Ministry of
Environment and
Water - Bulgaria

Federal Environment Agency – Austria

Task Force on
GENETICALLY MODIFIED ORGANISMS

Sofia, 6th – 7th April 2000

UNITED NATIONS - ECONOMIC COMMISSION FOR EUROPE

Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Aarhus-Convention)

CONFERENCE PAPERS / TAGUNGSBERICHTE
VOL. 27 / BD. 27
CP-027

Wien / Vienna 2000

Impressum

Editors: Umweltbundesamt GmbH (Federal Environment Agency Ltd)
Spittelauer Lände 5, A-1090 Wien (Vienna), Austria,
Ministry of Environment and Water,
67, William Gladstone str., BG-1000 Sofia, Bulgaria

Editorial Coordination/Layout: M. Miklau, J. Mayer, H. Gaugitsch

Printed by: Riegelnik, Vienna.

ISBN 3-85457-546-7

Introduction

Dear readers,

The Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, signed by nearly all European Environment Ministers in Aarhus in June 1998, is an important instrument for all signatories, including the European Union, to enforce the role of effective public participation in decisions related to our environment.

This is especially relevant for questions related to the use and release of genetically modified organisms, to which the public in Austria and other European countries is very sensitive, as has been confirmed by a very popular Austrian people's initiative on Gene Technology and a recent Eurobarometer opinion poll. Although many applications in human medicine and pharmaceutical production have gained widespread acceptance, the use of GMOs in agriculture and releases into the environment will continue to need critical monitoring and risk assessment.

At the first meeting of the Signatories to the Aarhus Convention in the Republic of Moldova in 1999, Austria took the lead of a task force on the issue of public participation with regard to decisions on the release of genetically modified organisms (GMOs) into the environment. The aim of this task force was to prepare a report summarising different national views and experiences in this area, as well as relevant international processes and developments, and to make recommendations for further action.

The first meeting of this Task Force was held in Sofia, Bulgaria, on 6-7 April 2000 in co-operation between Austria and the Bulgarian Ministry of Environment and Water, and with active participation of both Government and NGO delegations. The present booklet, edited by the co-operation partners, shall serve as a background documentation for further discussions at the Second Meeting of Signatories in Dubrovnik in July 2000, and beyond.

I would like to thank the Bulgarian Minister of Environment and Water, Ms Evdokia Maneva, and her staff for the excellent co-operation in organising this meeting and other joint projects, and I wish successful work to all participants of the Second Meeting of Signatories of the Aarhus Convention in Dubrovnik.

Vienna, June 2000

Wilhelm Molterer

Federal Minister for Agriculture, Forestry, Environment and Water Management, Austria

Welcome Statement to the Task Force Meeting in Sofia

Dear Ladies and Gentlemen,

It is an honour and pleasure for me to welcome you in Sofia and to open the Meeting of the GMO Working group in the framework of the Convention for Access to Environmental Information, Public Participation in Decision-Making and Access to Justice.

The society today is very sensitive to questions related to Genetically Modified Organisms, also related with the guarantee of the access to environmental information, and to what the research laboratories and the industry in this field are doing. That's why meetings like today's, in which representatives of the state institutions, scientific circles and NGOs are trying to reach an agreement for informing and involving the public in the process of decision-making regarding these issues are of great importance.

The Bulgarian policy in this field is oriented towards creation of appropriate legislation, which responds to the European Union Directives 90/219 and 90/220, and the Cartagena Protocol on Biosafety, which will be signed by us in the near future.

We are carrying out a project for a Law on Genetically Modified Organisms, which will be presented by the end of this year to the National Assembly for discussion and adoption. This Law will also treat the public access to information regarding Genetically Modified Organisms, in line with the Aarhus Convention.

In partnership with the Austrian Federal Environment Agency we are preparing a project for a Regulation on collection of and public access to environmental information, which also includes matters related to GMOs.

Our National Plan for Biodiversity is ready.

In 1996 a National council for the safe handling of genetically modified higher plants was created in Bulgaria. In the National council are represented all interested ministries, including the Ministry of Environment and Water. The council issues permits for mass cultivation, production, release and spreading of genetically modified plants.

The council provides information on its decisions to the public through the media. A bulletin will be issued, in which the protocols from all sessions of the council will be published.

In conclusion I want to stress that in its policy Bulgaria will strictly follow and apply the adopted international agreements in the field of Genetically Modified Organisms, above all the Cartagena Protocol, the Aarhus Convention, the Directives of the European Union in line with the accession of the country to the Union.

I wish you successful work and a pleasant stay in Bulgaria.

Sofia, 6 April 2000

Evdokia Maneva

Minister of Environment and Water, Bulgaria

Contents

PART A UN-ECE MEETING REPORT

UNITED NATIONS **E**

Economic and Social Council

Distr.
GENERAL
CEP/WG.5/2000/6

18 April 2000
ORIGINAL: ENGLISH

ECONOMIC COMMISSION FOR EUROPE

COMMITTEE ON ENVIRONMENTAL POLICY

Meeting of the Signatories to
the Convention on Access to Information,
Public Participation in Decision-making and
Access to Justice in Environmental Matters
(Second meeting, Dubrovnik, Croatia, 3-5 July 2000)
(Item 4 (d) of the provisional agenda)

REPORT OF THE FIRST MEETING OF THE TASK FORCE ON GENETICALLY MODIFIED ORGANISMS

1. At their first meeting (19-21 April 1999, Chisinau, Republic of Moldova), the Signatories to the Aarhus Convention established a task force on genetically modified organisms (GMOs), led by Austria, to prepare a report summarizing the experience of implementing the provisions of article 6, paragraph 11, as well as relevant international processes and developments, and to make recommendations for further action.

2. On 6-7 April 2000, the GMO task force held its first meeting in Sofia, Bulgaria. The meeting was organized by the Austrian Federal Ministry for the Environment, the Austrian Federal Environment Agency and the Bulgarian Ministry of Environment and Water. Financial support was provided by Italy and Norway through the UN/ECE Trust Fund for Assistance to Countries in Transition.

3. The meeting was attended by 25 experts designated by the Governments of Armenia, Austria, Belgium, Bulgaria, Denmark, Finland, Georgia, Germany, the Netherlands, Norway, the former Yugoslav Republic of Macedonia and the United Kingdom. Representatives from the European ECO Forum, the Regional Environmental Center for Central and Eastern Europe (REC) and a resource person from the Netherlands also participated. Mr. Helmut Gaugitsch (Austria) chaired the meeting.

4. The meeting was opened by Ms. Evdokia Maneva, Bulgarian Minister for Environment and Water, who underlined the importance of the Aarhus Convention in the context of genetically modified organisms.

5. The UN/ECE secretariat gave an update on the Aarhus Convention activities and explained the time frames in the preparation of the second meeting of the Signatories.

Overview of national experiences

6. In response to a questionnaire circulated by the secretariat and lead country, the following countries had submitted written statements describing their existing and planned regulatory frameworks applying to GMOs and outlining how the issues of information, participation and justice were dealt with in this context: Armenia, Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, Georgia, Germany, Iceland, Italy, Latvia, the Netherlands, Norway, Slovenia, Switzerland and the United Kingdom. The European Commission also provided a similar statement concerning the situation at European Community level.

7. The representatives of Austria and Bulgaria undertook to compile these statements, together with the list of participants and other relevant material, for submission as background material, in English only, at the second meeting of the Signatories.

8. The government-designated experts presented reports on existing or planned regulatory frameworks for biosafety and addressed the legal and practical aspects of access to information and public participation in their countries. From the presentations and from reports submitted by countries not present at the meeting, it appeared that there were strong differences between countries regarding whether and how biosafety as well as general access to information and public participation was regulated.

9. Most countries that had provided information to the meeting had general ('horizontal') legislation for access to information, which was also applicable to information on GMOs. Some countries had specific provisions in their GMO legislation on access to information, particularly identifying information that could not be kept confidential. The extent to which public participation was provided for in decision-making on the contained use and deliberate release of GMOs varied. Some countries did not have mandatory requirements in their legislation for public participation, but provided for it when deemed necessary. The moments in the decision-making process when the public was invited to participate could be either early or late in the decision-making process. In most countries, public participation was limited to decision-making in the field of releases of GMOs.

10. A representative from the European ECO Forum made a statement on its activities and views regarding public access to information and public participation in the sphere of GMOs.

11. Brief reports were given on the activities and findings of the REC and on the activities in the context of the project "Implementation of national biosafety frameworks in the pre-accession countries of Central and Eastern Europe", which is funded by the Netherlands Government.

Future steps

12. Following these presentations, a general discussion took place on the recommendations to be submitted to the Signatories to the Convention at their second meeting.

13. The meeting noted the express wish of the Signatories to the Convention that the issue of GMOs should be on the agenda of the first meeting of the Parties and that the application of the Convention in this area should be further developed

(ECE/CEP/43/Add.1/Rev.1). It was considered that the recent adoption of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, which contained provisions relevant to information and public participation, could pave the way for making further progress on this issue.

14. The items discussed were: (i) public access to information on GMO-related issues, and (ii) public participation in GMO-related issues. The meeting did not have time to discuss access to justice or other issues relevant to the Convention as they applied to GMOs. Some participants wished to emphasize that the views they expressed during the discussion were preliminary, given the shortage of time.

Public access to information on GMO-related issues

15. It was recommended that a good general level of public information and awareness on GMO-related issues should be promoted, as was intended by the information, education and awareness provisions in article 23 of the Protocol on Biosafety and the information-sharing requirements listed in its article 20 (Biosafety Clearing-House). This might facilitate both a fact-oriented discussion and more effective public participation in GMO-related decisions.

16. For the purpose of the Aarhus Convention, “environmental information” includes information on the state of elements of the environment, including GMOs, and the interaction among these elements as well as factors, activities or measures related to these elements (art. 2, para. 3, (a) and (b)). On this basis, public authorities, in response to a request for environmental information, are to make such information available to the public according to the provisions of article 4.

17. All provisions of article 5 on the active provision of information (including emergency and consumer information) are also relevant to information on GMOs, with “publicly accessible lists, registers or files” (para. 2(b)(i)) which should “progressively [become] available in electronic databases which are easily accessible to the public through public telecommunications networks” (para. 3), especially on Internet servers, the use and accessibility of which is steadily increasing.

18. These registers could contain inter alia the following information regarding the use of GMOs:

(a) A general description of the legal framework related to GMOs and GMO-containing products within the country (including labelling requirements of products and contact points for further information);

(b) Non-technical explanations on the issues regulated;

(c) A list of products which have gained market approval in the country, and the requirements for labelling of GMO products marketed (including links to further information on potential risks and risk assessment);

(d) Information, including a summary of the risk assessment, on applications and decisions on contained use;

(e) Information, including a summary of the risk assessment, on applications for release or marketing of a GMO;

(f) New information relating to risk that may become available while the application is under consideration;

(g) The advice to the competent authority of any expert committee or advisory board on the application;

(h) Information on decisions to grant or refuse a consent and any limitations and conditions attached to any consent granted, including reasons;

(i) New information subsequently notified to the competent authority about consents granted;

(j) Information on the results of the release, including information on monitoring, and its implications for any further release;

(k) Decisions taken by the competent authority to revoke or vary any consent granted;

(l) Non-technical summaries of applications and decisions on deliberate releases;

(m) Contact points for further information if full information is not given.

