Sub-item 2b is covered by the Aarhus Convention to the degree that it is considered to be an environmental issue.

(3) assess and prioritize technologies and their uses such that

a decisions reflect the worries and wishes of the population,
b the assignment of responsibility for decisions and their implementation is clearly defined,

c alternatives are taken into account
d possible harm is minimized,
e reversibility and flexibility is maximized,
f dependence on them is limited.

Sub-items 3a and 3b are covered by the Aarhus Convention to the degree that they are considered to be environmental issues. Sub-items 3a and 3b are also supported by the World Charter for Nature.

Genetic engineering and ethics in national law

The complete report is generally limited to an examination of the United Kingdom, Germany and France, which display a lively debate about commercial interests in the use of biotechnology in the plant and foods area. Secondarily, we consider Norway and Sweden. Norway has set out some very distinctive positions and rules regarding biotechnology, while Sweden has a long tradition of setting ethical topics on the political agenda. The examination should be seen as a contribution to the understanding of other countries' attitudes about the use of genetic engineering in the plant and foods area. This may add supplementary points of view to the Danish proposal on ethical guidelines for regulation and thereby contribute to a dialogue about new ethical considerations regarding the use of genetic engineering in the plant and foods area.

The method used in the report is essentially hermeneutic. This means a scientific approach in which interpretation and an understanding of motives, assumptions and reaction patterns sustain the study. The hermeneutic approach is evident in practice through the report's specific treatment of the situations in Germany, the UK and France and, in a shorter form, those in Sweden and Norway. The "ethical profiles" offered of these countries are thus based on an understanding of ethics as a value touchstone that is mirrored in various perceptions of what constitutes the good life. The report's approach is based on the ethical principles and criteria that are set out in the BioTIK Group's position paper *An ethical foundation for genetic engineering choices (1999).*

The report does not aim for a legal review of sets of rules. On the other hand, it attempts to identify aspects of the sets of rules about genetic engineering in the plant and foods area that are relevant in an ethical context. Therefore one will not find a narrow review of rules and procedures in the report. Instead, we emphasise the most important national principles of an ethical or legal nature that have special relevance for the area under study. An examination of individual legal principles and central ethical principles illuminates how the various countries implement joint principles, for example the precautionary principle, the prevention principle and the principle of sustainability, and whether or not these principles are given differing emphasis or have a special significance in the legal tradition of the countries in question.

In the following abridged version of the report, we give, by way of introduction, an overview of the most important ethical principles and considerations prevailing in the EU rules in the area. In this connection, we look more closely at the possibilities and limitations of incorporating ethical considerations in connection with national compliance with the requirements of EU rules. Later, we present a summary of the most important ethical principles, values and considerations that prevail in the five countries under study, in connection with national regulation of and debate about the use of genetic engineering in the plant and foods area. Finally, we evaluate the countries' ethical profiles in relation to the Danish ethical considerations.

Ethics and EU regulation

Various perceptions of the word ”ethics”

In the debate on biotechnology, one often sees formulations such as ”consideration for sustainability, health and ethics” or ”consideration for nature, society and ethics”. Some suppose that sustainability and health are not ethical considerations. But it is more accurate to see them as specifications of ethical considerations because they are considerations founded on a vision of the good life for the individual, for society and for nature.

One can speak of common benefits and of benefits for the individual that the individual must be able to take a position on by personal choice. In other words, the word ”ethics” is used for something that concerns private life and the individual’s view of life and values; also for something that refers to common values and benefits that we protect in the legal sense, for example - sometimes in a way that might mean that the individual cannot choose and act freely. It is thus fair to use the word ”ethics” in both social and private contexts. When referring to ethics on a social and political level, it is often necessary to be concrete and illustrate the benefits to which one is referring. On the other hand, the term can be used better in a less specific sense, when discussing private life.

There are also variations in the way the word ”ethics” is used in the countries we have studied, and, of course, variations within individual countries. Although in certain cultures one refers to ethics mainly as something that concerns private life, this does not mean a failure to appreciate that there are values and visions of the good life that are also fundamental in the public sector.

One reason that ethics is often used in reference to private life derives from our political and cultural history. The process of democratisation supports the individual’s rights and freedoms, including freedom of belief. The religious element, including the influence of the church, has been strongly linked to the moral and ethical life. The changed relation between church and state has, in a historical perspective, also led to a situation in which people in some cultures, for example the UK and France, consider ethical matters as something that concerns private and religious life especially. After the religious wars, it was important to protect citizens against the habit of thinking that the prince’s belief must also be the subject’s belief. This means that ethics and politics became separate to a greater degree, and this has been characteristic of the secularisation process. The UK has developed in a more liberal direction than France, and this is evident in the way in which ethics is considered to belong to the private sphere more than in France. France, on the other hand, has a tradition of an engaged intellectual elite who discuss ethics in the town square. In addition, France has a paternalistic political tradition, according to which those in power care about and take responsibility for citizens, in a way that in more liberal cultures would be considered an improper interference in the private area of ethical life.

Nowadays, it has become very popular to talk about ethics and values in a political and social context. That is also a recognition that our society is built upon certain values that we wish to protect, because we consider them to be the mainstays in building and maintaining a fair and good society.

Ethics in the plant and foods area

In the current debate on the plant and foods area, various prefixes are attached to the term ”ethics”. For example, the term ”food ethics” is often used in the UK, and ”consumer ethics” is often seen in Denmark. In the UK ”food ethics” refers specifically to considerations of animal welfare and consumers’ health and choices. ”Consumer ethics” applies to much more than food products, but refers particularly to the consumer.

Concerning the use of genetic engineering in the plant and foods area, it is an ethical consideration, for example, to seek to protect the individual by emphasising the informed nature of the individual’s choice. There are also other ethical situations in which one wishes to protect society and nature as a whole, by establishing opportunities and restrictions by means of the law. We find a parallel regarding the protection of patients in the Bioethics Convention (Oviedo Convention of 1997). There are ethical guidelines for the approval of medical trials, and the patient’s sovereign right to make decisions regarding his own body by informed consent is also set out. Deciding when it is up to the individual to make a choice and when it is up to society to make it, is an ethical question. That is, in the final analysis, these restrictions are determined on the basis of a vision of the good life and forethought for the living.

For the individual consumer, not all options are desirable. A real choice is conditioned by information, often in very complex contexts. A

society that protects vulnerable forms of life also sets limits on the responsibility placed on the consumer. In this way society will protect not only a third party (the vulnerable party) that might be hurt by the consumer's choice, but also the consumer himself, who might have difficulty comprehending the area of responsibility in question. The consumer's choice cannot be a choice between very risky food products and "safe" food products.

There are tasks that we consider to be the responsibility of society, and we would consider leaving them up to the individual to be an improper "privatisation" of the ethical sphere. If one has a broad vision of preserving biodiversity and an obligation to do so through a convention, the task cannot be transferred to the individual consumer, who cannot fulfil the responsibility through his/her choice of food products. If one wants to protect both the integrity of non-human nature and the integrity and dignity of human beings, it is difficult to do so by prioritising the protection of the consumer's autonomy (self-determination) and dignity and at the same time permit the marketing of vegetables containing animal genes. One must also discuss how to balance a consideration of the farmer's autonomy and dignity, perhaps particularly the poor farmer in the Third World, and the relation to industry and its desire to use so-called "terminator" genes. Terminator genes are not replicated in the usual way., and they therefore require that the farmer buy new seed every season. This creates an economic dependency. Another example is the use of antibiotic-resistant genes, which can lead to an increased use of antibiotics in food products but from a health perspective can harm vulnerable life forms.

On the other hand, society must not make choices that are actually nothing other than personal preferences or matters of taste. Consequently, it is important to determine when and why social benefits and the protection of vulnerable forms of life will take priority over the consumer's choice, the researcher's freedom and industrial production. Here ethical principles are of crucial significance because they especially can determine more precisely the moral status of living organisms and thereby draw the limits of what is good and evil. Moral status is an expression of the value that something has as an end in itself, without consideration for the use it has as a means to some other end. A respect for moral status is necessary in order to protect vulnerable forms of life, and this respect is fundamental to an ethics in the area of bio-law.