19. There was no agreement as to whether it was feasible to include in these registers places and plots where GMOs were grown commercially.

20. The European ECO Forum and REC felt that the actual applications and decisions themselves should also be placed on the register. Other participants pointed out that further information could also be obtained under freedom-of-information legislation.

21. The European ECO Forum, supported by the representatives from Georgia and REC, cited article 5, paragraph 8, of the Convention and emphasized that information on GMOs was important to enable consumers to make informed environmental choices. This should include labelling information on products which were GMOs, contained GMOs or were derived from GMOs and on products which were GMO-free. Information should be clear and complete, not misleading, and understandable. Development of standards should begin immediately in preparation of the first meeting of the Parties.

22. Other participants had reservations concerning the NGO proposal and felt that, although it was an important issue, there was not sufficient time to discuss it. The Chairman proposed to revert to the issue at a later date.

23. The following Internet sites were identified as examples of good practice regarding one or more of the above aspects:

- Netherlands Environment Ministry: http://www.minvrom.nl
- United Kingdom Department of the Environment, Transport and the Regions: http://www.environment.detr.gov.uk
- Austrian Federal Environment Agency: http://www.ubavie.gv.at/umweltregister/genbio/intro.htm
- Austrian biosafety server: http://www.gentechnik.gv.at
- Belgian biosafety server: http://biosafety.ihe.be
- Norwegian Directorate for Nature Management:http://www.dirnat.no/temasider/ See “Utsetting av genmodifiserte organismer”
- Norwegian Biotechnology Advisory Board: http://www.bion.no/

Public participation in GMO-related issues

24. There was general agreement that article 6, paragraph 11, of the Convention left it unclear to what extent and in what situations the provisions of article 6 should be applied to decision-making

on GMOs. Terms considered to contribute to this lack of clarity were 'feasible and appropriate'; 'within the framework of its national law'; 'provisions' (without any qualifier to indicate whether all or just some provisions of article 6 were to be applied); and the term 'deliberate release' itself, which was not defined in the Convention.

25. Various procedural options for extending the application of the Convention in GMO decision-making were discussed. These included:

- A decision of the Meeting of the Parties setting out its view on how article 6, paragraph 11, should be construed;
- A decision of the Meeting of the Parties to amend the Convention by including a reference to GMO-related activities in annex I and amending article 6, paragraph 11, accordingly;
- Guidelines on best practices, on improving the legal framework and on the practical arrangements;
- A protocol to the Convention covering GMO issues.

This list was not considered to be exhaustive, and it was felt that it was too early at this stage to identify the best option.

26. With respect to public participation in decision-making on GMOs, most of the discussion focused on identifying any problems which would be created by considering decision-making on GMOs as falling under annex I. There were different views as to which types of decisions on GMOs would be most suitable for inclusion in annex I. Most participants felt that the priority should be to focus on the deliberate release of GMOs, as this was explicitly referred to in article 6, paragraph 11, and in the Resolution of the Signatories (ECE/CEP/43/Add.1/Rev.1).

27. Some participants held that decisions on the contained use of GMOs should also be subject to public participation in accordance with the full provisions of article 6, as contained use might in practice involve both routine and accidental releases to the environment. It was pointed out that different categories of contained use involved different degrees of risk. Decision-making on contained use might deal with a particular type of contained use, rather than on a case-by-case basis. It was decided to defer further consideration of public participation in the context of the contained use of GMOs.

28. It was generally felt that a definition of "deliberate release" would be necessary in order to understand the implications of public participation provisions in this area. Experts representing EU countries preferred to use the EU definition in Directive 90/220/EEC as a basis for developing a definition under the Convention. Some participants, notably from NGOs, expressed concern that the EU definition did not cover routine releases from con-

tained uses. The Chairman noted that this question could be revisited in a future discussion on the contained use of GMOs. REC pointed out that there were several alternatives to the EU system available, including that of Norway which had been mentioned, and that these should be looked at in more detail. It was generally assumed that, for the purpose of applying provisions of article 6, "deliberate release" should be taken to also cover placing on the market of GMOs.

29. The meeting proceeded to examine each of the paragraphs of article 6 in turn to see whether they should be applicable in the context of decision-making on the deliberate release of GMOs. It was generally agreed that paragraphs 2-5, 7-8 and 10 could be applied to the deliberate release of GMOs without any adjustment.

30. In the case of paragraph 6, the following potential problems were identified:

(a) The expert designated by the Government of Germany indicated that Germany might have a problem with the requirement in the introductory paragraph that the public should be entitled to examine the information in question free of charge, in the context of GMO decision-making;

(b) It was considered that the references to "an estimate of the expected residues and emissions" in subparagraph (a) and to "emissions" in subparagraph (c) were not appropriate in the case of GMOs, and that it would be more appropriate to refer to "proposed waste treatment";

(c) With regard to subparagraph (e), some participants wanted more time to seek legal advice on whether this created an obligation on the applicant to actually study alternatives, or only an obligation on public authorities to provide information on alternatives where these had been studied.

31. With respect to paragraph 9, the expert designated by the Government of Germany indicated that in Germany the requirement to actively inform the public of the decision might create legal difficulties when applied to GMOs.

PART B COUNTRY STATMENTS

In preparation of the First Meeting of the Task force, the invited delegations were requested to prepare "country statements" covering the following issues and questions:

1. Please describe any existing or planned regulatory framework in your country in the area of deliberate release into the environment, and/or contained use, of genetically modified organisms (GMOs).

2. Does or will this regulatory framework contain provisions on the following matters in the area of deliberate release and/or contained use of GMOs:

(a) active and passive information to the public?

(b) public participation in decision making?

(c) access to justice in environmental matters?

3. What are or will be the contents of these provisions?

4. Which further legal and other instruments of public information and public participation in the GMO area exist or are planned in your country?

5. How is the public perception of deliberate release and/or contained use of GMOs in your country? What is the level of public debate on the issue?

6. What is your opinion about the feasibility and usefulness of round-table discussions, consensus conferences, technology assessment and the role that government, industry and NGOs/public should play in these instruments?

7. Do you have any further proposals regarding the implementation of Art 6.11 of the Aarhus Convention?

The reports presented by the delegates at the Task Force Meeting in Sofia as well as the written contributions submitted by the countries not represented are based on this questionnaire. Subsequently these statements are compiled in alphabetical order, followed by the comments of the Commission and the NGO Coalition.

1 ARMENIA

The problem of present workshop is one of those, which arise from fast progressive scientific and technological advances, political and commerce interests and democratic processes as well.

Achievements of gene engineering and biotechnologies promise vast possibilities to mankind, especially under conditions of overpopulation, lack of food in many countries and the necessity of effective medicines. Accordingly high civil responsibility exists for those who take the decisions on using the results of this achievements without analysis of their possible after-effects on human health and environmental safety. It is needed to clear up the question of possible consequences of GMO introduction into practice. Taking decisions on the usage of GMO and products got on their base or on applying them into farming industry, countries need to base on complete scientific knowledge but not only on economic arguments.

Let us remember the history of X-Rays. Having been discovered radioactivity did not give rise to alarm. However few decades later scientific advances from one side and political and military interests from another side gave birth to the monstrous disaster - nuclear weapons.

Nowadays most of GMO are not researched enough, there is lack of information on their characteristics and the consequences of their use, some scientific data on this subject are restricted. These circumstances do not facilitate the broad application of GMO to practice. More over there is some base for anxiety. Scientific research as well as biodiversity and agrobiodiversity monitoring show that production, transportation and usage of GMO and GMO-containing products, as well as GMO introduction into nature harm the natural balance of ecosystems, change their specific structure. I did not meet the information concerning after-effects of GMO use (through food, drugs) on human health. Nevertheless on the level of human population the effect of GMO can become apparent much later, and negative effect is not excluded. That is why in many countries exists certain anxiety towards broad usage of GMO.

In Russia since 1996 is in the force the law regulating activity in the field of gene engineering. According to this law the imported products containing genetically modified components need to pass certification and safety tests. In Georgia and Ukraine also alarm is expressed in connection of GMO introduction into country.

In Armenia the problem on usage of GMO and food prepared on their base is in the stage of discussion by the narrow groups of specialists. The experts of the Ministry of Nature Protection participated in the elaboration of Cartagena protocol on Biosafety, nevertheless the question is aside the overwhelming majority of population of country yet. Though it is very important to invite attention to this problem now, when at global level it is increasing the role of powerful companies producing and putting into commerce GMO-containing production. Under conditions of economic recession and stoppage of industrial enterprises, particularly of food production, fall of farming industry production and the absence of corresponding legislation, the country is open for importation of food, seed grain, drugs containing genetically modified components. Consumers depend on activity of individual undertakers. So the necessity exists to inform broad public on the problem of GMO usage. It is urgent also to create the legal framework for GMO use in the country.

Now days there do not exist Law concerning GMO in Armenia. Though country had achievements in the sphere of microbiology and had developed biotechnology, there have not been elaborated laws or regulations in these fields. There are not legal instruments on public information and public participation in the GMO area.

This problem is not included in Consumers Society agenda also.

Since declaring the independence, Armenia:

- adopted Rio decisions, Rio Declaration and Agenda 21,
- ratified the Convention on Biodiversity,
- ratified Convention on EIA in transboundary context,
- participated (at the governmental and non-governmental level) in elaboration of Aarhus Convention and signed it in Aarhus at the Ministerial conference. The question on its ratification is under consideration,
- participated in elaboration of Cartagena protocol on Biosafety and is preparing to sign it,

in addition in Armenia exists the public initiative group on Earth Charter. Earth Charter will be presented for signing to the United Nations General Assembly in 2002. In the 5-e Article of this document is written: "Prevent introduction into the environment of non-native or genetically modified species which are likely to cause harm to native species and the environment, and control and eradicate harmful non-native or modified species.

All these legal or moral international documents are recognised by Armenia. Some of them are ratified by country and hence are the part of national legal framework. In some of this documents are mentioned GMO, the others envisaged public participation in decision-making processes.

Concerning national regulatory documents it can be mentioned the follows:

In independent Armenia in 1991 there was adopted the first environmental law "**The principles of environmental legislation**". In this law the public participation in solution of environmental problems is mentioned.

The Law on Achievement in Selection (adopted on November 1999)– among others issues regulates the provision of rights and usage of selection sorts. Chapter 19 of this Law envisaged publications on new achievements in selection and broad public access to this information. Nevertheless GMO are not mentioned.

The Law on Flora – (adopted on November 1999)– According to chapter 18 there are prohibited:

- illegal importation of alien species, their acclimatisation and use for selection needs
- self-willed use of GMO obtained by biotechnologies.

In chapter 27, in the paragraph of obligations of plant users (iv) is mentioned "do not disrupt the integrity of natural plant ecosystems".