Respect for the vulnerable is shown by moral responsibility. One can thus say that everyone who by his actions and behaviour poses a possible threat to the vulnerable has a responsibility. With the freedom to act (autonomy) comes also a responsibility for the other, writes Emmanuel Levinas. The concept of dignity also implies showing moral responsibility, because dignity, as a virtue, subsumes responsibility. Where responsibility for the development and use of biotechnology in the plant and foods area is concerned, the state, the biotechnology industry and the farmer each have a distinct responsibility. An ethics in this area must involve more than the state and consumers reflecting on their responsibilities; businesses must also prepare an ethics that makes clear, among other things, the individual company's responsibility towards both the consumer and all living organisms.

EU rules, shared political visions and key principles

This section attempts to give a short introduction to the most important aspects of the joint regulations and policies that must be taken into account in connection with an analysis of ethics in national law, politics and debate. Among the countries studied, Norway is the only one that is not a member of the EU. We therefore find it appropriate to analyse the joint EU rules for the purpose of sketching how ethics plays a role in the joint regulations in this area and of clarifying the possibilities that exist for letting ethics play a role in national regulation of genetic engineering in the plant and foods area. On the basis of this analysis, we intend to lay a foundation for any comparison, to make it easier to understand the individual countries' ethics and debates, and also to outline what characterises perception of the role of ethics in the regulation of genetic engineering in the area. The central EU rules for the use of genetic engineering in the plant and foods area are the following:

- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (the "Directive on deliberate release").
- Directive 90/219/EEC on the contained use of genetically modified micro-organisms (the "Directive on contained use"). The directive was most recently revised by Directive 98/81/EC.
- Regulation No. 258/97 concerning novel foods and novel food ingredients (the "Novel Food regulation").

The Directive on deliberate release and the Directive on contained use comprise a set of rules for the management of GMOs under contained conditions, and for the release and marketing of GMOs. The Novel Food regulation contains rules on the labelling of new food products - including food products containing or produced on the basis of GMOs.

a. The Treaty basis and the inclusion of national ethical considerations

The Treaty on the establishment of the European Community (TEU), article 249, describes rules of which the Union's institutions can make use. Of these, only directives and regulations are binding. The difference between these two is that regulations are universal. They are binding on all individual units and apply immediately in every member state, whereas a directive is binding for every member state at which it is directed according to its particular objective, but it lets the national authorities determine the specific form and means of implementation (TEU art. 29). That is, regulations apply immediately without needing to be rewritten for national law. On the other hand, directives must be implemented before citizens in the member states can be given rights and be subjected to obligations. One can distinguish between two types of directive: minimum directives and total harmonisation directives. The type of directive cannot be seen directly in the text of the directive. But often the document's formulation or its Treaty basis gives an indication of this.

The Directive on contained use of GMOs: a minimum directive

Minimum directives indicate, as the term suggests, a minimum of requirements by the EU that can be supplemented with stronger national requirements if the member states find this necessary or desirable. The Directive on contained use (90/219) is a minimum directive. This can be seen in its Treaty basis in TEU, article 175 (previously article 130s).[25] It is important to stress, however, that if one wishes to tighten the national rules on the basis of more specific ethical considerations, for example, these considerations may not conflict with the Treaty basis. This is because one wishes to avoid measures that can cause a trade barrier, a distortion of competition or other problems for the single market's functioning.

Directive on deliberate release: a total harmonisation directive

The Directive on deliberate release is a total harmonisation directive, which means in practice that the individual member states may not deviate from the harmonisation rules by setting forth special rules of a more relaxed or more stringent nature. The harmonisation rules are used especially in the health care area, in the safety and environmental protection area and in connection with consumer protection with a view to maintaining the same high standards of protection in all of the member states.

The Directive contains a protection provision (article 23) that refers to the Treaty basis, article 95 (previously art. 100A). The member states can, with reference to article 95 (4) of the Treaty, which constitutes the so-called environmental guarantee, seek a dispensation from the Commission if the country believes that a given measure, according to the Directive on deliberate release, will cause harm to the environment within the country's borders. The decision on whether dispensation from a total harmonisation directive can be granted lies with the Commission, which examines whether an exception for the country in question will result in an obstacle to the functioning of the single market. TEU, article 95 (4) refers to article 30 of the Treaty, which is the so-called public morals provision giving the member states the opportunity to seek dispensation from the rules issued by the Council or the Commission on the basis of non-economic grounds. According to Tine Sommer, LLD, however, the member states cannot seek to introduce tighter rules than the harmonisation rules by referral to the public morals provision except regarding the considerations specified in the provision. This means that special national ethical considerations or principles cannot be used as a justification of a request for permission to enact tighter national rules.

The new Directive on deliberate release (2001/18/EC) is still undergoing implementation in the individual member states. The deadline for complying with the Directive's requirements is 17 October 2002. It should be mentioned, however, that work is already under way to implement a change in the "new" Directive

[25] *In article 176 of the Treaty it is stressed that:*
The protective measures adopted pursuant to Article 175 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with this Treaty. They shall be notified to the Commission.

on deliberate release, through a new regulation that will also treat the traceability and labelling of genetically modified organisms and the traceability of food and feed made from genetically modified organisms (COM [2001] 182). The proposal from the Commission was submitted on the basis of a desire to determine the framework provisions for the traceability of GMOs at all stages of marketing. The proposal must therefore be seen in the context of the proposal for a new regulation in the foods and feed area (COM [2001] 425), which will replace the Novel Food regulation regarding the rules for GMO food, feed and additives.[26]

The Novel Food regulation

The Novel Food regulation is not directed specifically towards genetically modified foods and feed. The Directive on deliberate release contains, as mentioned above, a protection provision. This potential opportunity for temporary national deviations from a set of rules that the protection provision allows is not found in the regulation, which is binding in all individual units. Therefore the EU Commission has submitted a proposal for a new regulation on genetically modified foods and feed.

The new regulation will treat only food products, food product ingredients and additives made from or based on GMOs and food, feed and additives that are made on the basis of GMOs. The proposal on traceability and labelling and on a new regulation in the food product area that is directed specifically towards genetically modified foods and feed is an attempt by the Commission to fulfil the member states' desire for stricter rules in this area. This is because there is political disagreement about the requirements for traceability rules in regard to the Union's objective of protecting the health of people and animals and the environment.

b. The European Union's political and ethical considerations

Moratorium

The word "moratorium" means respite or postponement and is the popular designation for the two declarations that Denmark, France, Luxembourg, Italy and Greece signed in 1999 and 2001 (when Austria also signed). These are politically based moratoriums, which means that there is no legal authority in a joint legal document.[27] The temporary cessation of the release and marketing of GMOs in the EU was occasioned by the fact that these countries, in protest against the previous Directive on deliberate release, which they did not think lived up to the precautionary principle, among other things, signed a joint declaration on voting against every application for marketing of GMOs.[28] The moratoriums function in such a way that the countries take advantage of the fact that together they amount to a minority sufficient to block permits from getting through the EU. The moratorium declaration from 2001 includes the following statement:

> Having regard to the principle of prevention and precaution, the delegations of the following Member States: Denmark, Greece, France, Italy, Austria and Luxembourg reaffirm the need to introduce a more rigorous, transparent and comprehensive framework concerning risk assessment and risk management (taking account of the specific characteristics of European eco-systems), monitoring, traceability and labelling of GMOs and to generally restore the confidence of the public and of operators.[29]

Labelling and traceability are considered essential for re-establishing confidence. In addition, there is a reference to the prevention principle and the precautionary principle as key principles for future rules. The passage thus demonstrates that ethical considerations play a rather large role in connection with the establishment of the moratorium. The reason for this is that

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[26] The basic memorandum on the proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed, COM (2001) 425, final. Copy submitted to the Danish Parliament's European Committee. Basic memorandum concerning traceability and labelling of genetically modified organisms in food products COM (2001)182, final. Copy submitted to the Danish Parliament's European Committee.

[27] A moratorium can also be passed unanimously in the EU and be made legally binding. In this case, a moratorium will mean that legal documents must be prepared according to the EU's ordinary procedures, and they replace the Directive on deliberate release.

[28] The basis of this de facto moratorium is described in greater detail in connection with the review of the case on the release of Bt corn 176 in chapter 3 on France.

[29] Statement 12/01. On the moratorium for genetically modified crops in the EU.

the moratorium expresses a lack of confidence in the coverage of the current rules for the area. The lack of confidence can be seen as an indication that the involved countries' national perceptions of the concrete ethical considerations that are important to bring into practice the prevention and precautionary principles, are not in accordance with practice under the existing rules. There is disagreement among the six countries about whether the requirements in the new Directive on deliberate release (2001/18/EC) are sufficient to warrant lifting the moratorium.