The Law of RoA on Food Safety (adopted on December 1999) - regulates the requirements in the field of food use, production, importation, etc. In the 5th article is mentioned, that staple foods have to answer the requirements of national sanitary regulations. In case of their absence the requirements of Codex Alimentaris of UN FAO are declared valid. In article 6, in the 2nd paragraph is noted, that technical orders have to be scientifically based and to be in concordance with international and intergovernmental standards. In article 7 is noted that imported food needs to satisfy the requirements of national (international, if no national exist) legal safety regulatory norms.

In this law GMO also are not mentioned, but the Law recognise the adaptability of international requirements.

The Law of RoA on EIA (adopted in December 1995) requires thrice-repeated public participation in the EIA process of planning economic activity. This part is very detailed, but is not implemented properly because the required special regulation is not in place. Recently by NGO there has been developed the Guidelines on public participation in EIA. But the question concerning GMO is not discussed there.

Anyway, the Law is adopted and it is needed to implement its provisions. It means, that in case of imports of GMOs, it is necessary to inform the public about this action and its after-effects in order to make large sections of the public familiar to the subject.

Though at present scientists can not give adequate information concerning post-effect of GMO use, nevertheless they have to be involved in EIA process first of all. Unfortunately nowadays the science in the republic is stagnated. The economic recession in transition period, probably in the worst way, affected such associated with progress fields of activity as are science and industry. At present in the country there aren't claiming, and consequently actively involved in public work, groups of scientists. Formerly big scientific collectives decomposed, the scientific research is fragmented.

The problem of GMO use is international, the analysis of task needs competitive approach in all countries. Speaking about public participation in the process of GMO discussions I think the major attention has to be paid to scientists opinion. If there is any risk in GMO usage the scientists are obliged to alarm officials and public. A big role have also NGOs, specially professional. In Armenia exist around 60 environmental NGOs, some of them active enough, but no one of them has declared GMO problem in their agenda. The problems of now-day survival generated another priorities.

As the GMO problem is international, it is necessary to win the support of international financial and donor organisations to develop and implement the transnational scientific program, aiming the careful research in the field of characteristics and impact of GMO. And very important is to use the existing scientific potential of all countries.

It is important also to issue on international level the periodic information bulletin on GMO subject (brief information on news in biotechnology, scientific results and prognosis, etc.). The bulletin has to be disseminated among the involved countries. On the national level can be appointed the organisation (focal point) responsible for translation of bulletin to national language and dissemination it through the country. Very useful will be also conduction of national seminars with participation of farmers, scientists, representatives of governmental structures, NGOs. The results of this activity will promote the elaboration of appropriate national law on GMO issues and public participation in the decision making process in the field of GMO use.

We all participate in the global process of strengthening the principles of Sustainable Development. Our countries within the limits of their possibilities have to follow the wise approach in their development policy.

Abbreviations:

EIA – environmental impact assessment

GMO – genetically modified organisms

NGOs – non-governmental organisations

RoA – Republic of Armenia

2 AUSTRIA

1. Regulatory Framework

The EU Directives 90/219/EEC and 90/220/EEC have been implemented by the Austrian Law on Genetic Engineering (in force since 1 January 1995 and amended 22 May 1998).

The following additional Regulations (Ordinances) complement the framework law:

- March 1996: Ordinance on the Safety of contained uses of GMOs
- February 1997: Ordinance on Deliberate Release
- February 1997(amended May 1998): Ordinance on Public Hearings
- February 1997: Ordinance prohibiting the use and sale of the Bt-Maize 176
- November 1997: Ordinance on the Limitation of GMO Emissions with Liquid Effluents
- February 1998: Ordinance on Labelling of Products which Contain or Consist of GMOs
- March 1999: Ordinance on Labelling of genetically modified plant varieties and seeds of genetically modified plant varieities
- June 1999: Ordinance prohibiting in particular the cultivation of Bt-Maize MON810

In April 1998 the Austrian Codex Alimentarius Commission has adopted a guideline on criteria for labelling food as „gene technology – free".

2.a.) Provisions on active and passive information to the public:

Yes, the Framework Law and the Ordinances on Public Hearings contain such provisions (see point 3)

2.b.) Provisons on public participation in decisions making:

Yes, see 2.a. and 3.

2.c.) Access to justice in environmental matters:

Yes, the amended Framwork Law. See point 3 for further details.

3. Contents of these provisions:

3.a and b.) A public „Gene Technology Register" has been established by the Competent Authority (CA) in 1998 and is regularly updated. It contains a list and description of products approved for placing on the market in the EU according to Directive 90/220/EEC.

The so called „Gene Technology Book" which documents the state of science and technology for contained uses, releases, placing on the market and gene analysis and gene therapy is established by the Austrian Law on Genetic Engineering (see above). It is accessible to the public.

Every three years the Austrian Advisory Body on Genetic Engineering reports to the Austrian Parliament (for the first time in 1998).

On a voluntary basis, the Competent Authorities (http://www.gentechnik.gv.at; http://www.bmwf.gv.at/4fte/gentechnik/index.htm) including the Federal Environment Agency (http://www.ubavie.gv.at/umweltregister/genbio/intro.htm) make available information to the public via their Internet Site. Requests from the public are answered, as long as they do not concern confidential business information.

A platform of scientists, called „Gene Technology and Us" organised an exhibition „Gene Technology: Pros and Cons" which is shown in various Austrian cities.

Despite the public hearing described below, no additional active public information is compulsory by law.

Administrative Procedure involving the public:

In case of deliberate release a notification has to be submitted to the CA, which has 90 days to take a decision. Within those 90 days, a public hearing has to be performed. Requests of the CA for further information from the applicant stop the clock. The notification is not only accessible to the public at the Competent Authority but also at the regional and local level (Offices at the Federal State, Offices of the Provinces and the Local Community, where the deliberate release is planned), which facilitates insight into the documents by the interested persons. A summary of the notification has to be sent to anybody requesting it.

For certain higher risk and large scale applications of GMOs in contained use a similar public hearing procedure is compulsory.

In its decision the CA has to take the results of the public hearing into account.

The Ordinance on Public Hearings gives further specifications on the Scope, the publication of an application (e.g. in local newspapers) and the procedure of the Public Hearing (persons/institutions have to give reasoned objections to the application as a prerequisite to be involved in the public hearing).

3.c.) The amended law of May 1998 gives the right to appeal to decisions of the Competent Authority on deliberate release applications to the following persons/institutions: the notifier; the local community where the deliberate release is to take place and any neighbouring local communities; the owner of the plot of the deliberate release and any neighbours to the plot; the Federal State where the deliberate release is planned. Not the notifier but all the other mentioned persons/institutions have to give reasoned objections in the course of the administrative procedure in order to receive the right to appeal.

4. Further legal and other instruments:

Any necessary changes resulting from the Cartagena Protocol on Biosafety, as well as – after its adoption - the revision of Directive 90/220/EEC has to be implemented by Austria.In accordance with future steps at the level of the EU, a further development of any regulation on labelling food as „gene technology – free“ is planned.

In addition, the law on Access to information on the environment, implementing the relevant EU Directive 90/313/EEC, has been in force since 1993 and amended 1999. In order to implement the Aarhus Convention, the Austrian law on Access to information on the environment might have to be changed.

5. Public Perception and Public Debate:

While there is currently rather wide support for the application of genetic engineering in the medical/pharmaceutical sector and the contribution of genetic engineering to basic reserach in contained use is in general not disputed, the public acceptance of deliberate release of GMOs and the application of genetic engineering in the agriculture and food sector is very low.

A peoples`initiative in 1997 requested the following 3 points for Austria: no patenting of life, no deliberate release of GMOs, no genetically modified food. This initiative gained 1.2 Mio signatures (about 20% of the total number of electorates) and had to be dealt with by the Austrian Parliament. As a result of the subsequent discussions the Framwork law has been amended in 1998 in the following points: Provisions on Civil Liability, Increased Public Participation (see point 3.c. above), change of the composition and nomination of the Scientific Committee for Deliberate Release and Marketing, Register on GMOs (see points 3.a. and b. above), increased penalties.

On the basis of a high percentage of organic farming in Austrian agriculture, requests have been voiced to prohibit GMO products in Austria and to establish „GMO free production zones". Upon a private initiative and at the government level, provisions for criteria for a „gene technology – free" label of products have been developed.

The level of public debate was highest around the time of the peoples` initiative in spring 1997 and is still quite high.

6. Feasibility and Usefulness of Round-table discussions, consensus conferences, technology assessment etc.

There clearly is the need for an improved and intensified dialogue between stakeholders but also for an improved public debate.

There is no significant experience in Austria with established mechanisms like round-tables and consensus conferences. However, these could prove as useful instruments for the mentioned purposes. However, they are very time and labour consuming as well as cost intensive which has to be taken into account in the planning phase.

The public debate could benefit from an increased knowledge of the topic. However, it is regarded as crucial that the information given is as neutral and objective as possible in order to give the public the possibility to come to own conclusions on the basis of neutral, unbiased and thorough information. Government should play a key role in providing this.

NGOs, industry and other interest groups are regarded as important additional sources of information, their interest and background should be always made clear to the public.

Technology Assessment (TA) in the GMO area has been used to a certain extent in Austria. A parliamentary enquiry commission with the topic „Technology Assessment taking genetic engineering as an example" was held in 1992, the results partly influencing the drafting of the GMO regulation in Austria. Product – oriented, and even more important „problem – oriented" TA should be used nationally and internationally as a way of forming the basis for decision making by providing a choice of options.

7. Further proposals regarding the implementation of Art 6.11 of the Aarhus Convention

The discussions on further steps in the implementation of Art 6.11 would benefit from a profound compilation and common understanding in the following areas:

- Better understanding of what is meant by „the public" in the context of GMO applications
- Public information and participation in related areas (e.g. chemicals)
- Differences of specific provisions with respect to public information/participation in the GMO area and other areas, if any
- Role of public information/participation in the public perception of genetic engineering. Does experience exist, if increased public information/participation increase acceptance of the technology?
- Comparison of regulatory decision making in biotechnology to other related areas (environment, agriculture): How is the public involved (NGOs, social partners, no specific involvement etc.)?
- Transparency and documentation of decision making?
- Which limitations to public information/participation are identified?

3 BELGIUM

Flemish Experiences with Public Information and Participation in Decision-Making Procedures Relating to GMO's

I. Brief introduction into the Belgian federal system.

As a federal state, Belgium consists of three regional governments (Flemish, Walloon, Brussels Capital) and a federal government. Competences are divided amongst the different authorities.

In the field of genetic modification competences are divided as follows: the Regions take care of the environmental issues in general. As a consequence the provisions of the European Directive 90/219/EEC on the containd use of GMM's, with a possible environmental impact, are adopted in regional legislation. Since trade and commerce are federal issues, the federal government has a competence to regulate the matters included in the European Directive 90/220, concerning deliberate release of GMO's in the environment. The regions however considered the field trials in part B of Directive 90/220/EEC also as an environmental issue. They claimed a shared competence in this area.

As a result, the four governments signed a cooperation agreement on biotechnology on the 25th of april 1997. This agreement assures that the implementation of the two Directives in national law will take place in a harmonised way and that the four different levels will cooperate in the application of the provisions.

II. Statements

1, 2 and 3. Regulatory framework

Directive 90/220 on deliberate release of GMO's into the environment (federal competence)

The Royal Decree (RD) of 18 december 1998 implements the Directive 90/220 in national legislation.

The Ministry of Agriculture is the competent body for authorising a deliberate release of GMO's (for experimental purposes as well as for trade purposes). Each authorisation is obligatory preceded by an advice of the Biosafety Council. In this council the 3 regions and the federal State have equal voting rights.

The decisions are made public on the internet, but only after the autorisation. Prior to the authorisation, the RD does not contain provisions concerning information or participation of the public.

Directive 90/219 on contained use of GMO's (regional competence)

Actual situation

Directive 90/219 is adopted in the legislation of the three regions by means of Executive Bills. The procedure for a first application of contained use activities is interlinked with the procedure of environmental permits. These permits concern the **establishment**, whereas the contained use authorisations concern the **activity**. The environmental permits entail a heavy procedure, without distinction between e.g. class 1 and class 4 activities.

The **environmental permits procedure** prescribes that the user should submit a public file (including a summary of the activities, an application form,…) to the autorities responsible for the environmental permit (Province of location). The Community where the activity is planned can order a public consultation. This offers the possibilty for the public to consult the public file, to attend an informatory session and to lodge their remarks and objections.

For the **authorisation of the activity**, the user submits simultaneously a technical file (including the public file, confidential information and more detailed information) to the technical expert (SBB: Section Biotechnology and Biosafety). After evaluation of the application within 45 days, the SBB formulates a recommandation and sends it to the competent regional authority (Regional Ministry of Environment - Department of Environmental Permits: DEP). This department then decides on a final authorisation for contained use of GMO's. No public involvement is foreseen in this stage.

This authorisation is considered as a condition to obtain a environmental permit. The Province allows the permit as soon as they receive the autorisation. In the stage of the environmental permit, the results of the public consultation are taken into account.

Subsequent applications for activities of contained use, carried out in an establishment that already obtained an environmental permit, require no new permit. The only requirement to start a new activity in the same establishment is an autorisation of the DEP, without any interference of the public.

To conclude, the information and participation of the public is assured in case of a first activity of contained use.

New Directive 98/81/EEC

In june 2000, the new Directive 98/81 on contained use of GMO's should be implemented in national law. The drafting group on the implementation of Directive 98/81 looks for a way to make the public consultation procedure applicable for first and subsequent activities of contained use. At the same time, the heavy procedure for activities of risk class 1 (and 2) should be simplified. For the time being, the above mentioned overall legal system, will however be maintained, in view of a timely transposition.

In the long run, the Regional governments consider the possibility of creating new decrees, containing an independent legal system for regulating the contained use of GMM's.

This workshop can be very useful and interesting in that perspective.

4. Other instruments

Up untill now, no other legal instruments for public information or participation in the GMO area are provided for. The Flemish region has a Decree on Acces to Information, which applies in a horizontal way.

Other, non-legal instruments of information:

- BELGIAN BIOSAFETY SERVER: Webside installed by the Section Biosafety and Biotechnology (SBB), with information on all legal aspects, actuality, reports of the meetings of working groups, autorisations of deliberate release… *http://biosafety.ihe.be*
- V.I.B.: Flemish Institute of Biotechnology: governmental body, intended to inform the public on biotechnology with booklets,…*http://www.vib.be*
- MINA: Advisory Body on Nature and Environment, which consist of experts representing the different sectors involved. (agriculture, industry, environment, government, universities, other interest groups,…) *http://mina-raad.instnat.be*

5. Public Perception/debate

Belgium suffered several crises in the recent years that involved food safety, health and environmental issues. The dioxine crisis, the mad cow disease, coca-cola hysteria,… were phenomenons that intensified the public debate on food safety, including the discussion on genetically modified organisms.

More people become conscious of what they eat. They become suspicious of so called "novel food". The good will of the public opinion towards GMO's in general is decreasing.

The impression exists that the public is not fully/correctly informed however. The government and the biotechnology-industry have made a capital mistake in the past years by not informing the public on what biotechnology exactly is, what the consquences can be...

NGO's as Greenpeace, Friends of the Earth and other NGO's or organisations, do set up campaigns and info sessions to inform people on GMO's.

The public hardly wonders about the actual techniques of biotechnology, the usefulness, the risks on health and the environment,… The main concerns are of a wider social and especially ethical nature.

6. Instruments for debate/information

Public debate, round-table discussions, etc… are useful, provided that all concerned parties do participate. Only on that condition genetic modification can be approached in a balanced way. The media, all kinds of social pressure groups, NGO's, spokespersons of the biotechnology industry,… can add to this debate.

To "translate" such a technical discussion to the broader public, also the governement can play a vital role.

7. Implementation article 6.11

Since article 6.11 is vague, the question arises, which "provisions" of article 6.11 are considered as priorities in the implementation of the Aarhus Convention in national law.

This needs some clarification.

We therefore proposes to spell out some guidelines at the first COP under the Convention.

4 BULGARIA

"Aarhus Convention" GMO Task Force

Country Statement by Bulgaria

Country experiences in regulation and administration

After the political changes in 1989 the government and the responsible organizations began to study and to prepare rules and administrative acts to regulate some aspects of the biotechnology R&D and applications.

Until 1996 there were only governmental and institutional decisions about some regulations in the different areas of the biotechnology. Some of them are secondary related with the biotechnology issues, but in main they regulate products and applications of food, veterinary and agricultural industries.

Since August 16th 1996 Bulgaria became the first country in CEE which established national regulations for biosafety of genetically modified higher plants.

Regulatory Environment

AT PRESENT

- UPOV shaped Plant Breeders Rights Protection Act as well as Parent Act passed (since April 24, 1998 Bulgaria is a real member of the convention from 1991);
- Harmonized with Directive 90/220 EC, Regulation for the Release of Genetically Modified Higher Plants, Developed through Recombinant DNA Technology – since 16 August 1996.

NEAR FUTURE

- Law for biosafety of GMO;
- Law for biodiversity.

Governmental bodies, dealing with the respective issues related with the biosafety.

Ministry of Environment and Water

Ministry of Agriculture and Forestry functions:

- Council for Biosafety of Genetically Modified Higher Plants;
- National Service for Plant Protection, Quarantine and Agrochemistry – pests and plant diseases;
- State Commission for Variety Testing - approves new plant varieties.
- Central Veterinary Service - animal quarantine;
- General Inspection for Approbation and Seed Control

Ministry of Health Care function:

- Central Institute for Drugs - approves new drugs and medicines, as well as imports.
- Central Hygiene Epidemiological Inspection - controlling the safe production and distribution of foods.

Members of the Council for Biosafety of GMP

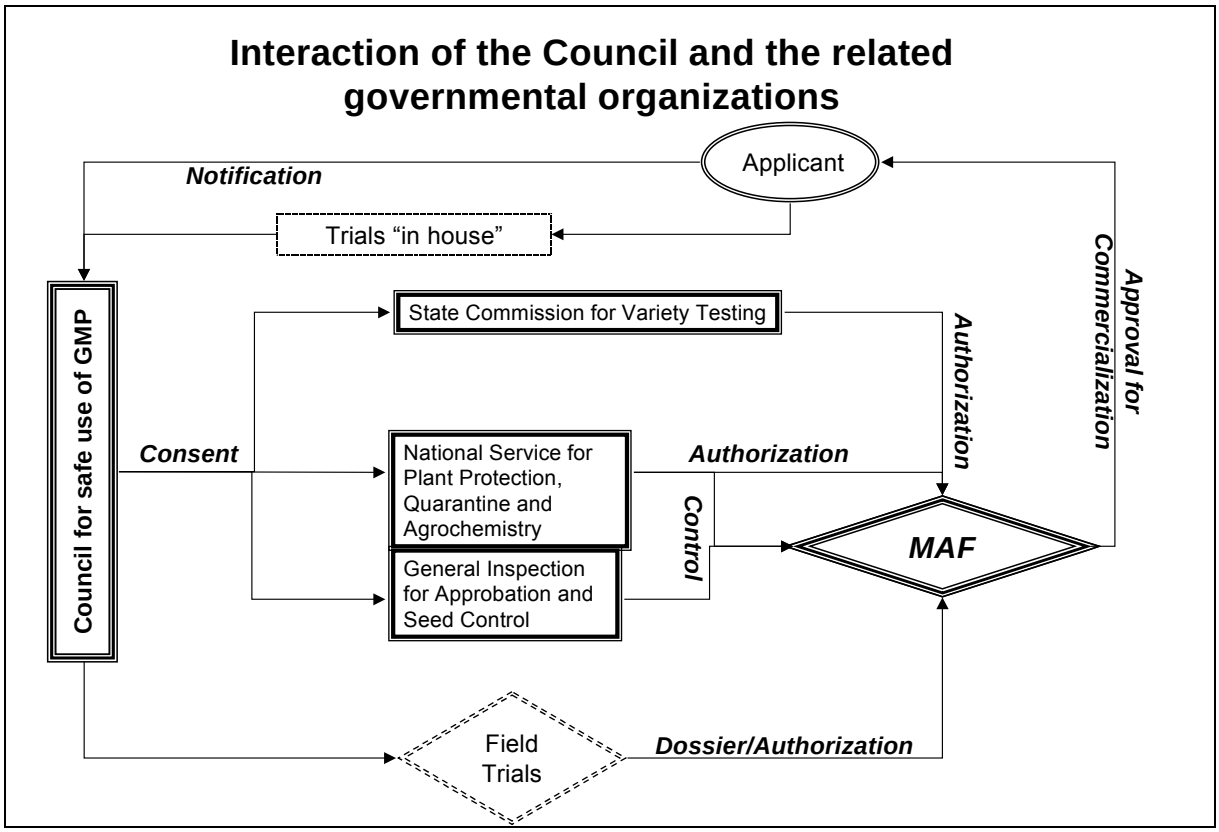
- Chairman is the Minister of Agriculture and Forestry.
- Secretary – Distinguished Scientist.

- **Members:**
- Representatives of the:
- Ministry of Agriculture and Forestry (Agricultural Department) – Deputy Chair;
- Ministry of Environment and Waters – Secretary General;
- Ministry of Health (National Center for Hygiene, Medical Ecology and Nutrition);
- State Commission for Variety Testing;
- General Inspection for Approbation and Seed Control;
- National Service for Plant Protection, Quarantine and Agrochemistry.

- The Academic sector:
- The Institute of Genetic Engineering at Kostinbrod – Executive Secretary;
- The Institute of Wheat and Sunflower in General Toshevo.

The Procedure for Notification and Approval

- The time for examination of the proposed transgenic varieties is extended up to tree years. The duration depends on the nature and origin of the plant species;
- The applicant issues a standard application form, formulated in accordance with Directives 90/220;
- After proper consideration of the delivered information by the applicant the Council decides whether the field trials should be proceeded;
- In case the trials are successful the commercialization is expected to be approved.