Besides these five countries, seven others signed another declaration in 1999 that requested a temporary suspension of release, so as to await the Commission's white paper on environmental responsibility. These countries were Austria, Belgium, Finland, Germany, The Netherlands, Spain and Sweden. This moratorium declaration contains the following statement:

> Against this background the Governments of these member States, having regard to the precautionary principle set out in Article 174 (2) of the Treaty intend:
>
> To take a thoroughly precautionary approach in dealing with notifications and authorisations for the placing on the market of GMOs,
> Not to authorise the placing on the market of any GMOs until it is demonstrated that there is no adverse effect on the environment and human health, and
> To the extent legally possible, apply immediately the principles, especially regarding traceability and labelling, laid down in the political agreement for a revision of Directive 90/220/EC reached by the Council on 24/25 June 1999.[30]

This moratorium also requires labelling and traceability. In addition, it is noteworthy that the precautionary principle is made more precise. The principle is used in this context as a request not to use and market GMOs before it has been established that GMOs are not harmful to the environment and human health. This interpretation of the precautionary principle is in accordance with the description of the principle that is found in the Rio Declaration (principle 15). It stands in contrast to other interpretations of the precautionary principle (this is treated in the section on the precautionary principle), in which one maintains that the release of GMOs in the environment may take place although there exists no evidence that it is not harmful.

Joint political guidelines in the plant and foods area

The EU's policy on genetic engineering in the plant and foods area is often based on green papers. A green paper is a document issued by the Commission for the purpose of laying the foundation for a discussion. The document usually consists of an analysis of an issue and an indication of possible joint schemes in the context of the EU. Through hearings arranged on the basis of the foundation of the discussion in the green paper, a foundation can be laid for the issuance of a white paper. The white paper expresses a detailed and carefully planned policy set forth by the Commission. A white paper thus constitutes an action plan for the EU that is submitted for discussion with a view to establishing a joint political decision about future measures, for example, in the form of proposals for directives. Examples of white papers that have been prepared, and that reflect the EU's action plan with relevance to the use of genetic engineering in the plant and foods area, are the Commission's white paper from 2000 on food product safety and its white paper from 2000 on environmental responsibility. The white papers refer to a general policy on the environment and the food product area that is expressed in the EU Treaty. Title XIV of the Treaty, on consumer protection, states:

> In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information and education and to organise themselves in order to safeguard their interests.[31]

Title XIX of the Treaty, on the environment, states:

> 1. Community policy on the environment shall contribute to pursuit of the objectives: preserving, protecting and improving the quality of the environment; protecting human health ; prudent and rational utilisation of natural resources; promoting measures at international level to deal with regional or worldwide environmental problems
> 2. Community policy on the environment shall

[30] *Claire Marris, Swings and roundabouts: French public policy on agricultural GMOs 1996-1999 (Centre d'Économie et d'Ethique pour l'Environnement et le Développement: Paris, 2000).*

[31] *The Danish Parliament's EU Information Centre, 2001, TEF: artikel 153EF stk. 1.*

> aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It should be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.[32]

The white paper on environmental responsibility resulted in a proposal for a directive on environmental responsibility that the Commission submitted on 23 January 2002. The most important policy effort areas that were emphasised in the two white papers were the following:

- Establishment of a joint European food product authority.
- Greatest possible protection of the health of human beings and of nature.
- Application of the precautionary principle.
- Information for consumers in the form of direct discussion as well as labelling of food products.
- Greater openness at all levels of food product policy.
- Application of the Polluter Pays Principle in cases of environmental damage.
- Requirement on demonstrating responsibility towards the natural environment, with reference to the view of nature as a ”public asset”.

The precautionary principle is mentioned both in the joint strategies in the environmental area for control and prevention of environmental damage and in food product safety. It is characteristic of both areas that the principle is mentioned as a fundamental principle, but it is unclear of what the precautions prescribed actually consist. In the environmental area the principle is closely linked to the prevention principle. In the light of this association, the prevention principle is also used in relation to the principle that the polluter pays, in those instances where the latter principle takes effect after prevention or precautions with GMOs, for example, are considered not to have been fulfilled. In association with the last two principles mentioned, when concrete examples are given of what is meant by prevention and the polluter’s paying, nothing specific is said about the precautionary principle. The reason for this might be that one perceives the measures undertaken in accordance with the two other principles as an expression of greater caution, where in such cases the precautionary principle aims at cautious action and not restraint or inaction. In the area of food product safety, the use of the principle has not been clearly presented. In the official summary of the Commission’s white paper on food product safety from January 2000, section 2, on food product safety legislation, four examples of food product safety principles are mentioned. Items 2 and 3 are as follows:

- proper risk analysis through a) risk assessment (scientific advice and information analysis), b) risk management (regulation and control) and c) risk communication
- and the application of the precautionary principle if appropriate

The application of the precautionary principle is distinguished here from risk analysis and risk assessment.[33] This might be a suggestion that the precautionary principle here is intended to accomplish something other than cautious action - namely, restraint or perhaps omission of measures that one finds too uncertain.

Apart from the precautionary principle, there should also be some commentary on the white paper on the food product safety group’s initiative to create a joint European food product authority. It is noteworthy that this authority’s work would include animal health and welfare and would also take into consideration risk assessment in the environmental area. One can choose to see this as a step in the direction of a food product strategy that is moving away from the general consumer-oriented strategy and towards a broader strategy that opens up the possibility of including ethical considerations about living nature in its entirety, among other things. Certain aspects of the white paper on the liability for environmental damage might also point in this direction. Although the white paper treats primarily the responsibility and liability of those who cause damage, certain elements in the Commission’s considerations might be perceived as challenging the perception that environmental responsibility concerns primarily the responsibility for the health of human beings and property. The white paper on liability for environmental damage points immediately in the direction of a desire to

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[32] The Danish Parliament’s EU Information Centre, 2001, TEF: artikel 174EF stk. 1 and 2.

[33] Since 2000, however, the Commission has had a tendency to connect the precautionary principle to risk analysis and risk assessment. See Annex 5 of Robert May, ed., Review of Risk Procedures used by the Government’s Advisory Committees, Dealing with Food Safety (July 2000).

stress individual as well as joint responsibility for living nature in its entirety.

c. Common key ethical principles

The most important ethical considerations in EU policy are the prevention principle, the precautionary principle, the principle of sustainability and consideration for the consumer's free, informed choice. The principle that the polluter pays is mentioned in the Treaty. The principle may be said to be based on the idea of the ethical responsibility of the individual not to cause harm to the health of human beings and to the environment. We have, however, chosen not to look closely at the polluter pays principle, since it appears in and is used primarily for financial and legal instruments, i.e. to enable the assignment of financial liability. The principles make up part of joint European policy and are reflected indirectly in the joint regulations: they are best illustrated from an environmental perspective, but the fact is that the principle of sustainability, the prevention principle and the precautionary principle are all valid key principles for ethical considerations in the plant and foods area.

The principle of sustainability

In the context of the EU, this often appears as a key principle in the environmental area. It is used in economic, social and environmental contexts, and for this reason it can be difficult to define. In the light of this, one can say that the principle has ethical, social, natural philosophical, economic and legal dimensions.[34] The term "sustainability" refers to something that can be held up or that itself holds something up or bears something. When one speaks of "sustainable development", one refers to more than the situation here and now. The concept points to the future and includes both present and future generations. So the concept's ethical dimension focuses on a joint ethical responsibility that is also associated with clear-cut values or perceptions of what is ethically sound. In other words, the concept involves a consideration of the values that should be emphasised and the ethical considerations that should be made in relation to the desire to obtain or preserve the good life now and in the future.[35]

Although the principle is not explicitly expressed in all the relevant rules, it should nevertheless be mentioned because it can be considered a key principle for many political visions in the area in question. In the EU Treaty, Title XIX, "Environment", in which the precautionary principle and the prevention principle are mentioned, there is a reference in article 174 TEU (1) to a number of objectives in the environmental area. Among these are the protection of the health of human beings and the protection, preservation and improvement of the quality of the environment. In the light of the ethical dimension of the principle of sustainability, these objectives can be said to fall within the framework of the terminology of the principle of sustainability. The prevention principle and the precautionary principle are closely linked to the principle of sustainability because one must assume that, in accordance with the precautionary principle, prevention is undertaken on the basis of a general intention to create sustainable development. In this regard, it is tempting to see the ethical dimension of the principle of sustainability as a framework for applying the precautionary and prevention principles.