- **Active and passive information to the public:** Preliminary passive information – the public has access to the Councils materials. The Bill for GMO stipulates active information according the requirements of the expected new Law for Information.
- **Public participation in decision making:** According the Bill public representatives, as NGO, can participate in the National Council for Biosafety.
- **Access to justice in environmental matters:** Section 8 of the Bill deals with the penalties for valuations of its orders.

The Law for GMO

- **The Topic:**
  The Law will cover the R&D experiments as well as the deliberate release and commercialization of GMO's (synchronized with 90/219 and 90/220 EC after adoption with Cartagena Protocol at the end of this year).

- **The Area:**
  - Plants;
  - Animals;
  - Microorganisms;
  - Pharmacy;
  - Food.

Information exchange and public participation

Our opinion - the information is an important condition for the properly development of the biosafety.

Education

- Trust will be a decisive factor in consumers' ultimate acceptance of food biotechnology.
- Consumers have a fundamental right to know what is in their food.
- Most people are not fully aware that we have relied on various forms of biotechnology in food production since the beginning of civilization.
- To help make informed choices about food biotechnology products, consumers will need basic information on food production, biology, risk management and government regulation of food biotechnology.

Public perception:

- Real learning and understanding by the Society of the modern biotechnology has not taken place so far;
- Weak dialogue between the scientists and the media; scientists and decision-makers (politicians) and the media and politicians;
- No discussion has been provided between the greens, other non-governmental organizations and the scientists;
- Contacts between the scientists and the representatives of the multinational companies and local entrepreneurs are taking place just now;
- Lack of public debate on the ethical implementations of changing the genetic make-up of an organism or on the environmental impact of transgenic crops, legislation and consumer acceptance.
- Efforts in to improve the public debate on GMO were made by the Council just now. Two important meetings between the parties were organized recently.

Information exchange between scientists, Industry and public servants

- Participation and joint organisation of Workshops on biosafety issues.
- Presentations, organised by Companies – Monsanto, HiBred Pioneer, etc.

Scientists and politics and Non governmental organizations

- Workshops – representatives of politics and NGOs participated all the workshops on biosafety, we organized.
- Joint work and round table discussions

Topics:

- Law about biosafety of GMO;
- Training of experts;
- Establishing of national and international information network(s);
- Round Table discussions, seminars and workshops, publishing of bulletin;
- Open meetings should show that the biotechnology could not be developed "behind close doors" as "just another" new technology. Scientific, governmental organizations and associations, non-governmental and environmental organizations, representatives of the private companies, etc. should attend such meetings. The results should be available to the public and the media;
- Establishment of close relationship between the media and scientific organizations in order to avoid the impression of secrecy or "closed door policy" - popular publications in the newspapers, interviews in the radio, video movies in TV etc;
- Continuous dialogue with the industry and respective governmental people responsible for the development of the biotechnology and for the environment.

Following actions are considered to be feasible and useful

- Establishing of national and international information network(s);
- Round Table discussions, seminars and workshops, publishing of bulletin;
- Open meetings should show that the biotechnology could not be developed "behind close doors" as "just another" new technology. Scientific, governmental organizations and associations, non-governmental and environmental organizations, representatives of the private companies, etc. should attend such meetings. The results should be available to the public and the media;
- Establishment of close relationship between the media and scientific organizations in order to avoid the impression of secrecy or "closed door policy" - popular publications in the newspapers, interviews in the radio, video movies in TV etc;
- Continuous dialogue with the industry and respective governmental people responsible for the development of the biotechnology and for the environment.
- Product oriented, and even more – problem oriented Technology Assessment in GMO area should be used nationally and internationally as a way of forming the basis for decision making by providing choices of decisions options.

5 DENMARK

1.:

The Danish regulatory framework in the area of deliberate release and contained use of GMO's naturally is based on an implementation of the EU directives 90/220/EEC and 90/219/EEC and consists of Act. no. 356 of June 6, 1991 on Environment and Genetic Engineering with connected Statutory Orders. The provisions contained herein lay down an absolute obligation to obtain an approval prior to any given activity with GMO's.

2. & 3.:

The Act on Environment and Genetic Engineering (art. 9, para. 7) requires involvement by the public concerning questions relating to the deliberate release of GMO's into the environment. The obligation is reiterated by its inclusion in Statutory Order no. 1098 of 11 December, 1992 on the Approval of Experimental Release and of Marketing of Genetically Modified Organisms (art. 3, para. 2). In preparation of the decision of the Minister for the Environment and Energy the National Forest and Nature Agency in practice adheres to the obligation by circulating parts of the application (for Part B field trials the SNIF document) for comments to around 50 parties including major environmental and consumer groups. The received comments are incorporated in the memorandum to the Minister on the basis of which he takes the final decision on the release of the GMO. Any group or organisation can become part of this hearing process.

Applications for placing on the market of a GMO are also circulated to the Special Committee on Environmental Matters in which other ministries and organisations are represented and thereby consulted.

In addition to the above public participation the public also has access to information on the deliberate release through the web site of the Danish Parliament. This access arises from the obligation of the Ministry of Environment and Energy to inform the Parliament's Environment and Spatial Planning Committee of receipt of all applications for deliberate release into the environment and by the time the decision has been prepared by the National Forest and Nature Agency to inform the Committee of the intended decision of the Minister. Lastly a more traditional procedure of informing about the GMO-consents is followed by the publication of information about these decisions in the professional paper of the Danish Environmental Protection Agency.

The obligations and practice concerning participation and information to the public is different in the area of contained use of GMO's. A central database covering all activities with contained use is provided for in Statutory Order no. 579 of 1 September, 1987 on The Register of Genetic Engineering (art. 1). The database is administered by the Ministry of Labour which is the competent authority for the interior matters arising from the use of GMO's e.g research and large scale experiments. When a new consent for production with GMM's is given the public is informed through newspaper adds both in a national and a local paper.

Access to justice in environmental matters in the area of release and contained use of GMO's is regulated by the Act on Environment and Genetic Engineering as well as general provisions on examination of administrative decision by the courts. A special Environmental Appeal Board is established by the Danish Environmental Protection Act. This board has competence to deal with some types of GMO cases especially in the field of contained use. Competence to appeal decisions to the Board lies with the party to whom the decision is directed, any party having an individual, significant interest in the outcome of the case, and regional councils and local councils involved (art. 30 para. 1). This article also enumerates some specific organisations that can lodge complaints.

Decisions on release into the environment made by the Minister for the Environment and Energy are not covered by the competence of the Appeal Board. This is due to the tight time

limits in the EU directive on deliberate release into the environment and the common EU procedure for placing on the market. Consent for release into the environment of a GMO can, because of its status as an administrative decision, be brought before a court of law. The court only has competence to test the factual/formal elements of such a decision and not the elements that express administrative discretion.

4.:

In the future the GMO release decisions will be published at the web site of the National Forest and Nature Agency alongside the availability on the web site of the Parliament: www.folketinget.dk.

A web site with data on the location and type of GMO's released in field trials since the beginning of this activity in the early 90'ies is also being prepared.

5.:

Public debate in Denmark is very vivid and the public generally has quite a high level of knowledge on the issue. This results in an ongoing debate about the safety for human health and the environment especially in release cases. Contained use is no longer the focus of attention in the public debate as was the case a decade ago. Generally the perception very much depends on the use of the GMO.

6.:

Denmark has carried out a number of consensus conferences on different GMO related issues and they have proved very useful in communicating the opinion of the public to the decision makers. Generally all initiatives that enhances the public debate about the GMO issue are welcomed and in order for the debate to be informative and balanced both industry, NGO's/public and government must take active part in it.

6 ESTONIA

1. Regulatory framework

The legislation concerning genetically modified organisms (GMOs) is ready and the last part of it will be ready in the nearest future. The Act on contained use of GMMs (genetically modified micro-organisms) and its supplementary legal acts are currently prepared by the Ministry of Social Affairs:

- Government Regulation establishing the Advisory Committee of Genetic Modification and approving its statute;
- Government Regulation establishing a register of genetic modifications and approving the statute of the register;
- Government Regulation approving the form of permit for genetic modifications;
- Government Regulation establishing the application format for perfomance of genetic modifications and specified list of information to be provided in the application.

The release of genetically modified organisms (GMOs) into the environment and their marketing is regulated by the Act passed on 12 January 1999.

The Environmental Control Act (1997) has assigned the task of monitoring the release of GMOs into the environment to the Environmental Inspectorate.

Regulation on novel food (this includes GMO food) has been prepared by the Ministry of Agriculture.

The permit of processing of novel food consists of two permits – one from Ministry of the Environment (at the aspect of release into the environment) and the other from the Ministry of Agriculture (at the aspect of food safety).

Secondary legislation: Government regulation “Establishment of Committee of Gene Technology and approval of its statute” entered into force in October 1999.

Currently three supplementary legal acts are under preparation and will be ready during first half of 2000:

- Regulation of the Minister of the Environment establishing the form of permit for placing on market of products containing genetically modified organisms.
- Regulation of the Minister of the Environment approving the form of permit for release into the environment of genetically modified organisms.
- Specified list of information to be provided in the application and the format of application for release into the environment of genetically modified organisms and for placing on market of products containing genetically modified organisms.

2. a) This regulatory framework contains provisions on active and passive information to the public (see point 3)

b) and public participation in decision making (see point 3);

c) it does not contain access to justice in environmental matters.

3. Content of these provisions.

Ministry of the Enironment forwards the applications of releasing GMO into the environment or marketing of GMO to the Committee on Gene Techology (CGT).

CGT arranges international exchange of information on release into the environment and placing on the market of GMO-s.

CGT notifies the appropriate local municipality about the location of the site of release into the environment envisaged in the application.

All the applications of releasing of GMO into the environment or the marketing of GMO shall be published in a mass medium of national distribution, indicating inter alia:

1) the place where it is possible to familiarise oneself with the content of the application;
2) the time period during which it is possible to express opinions about the planned release of GMO into the environment. This time period is not longer than 30 working days.

The Person who has got the permit shall inform within one month after intentional release of GMO into the environment the Ministry of the Environment about the results.

All the GMO products must be marked and labelled so that every consumer could have relevant information about this product.

4. Estonia is going to sign the Protocol on Biosafety in summer 2000 (in framework of Convention on Biological Diversity. It contains, inter alia, provisions concerning public awareness and participation. Estonia will enforce these provisions during approximately 2 years.

The Estonian Fund of Nature will organise a public debate on GMOs in the internet.

5. During last couple of years quite many articles about GMOs have been published in press, many debates and discussions have been in mass media (TV, radio), even some seminars have been organised. It has turned out that public perception is very low. But people are quite open for opinions at both side – for and against GMOs, and the general attitude is not as negative as in many other countries in Europe.

The level of public debate is too low, it should be more intensive, more seminars should be organised, especially for school teachers, journalists, government officers and other members of public life.