The prevention principle and the precautionary principle

The prevention principle and the precautionary principle are both key principles in the EU's environmental policy and regulations (see TEU art. 174 [2]). The two principles are also applied in other EU legal contexts, however. One can debate to what extent the prevention principle and the precautionary principle in themselves can be described as ethical principles. On one hand, the principles might be said to indicate a "neutral" framework for the regulation of genetic engineering in the plant and foods area. To say that one must act in a preventive or cautious manner does not in itself indicate a specific mode of action in practice. On the other hand, these are principles that generally have meaning within an ethical framework. One cannot refer to making a preventive effort or acting with caution without seeing this in the context of certain general objectives. So, every prioritisation regarding acting in accordance with these two principles can be considered an ethical prioritisation. As a starting point, the two directives and the regulation have the general objective of *protecting the health of human beings and the environment.* This objective attributes to the health of human

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[34] *Peter Kemp, "Ethics of Sustainability", in Revue Internationale de Philosophie Moderne, Acta Institutionis Philosophiae et Aestheticae, Vol. 18, 2000. (Centre International. pour L'Étude Comparée de Philosophie et d'Esthétique, Tokyo). 16-17.*

[35] *Ibid. 17-18.*

beings (a life without illness so far as possible), and to nature and the environment, a value in relation to the good life for the European population. The question is, though, just how the two general ethical considerations are to be implemented in practice. The prevention principle is mentioned in the Preamble to the Directive on deliberate release, in item 6, as follows:

> Under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken (2001(18/EC: Preamble).

The principle appears so vaguely formulated that its actual legal implications are rather doubtful.[36] The principle is, however, centrally placed in the Commission's white paper on liability for environmental damage. The prevention principle is made more concrete here as a prevention of environmental damage to biodiversity for example. The principle can best be understood on the basis of the idea of a common responsibility for respecting the environment, which can be further justified in that nature and the environment are ascribed an ethical value as a "public asset" that should be protected. In the synopsis of the white paper, prevention is tied to the issuance of stipulations on risk assessment, special rules on dangerous materials and special stipulations on risk assessment and ongoing control of GMOs. In contrast to the precautionary principle, the prevention principle can be described as exclusively future-oriented and dynamic because it sets out certain elements of a framework for action. Non-action is ruled out, as prevention assumes that one does something actively in order to prevent an undesirable outcome.

The responsibility element that lies in the prevention principle links it closely to the precautionary principle. A preventive effort in accordance with ethical consideration for the environment, and nature perceived as a "public asset", must also be assumed to be an action in accordance with the precautionary principle. Lack of prevention in relation to specific stipulations is irresponsible and can therefore not be considered cautious either.

In the context of the EU Treaty, the precautionary principle appears first in the Maastricht Treaty, 1992, which states that environmental policy builds upon the precautionary and prevention principles and on preventive care, among other things. The precautionary principle is linked closely to the aspect of uncertainty in the use of specific types of technology - including genetic engineering. The precautionary principle was confirmed in a larger international context in the Rio Declaration's principle 15:[37]

> In order to protect the environment, the precautionary approach shall be widely applied by states according to their capabilities. Where there are threats of serious irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[38]

The passage gives an interpretation of what the precautionary principle entails. The precautionary principle is construed here as a principle that will ensure that the consequences of a given action are considered in advance with a view to taking measures to avoid damage to the environment. In this context, the principle requires a reservation about measures in the absence of scientifically evaluated examples of their consequences. Here, the principle will ensure that it is not economic factors, but rather an ethical consideration for the environment and other issues that determine whether carrying out a given action is defensible. In doubtful cases, the natural surroundings will take precedence over economic interests. In other words, the precautionary principle is actually to be used when there is scientific uncertainty about the consequences of a possible action and a risk of damage. Application of the precautionary principle assumes there is a likelihood of some danger of irreparable environmental impacts or adverse effects on the health of human beings. The principle does not necessarily refer to something that is risk-free, but can just as well refer to an action that will entail the least possible risk.

There is much disagreement about how the precautionary principle should be applied, and many unclear points and possibilities in the principle are also expressed in the EU Commission's statement on the principle in February 2000.[39]

In the Directive on deliberate release, the precautionary principle is mentioned in article 1, under "Objective":

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36 Peter Pagh, EU miljøret (Christian Ejlers' Forlag: Copenhagen, 1996) 58-60.

37 In an international context, the principle appears for the first time in connection with a conference on the protection of the North Sea in 1987.

38 Convention on Biological Diversity, 5 June 1992, Rio de Janeiro. Localised December 2001 on www.biodiv.org/doc/legal/cbd-en.pdf.

39 EU Commission, "Communication from the Commission on the precautionary principle" (2 February 2000).

> In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment. . . (2001/18/EC: article 1).

The question is how one is to understand the reference to the precautionary principle here. To begin with, the principle has no concrete legal significance. There is a reference to the principle, but no specification of what its concrete meaning is for practice of the directive's rules. The principle appears with a number of legal functions, but as a general requirement for risk assessment and ongoing control of consequences.[40] One of the problems connected to the application of the precautionary principle is that some of the basic ways of understanding the principle turn out to vary greatly when they are expressed in concrete regulations.

On the one hand there are those people who connect the precautionary principle with the requirement for proving that a given use of GMOs is not dangerous. Such proof is well-nigh unattainable, because one stresses the many different, complex factors that enter into or affect the use of GMOs, regardless of whether it is a matter of release into the environment or use in food production. In cases of uncertainty, the population and the environment should take priority, as every release or use of GMOs is rejected unless its harmlessness has been proved. This perception of the precautionary principle is often found among critics of the current rules regarding the use of genetic engineering in the plant and foods area.

Opposed to this perception of the precautionary principle is the so-called positivistic scientific perception, which favours the use of GMOs and assumes that it is not dangerous so long as the opposite has not been proved. In practice it is mainly this perception of the precautionary principle that prevails in the joint rules. The rules set forth a number of aspects that must be investigated and evaluated for the purpose of determining the risk of adverse consequences. If this risk assessment does not produce disturbing results, an application can be approved and the release or food product manufacture with the GMO in question can take place.

Consumer protection

Although it is not stated explicitly, the rules on labelling of products can be said to represent ethical values - namely, a consideration for the individual's autonomy (self-determination) expressed in the desire to look after the consumer's opportunity to make an informed choice. This is evident, for example, in the Commission's proposal for two new regulations on traceability and labelling, as well as in the existing set of rules about labelling and requirements for information that must be accessible to the individual consumer.

The Novel Food regulation, under item 8, states that supplementary requirements for labelling must be determined:

> These requirements must be subject to precise provisions in order to ensure that the necessary information is available to the consumer . . . (258/97: Preamble, item 8).[41]

The nature of such necessary information, however, is debatable. First of all, it entails the principle that the consumer should never be misled. However, one can also debate how much information is necessary in order to avoid misrepresentation on the basis of the information disclosed. There are several different perceptions of how much and what information is necessary in order to avoid misrepresentation. One can debate, for example, in the case of products that contain GMOs and plants into which animal genes have been inserted, whether it is misrepresentation if one discloses only that it is a GMO product. The question is not only of a purely practical nature, but has a clearly ethical dimension in relation to the consumer's ability to make an informed choice.

Another example of the way in which the joint rules imply ethical considerations is found in the requirement for openness, transparency and information in connection with the decision-making process in the Directive on deliberate release. These requirements can also be said to point towards a desire to show respect for the individual citizen's autonomy. In a somewhat simplified form, one can say that when the requirement for openness stipulates primarily that information from experts, producers and others must flow to the consumer and the public, the requirement focuses on transparency, that is, that one should be able to see, to the greatest extent possible, how the accessible information has been obtained. The two concepts thus complement each other.

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40 Peter Pagh, EU miljøret (Christian Ejlers' Forlag: Copenhagen, 1996) 61-63.

41 Our Italics.

Germany

The tendency to bring ethical issues into the debate in relation to developments in biotechnology and genetic engineering has grown in recent years in Germany. It is primarily the medico-ethical aspects of red genetic engineering that have come into the media's spotlight, however. In the political sphere, there is apparently not very much interest in undertaking an actual ethical debate about green genetic engineering, which concerns the plant and foods area. One of the reasons for this might be that in Germany one generally finds it difficult to use the word "ethics" about non-human spheres. Instead, the risk and safety perspective of a purely technical nature frames the German debate on green genetic engineering.

Similarly, German genetic engineering legislation is extremely deficient in concrete ethical considerations. Since the revision of the genetic engineering act in 1993, in which the German legislation was adjusted to the joint EU rules, there has been criticism of the nature of the opportunities under the law of bringing the public into the decision-making process. The reason for this is that since 1993 it has been possible for the public to ask questions in connection with the authorities' assessment of a given use of genetic engineering only if this is done in writing to the right authorities. Before 1993, public hearings in connection with the release of GMOs were an ordinary part of the procedures, and the German population also had a free opportunity to ask questions. In the light of this criticism, one can say that German regulation of the area reflects the same ambivalence as do the joint rules, where the attitude towards openness and access to information is concerned.

The most important principles that apply to the area of biotechnology and genetic engineering in the German legal tradition are as follows:

- **The originator principle** (Verursacher principle): The principle is aimed at the registrant's responsibility to evaluate potential risks.
- **The principle of preventive care** (Vorsorge principle): The principle concerns preventive action to protect the environment, etc.
- **The principle of sustainability** (Nachhaltigkeits principle) and **the principle of responsibility** (Verantwortungs principle): Responsibility for future generations is actually the primary ethical principle that underlies all the other key German principles.

Politicians and the public authorities stress that the consumer has a need for information about the purely technical risk and safety aspects of the use of genetic engineering. But there is awareness of the population's scepticism about, and fear of, the products of genetic engineering and the application of genetic engineering in the environment.

In particular the scandal surrounding BSE, as in the other countries studied, appears to have intensified political awareness of principles and considerations of an ethical nature. At the centre stands a desire to look after the health of human beings and to ensure a just society for the current as well as future generations. In that sense, the German ethical motivation to look after nature might be described as anthropocentric. Care for nature, animals, plants and so on is secondary in this context. It is mainly nature's value as the foundation of human lives that receives attention. As illustrated above, it is especially this responsibility and its role in relation to the desire for sustainable development that ensures the welfare of future generations. The most important ethical consideration that prevails in the use of genetic engineering in food product manufacture is the protection of the consumer's self-determination and autonomy. So, the ethical debate or the ethical considerations on whether or not one wants genetic engineering used in the plant and foods area is turned over to the private sphere. It is the individual consumer who in the final analysis must take up the ethical issue and decide whether he will purchase organic produce or accept products manufactured by means of genetic engineering.

Since the Germany biotechnology industry is among Europe's largest and is also undergoing strong growth, it will be very important to get Germany's support for a new convention on genetic engineering and ethics in the plant and foods area.

In the German debate on ethical issues regarding biotechnology and genetic engineering, there is a tendency to let the debate focus only on the medical area. But one cannot rule out on those grounds the possibility of a favourable attitude being taken to including ethics in the debate about genetic engineering in the plant and foods area as well.

France

French legislation on the use of genetic engineering in the plant and foods area is based exclusively on the joint EU rules. But France has set out a number of national requirements within the species-legislation area.

France is generally criticised for being technocratic when it comes to decision-making processes about the use of biotechnology in general, but the debate in recent years shows a tendency towards relaxing the extremely expert-based regulation and decision-making process.

The precautionary principle in particular has become a central principle for French procedures and policies in the area. On the basis of the report on the precautionary principle that outlines the principle in the French context, France has striven to promulgate this position in a European and international context, in the hope of swaying the joint regulations towards its own position.

In the French context, the precautionary principle must be understood primarily as a desire to introduce a number of measures. The principle appears therefore as an incentive to leading the political orientation and concrete regulation actively in the direction of a specific objective that is described as increased safety. Such increased safety is to be achieved within several areas. They include the environmental area, the health area, the food product area and the decision-making procedures in this area. In connection with the latter area, one perceives the precautionary principle as an incentive to develop information that will be given to the public about risks and to advance citizens' participation in the decision-making process. The precautionary principle must be practised in two areas: through bio-monitoring of ecosystems, ongoing control, risk management and the like; and through better labelling of food products. The latter implementation of the principle is done with a view to ensuring adequate information for consumers in order to instil general confidence about the use of genetic engineering in the plant and foods area. It is noteworthy that there is not more focus on the ethical aspects of protecting nature, in the light of the value ascribed to the latter in the Biodiversity Convention and the Habitat Directive.

The use of genetic engineering in the plant and foods area appeals to showing respect for the citizens' freedom through the right to free choice. Behind this consideration lies the autonomy principle, understood as respect for each individual person's right to self-determination. In concrete terms, the consumer's free choice can be said to be free only if it has an informed foundation and if the consumer has the opportunity to see which products are manufactured by means of genetic engineering, and which are not. The ethical guidelines and the vision of French law can be summarised in this formulation:

- Requirement of public participation and co-determination in the decision-making process.
- Transparency in the decision-making process, which in practice means information for the citizen as a basis for being able to choose freely.
- The positioning of the precautionary principle as a key item in the evaluation of genetic engineering's economic, health and social aspects.

The United Kingdom

There are three central elements involved in understanding British policy on genetic engineering and the British vision for the plant and foods area. First, the deep crisis in agriculture, partly because of BSE. Second, the population's lack of confidence in the government concerning control and safety in food production, not least as a result of the quality problems related to salmonella, for example. Under this heading there also seems to be much distrust of GM food, which in the press is called "Frankenstein food". Third, the government's optimism regarding the potential benefits of biotechnology for British society, such as an improved quality of life in general as well as economic growth, sound food products, and a healthy environment.

The government is seeking the population's confidence at the same time that it wishes to give biotechnology favourable conditions for growth. Two strategies in particular should be emphasised. One is the establishment of a new committee, the Agriculture and Environment Biotechnology Commission, which will watch the development of the biotechnology industry and advise the government on ethical and social issues. Another government body has also been created: the Food Standards Agency, which is intended to protect consumers. The creation of these institutions can be seen as a step in a strategy of openness in which the population's desires and needs will take a central place.

The second part of the strategy is an agreement on a research programme, Farm Scale Evaluations, which the British government has reached with segments of the corporate sector and agriculture. The British government does not support the EU moratorium on the release of GM crops. On the other hand, it has an agreement with the corporate sector that the commercial cultivation of new GM crops must wait until the conclusion of the Farm Scale Evaluations. This is a large research project that will examine four herbicide-tolerant crops' significance for biodiversity in comparison with that of the equivalent conventional crops. Since about 75% of Great Britain's geographical area is agricultural, it is considered necessary for agriculture to take into account the preservation of nature. Intensive cultivation has led to a sharp decline in wild animals and plant species; consequently, the government believes that obligations in accordance with the Biodiversity Convention must be integrated in agricultural policy. The objective of the project is to determine whether GM crops have a negative effect on biodiversity in comparison with conventional cultivation. The research project has met with enormous criticism - aroused partly by varied interpretations of the precautionary principle and partly by the scientific view on which the British government bases its policy - "sound science".

In the UK it appears that the public perception of the word "ethics" in this context concerns especially consideration for the consumer in the form of openness, labelling and transparency: that is, consideration for informed choice. In recent years, people have also spoken of "food ethics", which applies to consideration for the consumer especially, but also to a consideration for animal welfare. Other issues, such as consideration for the health of human beings and the preservation of biodiversity, are considered very important, but are perhaps not perceived directly as ethical issues. In general the term "ethics" is understood as something that belongs to the private sphere. Leaving ethics to the private sphere is in line with Anglo-Saxon philosophy, whose central idea has been that a just society protects the individual's freedom and property. The multicultural society of the UK also finds a justification in liberal political philosophy for protection of the individual's autonomy and hence the right to be different. In other words, both the authorities and the public seem to use the word "ethics" somewhat differently from how it is used in *An ethical foundation for genetic engineering choices.* This does not mean, however, that the British government does not set genetic engineering in an ethical framework, as we understand the concept from a Scandinavian perspective.

Sweden

It is noteworthy that, in the section defining its purpose, the Swedish legislation on genetic engineering sets out the requirement that a given use of biotechnology or genetic engineering must be ethically defensible. However, Chapter 1, s. 1, of *Miljöbalken*, the Swedis environment legislation, and regulation 1994:902 on the genetic engineering board's duties, are the closest one comes to a specification of whether or not work, experiments and production based on genetic engineering are ethically defensible. In accordance with the joint rules, Swedish legislation also stresses protection of the health of human beings and of the environment. It is characteristic of Swedish legislation that it not only sets requirements for ethically defensible use of genetic engineering out of consideration for the health of human beings and for the environment. It also states explicitly that there must be an evaluation of whether the use of genetic engineering is ethically defensible in relation to animals' health.