6. All discussions and conferences on GMO-themes are very important and useful. Surely should government, industry and NGOs/public be present in such meetings. As the general knowledge is low, it is very easy to manipulate people. It's necessary to have views of scientists and industry and NGOs in order to find consensus between conflicting interests (especially industry versus NGOs) and make adequate decisions.

7 FINLAND

1. Please describe any existing or planned regulatory framework in your country in the area of deliberate release into environment, and/or contained use, of genetically modified organisms (GMOs).

The legal framework in Finland covering GMOs both for deliberate release into the environment and for contained use consists of the Gene Technology Act, 377/95 and the Gene Technology Decree, 821/95.

The competent authority in accordance with the Gene Technology Act is the Board for Gene Technology. As a member of the European Union the national legislation is based on two EU directives, 90/219/EEC on the contained use of GMOs and 90/220/EEC on the deliberate release of GMOs. The national Gene Technology Act and Decree includes also the contained use of plants and animals as well as provisions on ethics which are not covered by the two directives. Directive 90/220/EEC is presently under revision, because experience in the implementation of the directive has revealed several problematic areas, including risk assessment, monitoring, ethics and public perception. After completion of the revision the directive will be implemented into the national Gene Technology Act and Decree.

2. and 3. Does or will this regulatory framework contain provisions on the following matters in the area of deliberate release and /or contained use of GMOs. What is the contents of these provisions?

a) active and passive information to the public?

In accordance with the Gene Technology Decree the Board for Gene Technology has as an consultative body, the Advisory Board for Biotechnology. The Council of State sets up the Advisory Board for a term of three years at a time. The Advisory Board has as members representatives of the relevant authorities, trade organisations, consumer and environmental NGO's, industry and research. The functions of the Advisory Board are e.g. to promote the cooperation between stakeholder groups and to develop and promote information and education regarding biotechnology. The Board produces reports to parliamentary committees and authorities, it arranges seminars on topical issues and publishes a newsletter, Gene Technology Today.

Regarding passive information to the public, the national regulatory framework contains horizontal legislation, which also covers information concerning GMOs. A reform of the legislation on access to and secrecy of government activities entered into force at the beginning of December 1999. The Act on the Openness of Government Activities implemented the right of access to information in official documents in the public domain.

The right of access to information was extended to all those exercising public authority irrespective of their organisational form. The authorities have an obligation to promote the openness of their activities by disseminating information on their activities and by producing relevant information. The openness of preparation is increased. The new Act also codifies the most central provisions on secrecy.

In the Gene Technology Act there are provisions on confidentiality and not confidential information is listed. The latter includes the name and address of the notifier, the description of the GMO important for classification, labelling and identification, information on the location, purpose, extent and monitoring of the use of GMOs and safety and rescue methods or summary assessment of the impacts of GMOs.

b) public participation in decision making?

There are no specific provisions on the public participation in decision making in the Gene Technology Act and Decree. However, according to section 15 of the horizontal Administrative Procedure Act (182/598) parties have a right to be heard before a decision concerning an administrative procedure is to be made. Moreover, the public opinion in questions of general nature concerning GMOs is directed to the Board for Gene Technology through the Advisory Board.

c) access to justice in environmental matters?

A decision issued by the Board for Gene Technology in virtue of the Gene Technology Act may be appealed to the Supreme Administrative Court (section 44 of the Gene Technology Act).

4. Which further legal and other instruments of public information and public participation in the GMO area exist or are planned in your country?

The Board for Gene Technology maintains Web-pages on the Internet, which contain information on the function of the Board for Gene Technology, legislation and the decisions on the approvals concerning the use of GMOs. The Board for Gene Technology also publishes on a regular basis press releases related to the approvals for the use of GMOs.

In accordance with the revised versions of the two directives mentioned above new obligations to inform and consult the public in the decision making process will be implemented into the Gene Technology Act. Possible implications of the Aarhus Convention on the national legislation will also be clarified.

5. How is the public perception of deliberate release and/or contained use of GMOs in your country? What is the level of public debate on the issue?

The Finns have a good level of knowledge and a low perception of risk related to GMOs compared to other Europeans according to the Eurobarometer survey of 1997. The attitudes to the use of genetic engineering was fairly positive. The number of deliberate releases is to date in Finland only 16 and they have not caused any widespread interest nor concern. There are, however, also groups and individuals among both the public and experts who have expressed their concern about various applications of the technology. According to recent research results one of the key factors determining the positive and negative attitudes to GMOs is how the basic nature of genetic engineering is perceived i.e. whether it is a continuation of traditional breeding or a completely new technology.

The public debate did not start in Finland until the first shipment of GM-soybean arrived. The debate, which has not been very intense, has centred on health and environmental impacts of GMOs. These are issues where the public feels that it would like to be involved and able to express an opinion, the limiting factor, however, being lack of knowledge about the technology and its various applications, regulation etc. The public debate has been predominated by critical views, which partly may be due to the fact that proponents (eg. trade and industry) has not participated much in it.

6. What is your opinion about the feasibility and usefulness of round-table discussions, consensus conferences, technology assessment and the role that government, industry and NGOs/public should play in these instruments?

The key problem affecting the dissemination of objective information concerning the use of gene technology and further affecting the objective evaluation of the usefulness of the technology for society is that there is no common language between the different stakeholders in the field. We consider promoting open discussion in which all stakeholder groups participate very useful for building trust.

The public has an important role especially in the discussion of ethical issues and of the overall acceptance of the technology. It is the public that finally decides whether we want the technology and on what conditions. It is also our experience that the public wants to have an active role in the discussions. However, to have a constructive role in the debate the level of knowledge of the public in these issues has to be raised. One of the future challenges is to develop mechanisms both to provide information to the public and to direct the public opinion on the application of gene technology to the decision making. The government should adapt an active role in informing the general public on the regulation of gene technology. It is our experience that the general public is especially interested in risk assessment of GMOs. Also industry should inform the public of the development of their products in a more open manner. In addition, scientists and consumer organisations have important roles in providing information.

The committee for future affairs of the Finnish Parliament has recently conducted a technology assessment on plant biotechnology in which experts, the public and NGO's participated. A report of the assessment was published (available also in the Internet) and the results communicated in a symposium arranged by the Parliament. The experience gained in the assessment is that it is a useful way to integrate different parties in the discussion in a constructive way, but the dissemination of the information should be further improved.

7. Do you have any further proposals regarding the implementation of Art. 6.11 of the Aarhus Convention?

Once the Aarhus Convention has entered into force, it would be desirable to assess whether provisions of Article 6 (11) could be further developed by amending the Convention.

8 GEORGIA

Mr. Chairman, Ladies and Gentlemen.

I represent the Ministry of Environment of Georgia. First of all I would like to say a few words about the Ministry itself. The Ministry of Environment was established in the year 1991. In 1995 Ms Nino Chkhobadze, a member of the Green Party of Georgia, was appointed as Minister of Environment. This year was marked with the start of the reforms both in the structure of the Ministry and in the Environmental Policy of the country. It should be noted that the main requirement of the Minster was to give complete and timely information to the public thus aiming at enhancing the public environmental awareness in order to enable the public participation in environmental decision-making.

The first steps were quite difficult. To get the post-soviet population interested in environmental protection questions, when the country experiences the most complicated social and economic problems, is a hard task. That is why the Ministry has initiated its work in several directions. First of all, we started to work with mass media and the NGOs. The weekly Saturday meetings with the non-governmental organisations in the Ministry of Environment have already become a tradition. The main aim of these meetings is to exchange information between the governmental and non-governmental structures. The meetings are rated as highly popular among the journalists who are their most frequent guests.

Since November 1998, a Discussion Club has been functioning at the Ministry. The main aim of the Discussion Club is to involve the public in the decision-making process. The representatives of non-governmental organisations, different ministries, the parliamentary committees, academic sector, mass media and others take part in the work of the Discussion Club.

Some 5 years ago the environmental legislation basis, which would regulate the relationship among the various subjects in the environmental field, was non-existent in Georgia. For today we have 12 laws that regulate certain parts of the environmental protection field. Up to 10 laws, among them the "Law on Regulating the Biotechnology", are being drafted at the moment.

As for the Genetically Modified Organisms and the products derived from them, this problem was first encountered in the year 1996, when the company ACDI imported Monsanto's transgenic potatoes.

The post-soviet Georgia like almost all the Central and Eastern European countries has found itself facing a serious problem - it has become a market for the realisation of doubtful products. The population and, in frequent cases, the government as well, does not know how the mentioned products are imported as there is no legislative basis and the regulatory bodies, which can control the import of the products derived by the genetic engineering or their consumption. It seems unlikely that the economically extremely poor Georgian scientific centres still lacking the necessary material-cum-technical basis and the experience of experimental research of similar issues, can give the appropriate assessment to the risks that can be revealed at the release of GMOs in the environment.

In connection with the mentioned fact of the import of transgenic potatoes to Georgia, the Seminar "Genetic Engineering - Opportunities and Risks" was held at the Georgian Parliament, which produced an appeal to the Chairman of the Parliament. As a result, the further planting and dissemination of the transgenic potato as a food product was banned in Georgia. At the same time the Ministry of Environment and non-governmental organisations started a joint work on the draft law which aims to protect the population and the biodiversity of Georgia from the dangers caused by the use of methods of genetic engineering.

In order to have the public informed on these concrete questions, for enhancing the public awareness and public involvement in decision making process we consider it necessary to prepare booklets, brochures, the informational materials, organise topical seminars and

meetings for the representatives of mass-media, to prepare TV and radio programmes on these problems. The NGOs should play a positive role in improving and lobbying the framework law on genetic engineering. Besides, we consider of utmost importance to have constructive dialogue and cooperation among the authorities, NGOs and scientists in decision-making processes.

We hope that the ratification of the Aarhus convention, the participation in such working meetings and the exchange of information will help us take a right route in our work with the public.

Thank you for your attention.

9 GERMANY

1. Regulatory Framework

in the Area of Deliberate Release into the Environment and contained use of GMOs.

Both the EC Directive 90/219 EEC on the Contained Use of Genetically Modified Micro-organisms and 90/220/EEC on the Deliberate Release into the Environment of GMOs are legally implemented in Germany by the Federal Act on Genetic Engineering of 20 June 1990 which was amended on 16 December 1993.

This Act is complemented by more detailed legal regulations called Ordinances (listed are only those which are relevant with a view to public participation/information):

- Ordinance on Genetic Engineering Hearings (October 1990, amended November 1996)
- Ordinance on Genetic Engineering Procedures (November 1990, amended November 1996)
- Ordinance on the Central Commission for Biological Safety (November 1990, amended August 1996).

2. Provisions in the Regulatory Framework on:

2a)… active and passive information to the public

Yes, the Act and the Ordinances provide provisions on informing the public. There is also the Government's recurrent obligation to report on experiences with the Genetic Engineering Act.

2b)… public participation in decision making

Yes, the Act and the Ordinances stipulate such provisions.

2c)… access to justice in environmental matters

Yes, see 3 c) below

3. Contents of the provisions

3a/b) Active and passive information to the public/public participation in decision making

The existing EC Directives 90/219/EEC and 90/220/EEC which are still in force contain provisions on public participation on a non-mandatory basis. Until now the Member States can stipulate legal provisions on public participation at their own discretion.