In addition, s. 1 (2) and (5) of *Miljöbalken* are both in accordance with the Habitat Directive's and the Biodiversity Convention's requirements on the protection of biological diversity and work for sustainable development. *Miljöbalken* describes sustainable development as an assurance of both the present and future generations' life in good health and a sound environment. *Miljöbalken* maintains that nature has a value that must be protected, but does not define its basis. This value (together with the right that is attributed to human beings to use and change nature) is the basis for the statements in Swedish legislation on human beings' responsibility for managing nature and its resources in an ethical and defensible manner.

In reality it is doubtful how far the requirement for an evaluation of what is ethically defensible is being fulfilled. Ethics does not appear to have any real power in the approval process for the use of genetic engineering in the plant and foods area in general, despite this requirement. In the concrete situation, risk assessment is the instrument that is used to lay the foundation for evaluating whether or not permission will be given for the use of genetic engineering. Despite this, the tradition of bringing ethics into the concrete regulation and evaluation of genetic engineering in all areas is maintained as a fundamental vision for future Swedish biotechnology policy.

As far as involving the public and providing information to the public are concerned, the Swedish rules say very little about this directly. The desire for a future Swedish biotechnology policy is largely to involve the population in the issues of genetic engineering and thus advance the democratic aspects of evaluation of this technology. Sweden generally desires tighter requirements for labelling products with GMOs.

Part of the Swedish vision for regulating genetic engineering in the plant and foods area is a proposal for the creation of a so-called biotechnology inspection agency. This would be an authority whose working field would lie under several departments and which would also be able to give an overview of the complete use of biotechnology in Sweden.

Although consumer organisations, the corporate sector and politicians disagree on the degree to which the country lives up to the vision of the use of biotechnology generally, there is apparently broad agreement among the parties about the work that should be done in the biotechnology area in future Swedish biotechnology policy. The key words in Sweden regarding genetic engineering and ethics in national law at the moment are as follows: openness, increased information about genetic engineering and biotechnology, labelling of food products and increased involvement of the population in the decision-making process.

Norway

In 1993 Norway passed an *"act on the manufacture and use of genetically modified organisms", also known as the "genetic engineering act".* Since 1999, according to this act, it has been possible to seek permission to sell food products manufactured by means of genetic engineering in Norway. In 2000, however, it was forbidden to sell food products that contain antibiotic-resistant genes.

Ethics plays an important role in the framework of Norwegian legislation. Norwegian legislation contains the possibility of rejecting an application for approval on the basis of an ethical evaluation, which according to Part 3, s. 10, of the act must be part of the approval procedure. The ethical objective in Norwegian legislation is that the use of genetic engineering in the plant and foods area must have social benefits and be able to promote sustainable development. In addition, Norway has a special agreement in relation to EU countries that, on the basis of Norwegian legislation, makes it possible to prohibit certain types of gene-manipulated food, solely on the basis of a suspicion that the product could be hazardous to health. Norway has already chosen to do this in several cases.

Norway has a tradition of using the precautionary principle in regulation of the use of genetic engineering in the plant and foods area. In the Norwegian legal tradition, the principle is called the *føre-var-prinsippet* though it is not mentioned explicitly in the Norwegian genetic engineering act. The principle holds that the authorities can reject a specific type of GMO on the basis of scientific uncertainty about the health or environmental risk that using it might pose. It has been debated in Norway whether the principle should continue to be used in regulation. The problem is that if Norway chooses to implement the EU's Novel Food rules, then this poses a risk of making it more difficult for Norway to maintain a consistent or restrictive use of the *føre-var-prinsippet* as a justification for public regulation of the use of genetic engineering in the plant and foods area.

When one looks at the debate that takes place about genetic engineering in the plant and foods area in Norway today, the tendency is towards the "consumer policy" that is pursued in this field in the other countries studied. So the trend in Norway now is towards a view that the ethical choice about whether or not one desires food products manufactured by means of genetic engineering is left to the individual consumer. The consumer's free choice is thus also in the centre of debate in the area in Norway.

The use of the *føre-var-prinsippet* and the central position of ethics in Norwegian genetic engineering legislation underscore Norway's unique position among the countries studied, as the one with the most restrictive and concrete ethically oriented regulation of the use of genetic engineering in the plant and foods area.

In connection with its national strategy for the use of biotechnology in the new century, Norway has set forth a number of framework conditions, one of which applies specifically to biotechnology and ethics. The condition for operating a biotechnology business is that it must be done in accordance with ethical principles, although the latter are not stated precisely but are rather set forth mainly in examples. These examples of ethical guidelines have much in common with the Danish ethical guidelines.

The current debate in Norway about the use of biotechnology - including in the plant and foods area - on the face of it seems favourable towards the use of biotechnology, but it is worth noting that it concerns use in research. Generally the attitude toward the use of genetic engineering in the plant and foods area is still very much divided. For example, the result of a conference of laypersons in 2000 was a recommendation of a moratorium in this area. In contrast, the report of an expert committee for the *Sosial- og Helsedepartementet* (the Ministry of Social and Health Affairs) dismissed the necessity of a moratorium.

Thus far, the Norwegian government has not taken a final position on whether it will pass a moratorium.

The countries' ethical profiles from the perspective of the Danish ethical guidelines

In the following sections, we examine the five countries' ethical profiles in relation to the Danish ethical guidelines. The four boxes below contain short descriptions of the four Danish criteria from the report *An ethical foundation for genetic engineering choices*. Below each box, we summarise the five countries' various positions in the ethical debate on and regulation of genetic engineering in the plant and foods area.

The relation between economic and qualitative benefits

If genetic engineering is to be accepted, it will have to be developed and used to the benefit of human beings, society and living organisms, provided that one prioritises the quality of life rather than purely quantitative benefits and hence only strives for quantitative benefits that are consistent with quality of life. Quantitative benefits for individual manufacturers and dealers are not considered to offset qualitative damage to human beings and/or animals.

(An ethical foundation for genetic engineering choices, 1999)

Germany

In Germany the debate on the use of genetic engineering in the plant and foods area concerns mostly the economic benefits of this technology for the nation. In the light of the fact that Germany stresses consideration for the health of human beings and for the environment as the most important considerations in relation to the evaluation of whether or not a given use of genetic engineering can be accepted, however, it becomes clear that Germany's evaluation of the economic benefits of this technology must also be seen in the light of the qualitative benefits for human beings and the environment. The discussion of the degree to which genetic engineering contributes to an improved quality of life in the form of better food products and the like is part of the German debate, although the safety aspect is more prominent. There is no feature of the German debate and Germany's political vision of the regulation of the area, however, that conflicts with the Danish ethical criterion that genetic engineering must be used for economic benefits in a way that is compatible with qualitative benefits for people, society and nature.

France

This consideration is not expressed explicitly in the French vision that lays the foundation for the current and future regulation of the genetic engineering area. Nevertheless, there are certain features of the French debate and the French vision that suggest that a similar consideration does exist in France. The reason for this assessment is to be found in the French understanding of the precautionary principle as the most important principle for the entire French regulation of the area. The precautionary principle also applies to the economic aspects of the use of genetic engineering in the plant and foods area. It applies especially to the idea of developing a regulatory function in two boards and emphasising, in the second board's work, an economic evaluation and an evaluation of the social players and the social factors involved in a given use of genetic engineering. The economic advantages must be balanced by other factors, and although there is no direct mention of improved quality of life, the objective of greater safety points clearly in the direction of an assessment of the qualitative benefits that can be obtained by the use of genetic engineering methods. The French vision of increased information and openness about the decision-making processes and of re-establishment of citizens' confidence in the approval procedure, labelling and genetic engineering in general, also involves areas that point clearly in the direction of improved food products and health. Consideration for the environment is also mentioned, but it is toned down, as is the role of ethics generally in France in this area compared with its role in the Danish guidelines.

The United Kingdom

The most important argument for the use of genetic engineering is the great benefits that the British society will obtain from it. The government emphasises the economic benefits for the corporate sector, agriculture and society altogether. It expects that citizens and consumers will obtain the benefits of an improved quality of life in general and better quality in food products. Benefits for the environment, including sustainable agriculture, are also mentioned. In other words, the British government maintains a typical utilitarian rationale on this issue. And this is partly related to the fact that genetic engineering is considered in the same way as every other form of technology. It must of course be used with care out of considera-

tion for the health of human beings and for the environment. Consequently, there is a focus on the risk aspect, which the government believes it can manage by basing it on ”sound science”. This concept involves a reductionist and optimistic scientific view. Perhaps the UK will support the Danish proposal for an acceptance of genetic engineering conditional on qualitative improvement and not exclusively economic benefits. But how the British will interpret this is another question. The liberal British philosophy also encompasses the view that one can do almost whatever one wishes as long as one does not harm others. This also means that one does not set limits on others' actions if there is not a strong justification for doing so. But economic benefit - that is also a benefit. Everything must be considered within a vision of sustainability and quality of life.

Sweden and Norway

Especially in Norwegian legislation and debate about strategy and regulation in general, there is also much emphasis on genetic engineering producing benefits for people, society and living nature in its entirety. One speaks of the economic and political advantages for Norway in making a research effort in this field. The political advantages are considered benefits in the sense that Norway will be able to wield greater influence in the direction of tighter rules in the use of genetic engineering in the plant and foods area. The aims are better food products, a better environment and improved health for the benefit of the population and living nature in general.

One does not find so clear a parallel to the Danish ethical guidelines in Sweden. This does not mean, however, that Sweden does not place an emphasis on the relation between economic and qualitative benefits. It is also our immediate assessment that Sweden would be able to endorse such a consideration.

Autonomy, dignity, integrity and vulnerability

Genetic engineering should be developed and used with respect for human beings' autonomy and dignity and with respect for the integrity and vulnerability of life.

(An Ethical Foundation for Genetic Engineering Choices, 1999)

Germany

It is uncertain how an ethical requirement of consideration for animals' and nature's integrity will be perceived in Germany. Possibly it would be inappropriate to specify the nature of the ethical responsibility in relation to nature and animals if one does not wish to become locked into an anthropocentric justification for such an ethical responsibility.

On the other hand, the criterion on respect for the vulnerability of living organisms, considered as an appeal for care and thoughtfulness, together with a consideration for and understanding of the importance of protecting nature's diversity, is completely in accordance with the interpretation of both the *Nachhaltigkeits* principle and the *Vorsorge* principle as they appear in the German legal tradition. The criterion that genetic engineering may not harm the environment or reduce nature's ordinary sustainability (as set out in the BioTIK Group's proposal for the ethical guidelines for the development and use of genetic engineering under item IV) will be completely consistent with the German tradition in this area. Germany has a strong tradition of giving heavy emphasis to individual persons' autonomy (self-determination) and dignity. So, consideration for human autonomy, dignity and integrity, as required in the Danish ethical guidelines, is already deeply rooted in the German notion of responsibility.

France

The French debate and the French vision distinguish themselves particularly in relation to the Danish consideration for human autonomy and dignity and human beings' and animals' integrity and vulnerability. France's political vision lies clearly in line with the Danish criteria regarding consideration for the individual person on the strength of his right to self-determination and respect for dignity (two guidelines that together maintain the idea of a person as a free individual). The French debate concerns to a great extent precisely these considerations, which are seen as a basis for maintaining a democratic position in decision-making procedures and so on.

On the other hand, the environmental considerations are not part of the picture. But one cannot conclude for this reason that France would not join in endorsing this consideration. It would be quite likely to do so. A consideration for the environment is mentioned only generally in the debate, but the main factor is that it is mentioned. It seems on the face of it that consideration for animals' or nature's integrity cannot be made compatible with the French humanistic tradition. On the other hand, consideration for animals' and nature's vulnerability is something that France wishes to work

for, as one senses from the control and research that already exist in the risk assessment of GM feed for animals. Here France aims not only at the health of human beings, but just as much at animal welfare. This consideration probably does not occupy much space in the debate because of the events under way in France that have led to a sharp focus on the question of trust between citizens and decision makers.

The United Kingdom

Respect for the autonomy of the individual is the cornerstone of the British tradition, and the British look after this principle through a consideration for the consumer. But in the United Kingdom one does not discuss whether these ethical principles could be guidelines for a strategy. The government does not question particularly whether there are ethical limits for the manipulation of living organisms in the plant and foods area. It is only the control of risks that is the focus of attention. However, a committee appointed by the Prime Minister has brought attention to the need to show special consideration for vulnerable groups that are unable to determine which risks they will subject themselves to.

All nature in the UK is cultural landscape, and the view of nature that the government stands for is anthropocentric to a great degree. Nature has no value aside from its value for people, regardless of whether one speaks of aesthetic value or economic value. Nevertheless, the UK can also affiliate itself with conventions that express ethical principles for the protection of both people and nature - without necessarily using all of the same ethical principles in its national rhetoric.

Sweden and Norway

Both Sweden and Norway place a great deal of emphasis on the protection of the health of human beings and of the environment. The two countries differ, however, in the ways in which they speak of the protection of nature. In the context of Norwegian regulations, there is a reluctance to give direct expression to the ethical basis for protecting nature because one has seen several examples of how a specification of the ethical basis can lead to inconsistency in legislation (see the Hearing Committee's answer to legislative bills).

On the other hand, Sweden has chosen to ascribe to nature a value that warrants protection in the text of the law. This value is grounded in the Habitat Directive's and Biodiversity Convention's requirements to protect biological diversity and to work for sustainable development. The problem, however, is that this basis is very broadly formulated and the Swedish legislation does not give a more precise definition of the value to be protected.

The closest one comes to an insight into what such a protection should consist of is the requirement to protect animals' health. Swedish legislation thus speaks of human beings' responsibility to care for nature and its resources in an ethically defensible manner, but does not set forth any guidelines for how this is to be done. The Swedish law, however, does not seem to conflict at all with the Danish ethical considerations that stipulate consideration both for human beings' self-determination (autonomy) and dignity and for human beings', animals' and nature's integrity and vulnerability. On the contrary, the consideration for nature's and animals' integrity and vulnerability could serve precisely as an interpretative framework for the definition of such a value to be protected without making it too narrow.

Norway clearly seeks ethical guidelines that can form a framework for an evaluation of the degree to which the use of genetic engineering in the plant and foods area is desirable. It is noteworthy that, in the Norwegian examples of ethical guidelines presented, a consideration for nature and animals does not seem to hold such a central position as seems evident in the Swedish regulations and debate. Nevertheless, it is our assessment that the requirement of consideration for animals' and nature's integrity and vulnerability is in accordance with the considerations at the forefront of the Norwegian evaluation of the use of genetic engineering in the plant and foods area.

Just distribution of benefits and burdens

If genetic engineering is to be accepted, it must promote justice (equity) in the way benefits and burdens (e.g. foods and commonly acceptable risks, respectively), are distributed among humans.

(An ethical foundation for genetic engineering choices, 1999)

Germany

The close relation found between the principles of sustainability and responsibility in German regulations, as described in the government's report of April 2000, is wholly in line with the Danish requirement for a just distribution of benefits and burdens. The German tradition of the Vorsorge principle is also evidence that this guideline will be incorporated in current

German regulation, by virtue of the regulation's insistence on a purposeful definition of responsibility. It should also be emphasised that the principle of responsibility focuses not only on a responsibility for future German generations; it has rather a more "global" character. It applies to all future generations.

France

In France, consideration for a just distribution of benefits and burdens is not perceived as something that has a serious role in the debate. One might say that to some extent the NGO Confédération Paysanne's campaign for the rights of small farms against industry (when it is a matter of being able to thrive economically in the face of increased use of genetic engineering in the plant and foods area) is the only factor that brings this aspect into the debate. And in contrast to the case in Germany, consideration for future generations does not appear in the French context in this area. Certain features associated with the precautionary principle in France could possibly be interpreted as an expression of consideration for future generations. In the French context, however, the precautionary principle is linked first of all to a desire to ensure the health and safety of current generations.

The United Kingdom

The British might well be in agreement with the rest of the EU on the value of sustainable development out of respect for both present and future generations - and perhaps out of consideration for nature itself, when they have to reach international agreements. One debate issue in the UK is international food safety. The question is whether the UK can say no to GMOs and at the same time expect that poor countries, which perhaps have a need for GMOs, will say yes. Responsibility for the Third World is adduced in defence of an optimistic genetic engineering policy. In addition, the British government expresses satisfaction with the Biosafety Protocol, more particularly that it is placed on the same footing as the WTO. This signals a will to assume responsibility for the Third World as well regarding consideration for the environment in international trade.