In contrast, German law contains mandatory provisions on public participation.

Contained use

In the case of installations destined for operations with GMOs of safety level 3 to 4 for industrial or commercial purposes, public consultation and a public hearing has to be carried out prior to the authority's decision-making. In the case of contained use, the Laender (federal states) authority, not the Federal authority, is responsible for decision-making

Deliberate releases

A public participation (without hearing) has to be carried out by the competent authority prior to decision-making. The competent authority is a federal institution (Robert Koch-Institut) which is connected to the Federal Ministry for Health.

Administrative procedure

The details on the procedures for contained-use installations and deliberate releases are stipulated in the Ordinance on Genetic Engineering Hearings (amended 1996). The Ordinance contains provisions on: announcement of the planned activity (licensing of an installation or deliberate release) by the competent authority, public access to the application file, procedure to object (in writing), public hearing of the objections (only in the case of contained-use installations).

The announcement of the planned activity (see above) by the competent authority is made via an official Bulletin and the local newspapers. The application documents shall be laid out for public inspection at the office of the responsible authority or, where appropriate, at the location close to the (planned) facility or at a location close to the planned release of GMOs into the environment.

Written objections shall be submitted to the competent authority at the latest: two weeks after the end of the public inspection procedure in the case of contained-use installations and one month in the case of deliberate releases.

The objections are summarized, made anonymous and then sent to the applicant to be taken note of.

The public hearing (only in the case of contained-use installations) shall take place within one month after the deadline for objections (see above) has elapsed.

The minutes of the public hearing shall be sent to the applicant and on request to the objecting persons.

The competent authority has to make a decision on the application for licensing the facility or the deliberate release within three months. Requests for further information from the applicant and the period of time required by the public hearing delay the process.

In the licensing decision, the licensing authority shows whether and how the public objections have been taken into consideration.

3c) The applicant and any neighbours to the contained-use installation or the plot have a right to appeal to a court, but there is in general no such right for other people or for environmental groups.

4. Information to the public

After the first amendment of the Genetic Engineering Act in 1993, the German Parliament decided that the Government should report on the experience gained by the amendment. This report was issued at the end of 1996 as on official Parliament paper. This document of almost100 pages gives a comprehensive overview. Several pages deal with public participation, their legal basis (EU and Germany) and a comparison of the procedures in the EU member states, in the US and Japan. On the basis of this 1996 report it was concluded that – unlike Germany – in most countries there is no mandatory public participation during the licensing procedure.

A further source of information given to the public are the yearly progress reports of the Central Commission for Biological Safety. The legal basis of the activities of this Commission is the Genetic Engineering Act and the above mentioned 1996 Ordinance in turn is based on this Act. The Commission must be involved in all essential authorisation procedures in the field of genetic engineering. The reports are given to the Federal Ministry for Health which publishes the reports.

Another committee advising the Government in this field was established in 1993, the Bureau for Technology Assessment. It provides statements and scientific expertise with regard to a large number of topics, inter alia on genetic engineering. The involvement of the general public is occasionally also dealt with by this committee. The statements and reports of this committee are accessible to the public.

5. Public perception of deliberate releases and contained use of GMOs. Level of public debate.

There is a differential perception of genetic engineering among the German public. On the one hand there is a positive public attitude towards genetic engineering in the medical field – called “red” genetic engineering. On the other hand, there is intense public debate on the pros and cons of expected benefits and drawbacks in the field of the so-called “green” genetic engineering. Like in other European countries, public opinion with a view to green genetic engineering is still more or less hesitant or even disapproving due to health concerns, especially in the food sector.

In the 1996 Government Report on the amended Genetic Engineering Act of 1993 (see above), one chapter is devoted to the topic ”public acceptance”.

6. Feasibility and usefulness of round-table discussions, consensus conferences etc.

Public debate on genetic engineering issues takes place on different levels and in different fora (e. g. newspaper articles and reader comments, TV and radio discussions, local discussions by various stakeholders, parliamentary questions and debates, written answers by the Government).

The 1996 Government Report on the amended Genetic Engineering Act of 1993 (see above) gives a critical assessment of the public hearings. Nevertheless public hearing is part of the legal provisions (see No. 3 above)..

10 HUNGARY

1. Please describe any existing or planned regulatory framework in your country in the area of deliberate release into the environment, and/or contained use, of genetically modified organisms (GMOs).

Act No. LIII. of 1996 on Nature Conservation (as one of the Acts implementing the Convention on Biological Diversity). Its Article 9 (6) puts actually a moratorium on GMOs which influence biodiversity until the production of GMOs, experiments with them, their breeding, distribution exportation and importation shall not be regulated in a separate Act.

Act No. XXVII. of 1998 on Biotechnology Activities and its enacting clauses: 1/1999 (I.14.) FVM, 44/1999 (IV.30.) FVM. They are the detailed laws on the production, handling, use, realese and transfer of GMOs.

2. Does or will this regulatory framework contain provisions on the following matters in the area of deliberate release and/or contained use of GMOs:

a) active and passive information to the public?

Yes. Articles 30 and 31 of this Act (No. XXVII of 1998) prescribe that users and consumers shall be informed about the applications of biotrechnology and about the environmental, economic, health, social effects and risks of GMOs. The amended Act No. IV. of 1957 on the general rules of public administration procedures shall also be applied.

b) public participation in decision making?

The Act established an (advisory) Biotechnology Committee to the biotechnology authorities (Ministry of Agriculture; M. of Environment; M. of Health). These authorities shall decide on the application for permits (on the use, … etc. of GMOs) taking into consideration the opinion of the Committee. The Committee includes also four representatives of social organisations on environment and health protection (NGOs) as well as representative of the Hungarian Academy of Sciences (Article 5).

c) access to justice in environmental matters?

Article 75. of the Act on public administration (see above) – among other legislation - ensures the access.

3. What are or will be the contents of these provisions?

See above (or attached legislation ?)

4. Which further legal and other instruments of public information and public participation in the GMO area exist or are planned in your country?

None

5. How is the public perception of deliberate release and/or contained use of GMOs in your country? What is the level of public debate on the issue?

Ambiguous or uncertain but responsible part of the public rejects GMOs or requires the strict regulation of deliberate release and use of GMOs. There is an energetic NGO and scientific work and an occasional media activity including articles, round-table discussions.

6. What is your opinion about the feasibility and usefulness of round-table discussions, consensus conferences, technology assessment and the role that government, industry and NGOs/public should play in these instruments?

All kind of further information opportunities are useful to guarantee proper information. The issue attracts the attention of the society and the government, science and industry is greatly interested in that.

7. Do you have any further proposals regarding the implementation of Art 6.11 of the Aarhus Convention?

There is a need for ideas and ways for better implementation of the Article in practice and routine work. The every-day life acceptance and enforcement of the obligation to give information and public right for information should be improved.

11 ICELAND

1. The Icelandic parliament passed an "Act on Genetically Modified Organisms in April 1996 (no. 18/1996). The Act covers contained use as well as releases into the environment of GMOs. On the basis of the Act and EU directives no. 90/219 and 90/220 two regulations were issued in 1997; regulation no. 330/1997 on the contained use of genetically modified organisms and regulation nr. 493/1997 on the deliberate release into the environment and the placing on the market of genetically modified organisms.

2. The Icelandic regulatory framework contains:

(a) Non-obligatory provisions for consultation with the public.

(b) No provisions for public participation in decision making;

(c) Access to justice in environmental matters.

3. Regulations no. 330/1997 and 493/1997 contain provisions which, warrant information to and consultation with the public. These are not, however, obligatory. There are no provisions in the regulatory framework for public participation in decision making in matters related to GMOs.

The Act on GMOs contains an objective liability clause which is also found in the two regulations.

The minister of the enviroment has decided that amendments of the regulation 493/97 on the deliberate release and the placing on the market of GMOs are planned in Iceland in accordance with pending amendments to EU-directive 90/220. These amendments will entail making availble to the public infomation on applications for releases into the environment of GMOs in as much as the information is not confidential and not in violation of protection of property rights. Risk assessment reports will also be made available to the public and comments invited.

Public perception of GMOs has not been vetted in Iceland.

It is most important to reach consensus on GMOs. Consensus conferences, technological assessments and round-table discussions are useful instruments provided that all stakeholders, i.e. the public, industry, government and NGOs, participate.

7. No further proposals regarding the implementation of Art. 6.11 of the Aarhus Convention.

12 ITALY

1) In 1993, Italy adopted two EC directives concerning confined use of Genetically Modified Micro-organisms (GMMs) and the deliberate release of Genetically Modified Organisms (GMOs). The directive 90/219/EC, about GMMs, was adopted by the Legislative Decree 91/93 and the directive 90/210/EC, about GMOs, by the Legislative Decree 92/93. In particular, the second directive concerns the deliberate release in the environment both for experimental purposes (part B) and for commercial uses (part C). Presently, this directive is under revision and the new directive, that provides more detailed criteria for risk evaluation and monitoring, should be adopted at european level within the end 2000.

2) The Italian Legislative Decree 92/93 defines which information are not confidential:

- general description of the GMO, name and address of the notifier;
- methods and plans for monitoring and emergency;
- evaluation on possible effects, in particular on the environment and the human health;

The public does not participate into the decision making process, but a public consultation or enquiry may be performed. The Italian competent Authority, the Ministry of health, may consult the public (as groups or associations) on every aspect concerning the deliberate release, or confined use, of GMOs. For the evaluation activities, the Ministry of health is supported by an advisor board involving other competent authorities (Ministries of environment, agriculture, industry, etc.).

Article 23 of the draft revision version of the directive 90/220/EC provides for a time frame of 30 days for the public to make observations to a decision of the competent Authority. A synthesis of the notification (request) for deliberate release is made public for such scrutiny.

3) The same “revised” directive also address the needs for a better information of the consumers with provisions concerning labelling and traceability of GMOs-containing products. Since the Cartagena Protocol provides for public participation during the authorisation process (for deliberate release) and for public access to the Biosafety Clearing House Mechanism, the consequent adjustments in the national Laws will be adopted after the ratification of the Protocol, if needed.

4) In Italy, no governmental body has a systematic public hearing mechanism: such public consultations are held only if needed. However, the public debate about GMOs is quite sustained, based on the initiatives of (mostly environmental) NGOs and the involved industries. Recent opinion pools, show that more than fifty per cent of italian consumers are against the presence of GMOs in their food, with an increasing trend from the last years (when GMOs rejection was around 75% of consumers).

5) The public perception of deliberate release and contained use of GMOs, in particular for food consumption, seems to be little confused and little worried. However, there is a certain debate on the deliberate release in the environment of GMOs. Considering the argument used on the general debate on GMOs, there is reason to believe that there is much stronger objection against the deliberate release than against the confined use of GMOs.