Sweden and Norway

Regarding the development of genetic engineering in the plant and foods area, these countries look favourably on research with a view to being able eventually to create new products that can promote sustainable development in relation to third-world countries and also in relation to future generations. The issue of creating better conditions for the Third World does not, however, have a central position in the two countries' debates on sustainability. The primary focus is now on sustainability for future generations and for the environment as a whole. In both Norway and Sweden, people place great emphasis on international work for sustainability from both these perspectives.

Co-determination and openness

If genetic engineering is to be accepted, it shall be based on openness to all viewpoints prior to every decision.
(An ethical foundation for genetic engineering choices, 1999)

Germany

The area of greatest similarity between the Danish ethical guidelines and the German vision for the use of ethics in national law is the consumer area. The Danish criteria on co-determination and openness, which build on regular hearings and information for the public and on communications among researchers, businesses, authorities and the population as well as other measures, will presumably be able to find endorsement in Germany. Not least because the population's scepticism about genetic engineering in this area is placing increasing pressure on politicians as well as producers. The idea that there must exist objective information about possible consequences in this connection has already been fulfilled in Germany. This has occurred because of the authorities' perception that increased information about safety and tight requirements for control can alert people to an understanding of the appropriateness of using genetic technology in the plant and foods area.

France

France is in the forefront among European countries when it comes to promoting openness through better labelling and methods of evaluating and comparing various products. It is not certain whether there will be additional citizen conferences in France in the future, however, because the criticism of the only one held thus far concerned precisely that all points of view had not been taken into consideration as had been intended. In addition, several researchers and officials suggest that such a model does not fit the French mentality regarding regulation. The vision of public participation and co-determination in the decision-making process,

and transparency in the procedures designed to give consumers the necessary information point, however, in the direction of giving higher priority to consideration for the individual citizen's co-determination in the decision-making process.

The United Kingdom

The British government considers the policy of openness to be central in the effort to foster confidence regarding the use of genetic engineering in the food product area. There are three strands in the policy of openness. The first is determination of the main lines of the policy and the collection of citizens' opinions of them. The second is openness and transparency in actual policy: transparency in the procedures and decisions. The third is openness in relation to labelling of food products. The government has attempted to involve the public, particularly by creating the Agriculture and Environment Biotechnology Commission and the Food Standard Agency. The AEBC demonstrates this partly by the many public meetings it holds. Before this, the involvement of citizens' opinions about genetic engineering policy had been rather weak, in the sense that the government had followed the advice of expert committees to a great extent. The new committees are broadly based and seek a discussion with the public. If the government continues to listen to its committees, this will mean greater openness in relation to various opinions. There are limits to how far the British government will go in the direction of greater openness, however, because of its fear that the population will say no to GMO food. The government fears that the public will reject GMO food products, and therefore requests that the research and media communities consider their statements to the public carefully. Both the AEBC and the FSA, as well as many other committees involved in genetic engineering in the plant and foods area, seek to strengthen the public's opportunity for access to official documents. On the labelling of food products, the government wishes to indicate the GMO content in the finished product. The government thinks that information about the manufacturing process will be too expensive. It thus supports, in principle, a policy of openness - but in practice this will be limited because other interests are more important.

Sweden and Norway

The areas where one finds the clearest agreement between the Danish ethical guidelines and the Norwegian and Swedish attitudes toward genetic engineering in the plant and foods area are related to the requirements for citizens' and consumers' co-determination and for openness about the decision-making process. This is most clear when one looks at the Swedish vision for future biotechnology policy. Here the key words are precisely openness, increased information and tighter requirements for labelling. In addition, Sweden seeks to move towards a policy that will involve the public in the decision-making process to a much greater degree than is the case today. There is a desire to be attentive to various evaluations of what can be designated as ethically defensible in connection with the use of genetic engineering. This applies in the medical field as well as the plant and foods area.

In Sweden, there are very few rules in this area at present. But such notions are also part of the Swedish vision for the area, and one can imagine that a new convention text will find support in the country. In Norway, the trend is for the decision about whether or not genetic engineering is desired in the plant and foods area to be left to a greater extent to the individual consumer and the consumer's personal ethical considerations. The requirement of tighter labelling rules is therefore on the agenda. In addition, the measures in Norway in this area in recent years show that Norway does not wish only to make decisions about using or not using genetic engineering in an open process. The open process has come a long way towards becoming a reality in Norway, through the hearings and reports that have taken place at regular intervals since 1995.

Curriculum vitae

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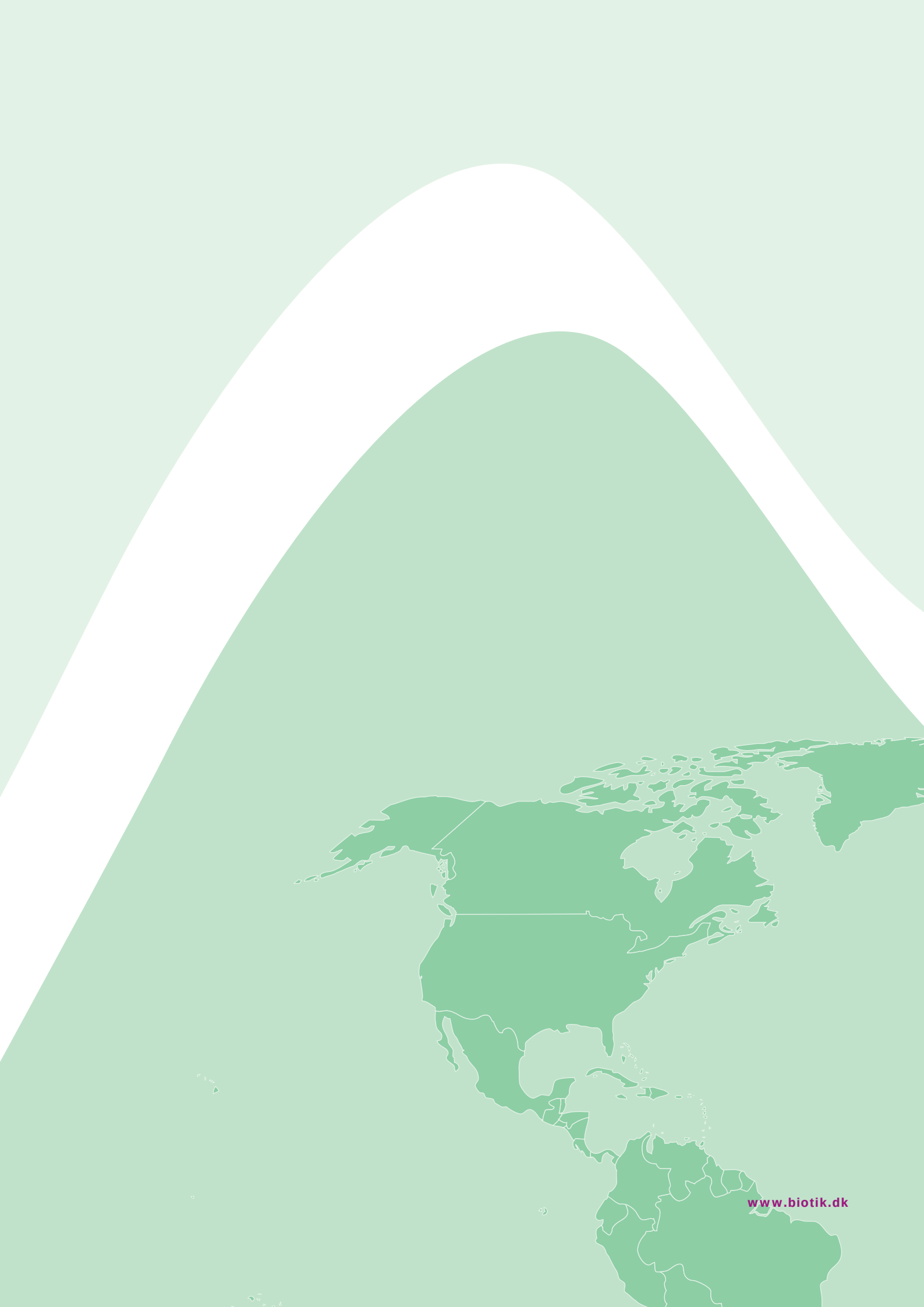

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