6) We think that the results of the technology assessment would be communicate to the public, for example, through a “public hearing” before to take any decision. Moreover, relevant information on GMO should be available at the time of the public participation procedure. Industries, specialists and NOGs/public should be involved in these conference to expose their point of view, while the competent authority should take its independent decision after these consultation.

7) A working group could be establish to work on a protocol to be attached to the Convention itself clarifying the provision of article 6.11.

13 LATVIA

UN/ECE Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters (Aarhus Convention) has been signed by Latvia in June of 1998. Accordingly with Article 6 paragraph 11 of the Convention, Parties "shall, apply to the extent feasible and appropriate provisions to decisions on whether to permit the deliberate release of genetically modified organisms (GMOs) into the environment". Therefore provisions of the Convention with simultaneously ongoing integration process to Europe Union (EU), development of the national economy towards to free market economy and others international processes such as Biosafety Protocol under Biodiversity Convention have caused a lot of discussions among scientists, state institutions and public within last years in Latvia on related issues covering different aspects of operations with GMOs.

In the frame of national laws responsibilities related to operations with GMOs have divided between different sectors. There are several laws having provisions for operations with GMOs such as:

Law on Supervision of Food Circulation (1998) declares requirement to ensure circulation of qualitative food which is not harmful for human health, life and environment, prevent risk, promote trade operations and protect consumers' interests. Therefore only food which complies with mandatory safety and quality requirements may circulate in Latvia.

Law on Environmental Protection (1991) contains general requirements regarding operations with GMOs: " The creation of new micro-organisms, viruses and forms and their utilisation and also the import of such organisms into Latvia is allowed only with the receiving of a positive notice of state impact assessment authority. Ministry of Welfare (MoW) is responsible for affirmation of the lists of microbiological preparation and viruses used and produced in industry, agriculture, medicine and other socio-economic fields in conformation with Ministry of Environmental Protection and Regional Development (MEPRD). The MoW and the MEPRD responsible for approving regulations of reproduction, use, transportation, utilisation and liquidation of micro-organisms, viruses and metabolites, normative of maximally permissible concentration of micro-organisms and its metabolites."

Law on Plant Protection (1998) includes issues covering operations with GMOs at agriculture, e.g. definition of GMOs, determines institutions of the Ministry of Agriculture, particularly, State Plant Protection Service as responsible for issuing the procedure of carrying out research and tests of and with harmful organisms, GMOs and plant protection means. Inspectors of the State Plant Protection Service have duty to control persons working in plants protection field and may prohibit circulation of GMOs that does not comply with certain requirements of legislation.

Law on Epidemiological Safety (1997) regulates the epidemiological safety and competence of the involvement of state institutions, municipalities, legal and physical persons, their rights and obligations in the area of epidemiological safety.

National program for integration into EU and Guide to the Approximation of EU Environmental Legislation foresees the development of legislation and corresponding infrastructure with assessment and monitoring system in order to improve the health care, environmental protection and food supply. Under umbrella of the above mentioned national laws and integration process to EU, the horizontal approach for transposition of *EU Directive 90/219/EC on the contained use of genetically modified micro-organisms* and *Directive 90/220/EC on deliberate release of genetically modified organisms into the environment for research and development purposes* were implemented in Latvian legislation. For defining Competent Authorities, Conformity Assessment (inspection bodies and analytical testing labs) system taking care of risk assessment, monitoring procedures and methods and register of safe GMOs and their metabolites have been drafted two Regulations of the Cabinet of Ministers:

- ***Regulations of the Cabinet of Ministers on Use and Deliberate Release of Genetically Modified Organisms*** - states requirements and procedures for use, deliberation and limited release into the environment and market GMOs or their components for delay/prevention any threat to human health, animals, biological diversity, property or environment caused by GMOs use or deliberation;
- ***Regulations of the Cabinet of Ministers on Statutes of Supervisory Board for Operations with Genetically Modified Organisms*** - states that Supervisory Board is co-ordinative and consultative institution for prevention or reduction use, deliberation and limited release into the environment and market GMOs or their components for delay/prevention threat to human health and environment. Main task of Supervisory Board is to consult competent authorities and consumers, to give proposals and inform public regarding use and circulation of GMOs.

Responsible institution for drafting mentioned Regulations of the Cabinet of Ministers is Ministry of Welfare, Latvian Food Centre. At the moment drafts of Regulations have been submitted at the Cabinet of Ministers and planned for affirmation at second quarter of 2000.

Drafted Regulations on Use and Deliberate Release of Genetically Modified Organisms requires provisions for necessary information in scope of:

- preparation of required information for applying to operational permits with GMOs,
- requirements for information to consumers within GMOs deliberation into the market.

Issuing of operational permits with GMOs

For issuing of GMOs operational permits responsible institutions are Ministry of Environmental Protection and Regional Development - for GMOs deliberation into environment and Ministry of Welfare, Latvian Food Centre - for GMOs deliberation into the market.

Operational permits are classified in four classes in accordance with type of planned operations and appropriate level of control. For applying to operational permit operator have to provide all required information for operations with certain type of GMOs, fulfil and submit written application form to GMOs Supervisory Board. Supervisory Board within 30-90 days (in dependence of GMOs type) from receiving of application form can allow or prohibit planned operations. In accordance with decision of Supervisory Board operational permits have been issued by the responsible institution.

The drafted regulations not contain requirement for establishing a national register or database on GMOs where all obtained and submitted information within the notification processes would be stored. Therefore due to share of responsibilities among different institutions, there is threat that information/data should be fragmented between different institutions and not easy accessible and understandable to public. Therefore has been identified need for establishing a joint electronic database on issued GMOs operational permits and statistical data on imported products containing GMOs and operating in the market.

Information to consumers regarding products containing GMOs

There is provision by drafted Regulations, that for guaranteeing freedom of consumers' choice and for ensuring objective information, GMOs' containing food has to be labelled. All products containing GMOs, produced in Latvia and also imported, packed in the country and provided for deliberation into the market must be labelled with trademarks containing such an information:

- name of product and GMOs it's containing,
- title of producer or distributor name/address,

- specification of product, provisions for use,
- appropriate sector of use: industry, agriculture, specific trade, wholesale trade,
- all products containing GMOs have to be marked with sentence "*This product contains GMOs*",
- products, which can contain GMOs, but is not verified, have to be marked with sentence "*This product can contain GMOs*".

In accordance with drafted Regulations on Statutes of Supervisory Board for Activities with GMOs, Supervisory Board has been defined as co-ordinative and consultative institution for:

- co-ordination, supervision and implementation of the state's policy for operations with GMOs,
- proposing and consulting competent institutions on activities related GMOs,
- supervision and controlling of proposed activities related GMOs in accordance with achievements of science,
- organising of the national and international information exchange.

In accordance with Regulations, Supervisory Board consists of representatives from Ministry of Environmental Protection and Regional Development, Ministry of Welfare, Latvian Food Centre, Ministry of Agriculture, State Plant Protection Service, Ministry of Economy, Latvian Academy of Science, Faculty of Biology, University of Latvia, Environmental Impact Assessment State Bureau, Latvian Society of Genetics and Selectionist (NGO status).

Therefore Supervisory Board is a competent authority making decision on issuing operational permits. Taking into account that Board consists of representatives from state institutions, scientifically establishments and professional association it would be used as possibility for representatives from public to influence decision making process on activities with GMOs. Nevertheless in functions of Board is not include duty for preparing regularly reports or in other way to report to public regarding ongoing activities, concerns and potential threats. The Board's functions and mechanisms for organising of the national and international information exchange have to be clarified in nearest future.

Responsibility of controlling and supervision of the activities related with GMOs have been divided between several competent authorities - Environmental State Inspection (under supervision of the MEPRD), State Sanitary Inspection and State Plant Protection Supervision Service (MoA), State Pharmacy Inspection (MoW). In dependence of sector where GMOs have to be used or deliberate everybody has rights to request for information or comply to Competent Authority, but seems that such system is quite complicate for general public.

Increase of public concerns on GMOs issues in Latvia is a result of different processes within last years such as - international experience and some noisy cases held by environmental and consumers' rights organisations in foreign countries, achievements of scientists, trade and business companies interests and provisions by integration to EU and others international processes. Due to these trends have been held various activities in Latvia concerning different aspects of GMOs:

- ***Seminars and workshops*** is most popular tool for discussing actual topics from the point of view of different stakeholders. Due to support from EU PHARE Program and Regional Environmental Centre for Central and Eastern Europe (REC) have been organised several workshops involving representatives from state institutions, scientifically institutions, mass media and various NGOs. Main objectives for workshops were to give information and raise public awareness on the GMOs potential problem in the Baltic States and particularly in Latvia, discuss current status of transposition of legislation and forthcoming implementation of EU requirements and transfer knowledge

from EU member states for starting a stakeholders' networking. Within seminars have been discussed GMOs potential influence and threat to environment, health, social-economical, ethical aspects and role of different stakeholders such as industry, science, public administration, media, NGOs and general public.

- Have been prepared, issued and delivered easy understandable ***printed materials*** in Latvian for wide public and covering different aspects of GMOs use. Environmental NGO Green Library gathered different materials on activities with GMOs at international level and organised announcement campaign for wide public informing about these materials and their accessibility for everybody. Unfortunately most of gathered materials covering international trends and examples, but there are not enough information adapted to national situation, current/potential problems and real advises for people and consumers how to act in concrete situation.
- There is established ***national network*** of involved and interested institutions and organisations, more oriented to biotechnology and gene engineery and defined need for further co-operation between different stakeholders.
- There were organised ***Info days*** at several regions of Latvia with attracting scientists, representatives from state administration, mass media and NGOs and explaining issue at international and national scale.
- There are established several ***home pages*** containing description of ongoing GMOs related activities at national and international level. Fragmentary information is accessible at the home pages of the MEPRD, MoW, MoA, Green Library and others.
- In the scope of workshops on GMOs different ***mass media*** showed strong interest regarding operations with GMOs at global and local level. After workshops followed a lot of articles at press media, were organised several discussions and round tables on TV and radio programs involving representatives from state institutions, trade organisations, consumer rights protection organisations, scientific and higher education organisations and NGOs. There dominated opinion that government has to protect human health, to guarantee freedom of choice, securing segregation and labelling, determine an acceptable risk level, guaranty responsibility and liability, socio-economic effects and patenting questions.

Launched activities on distribution of information and public awareness rising on issues related GMOs have pointed out not only strong public interest and concerns, but necessity for ***share of responsibilities between different stakeholders'***. Within discussions have been identified and analysed role of different stakeholders:

State Administration

The representatives from public administration stated that their strategy is to be open as much as possible. They pointed out that there are two ways of informing the public - one is official information required by law and other is advise and materials that public administration should provide on its own initiative. The information to public should be regular and contain interpretation about the results of studies, release areas, plants, organisms, GMOs containing products available on the market, concerns about GMOs. The public is also has to be informed about the development of national legislation and possibilities to participate in legislation drafting process. Public have to be ensured with easy access to the registers and databases where notification information is stored. Competent authorities have secure development of web sites and publishing regular press releases. Effective way for finding best available solutions and possibilities for consensus are workshops and discussions with involvement of different stakeholders.

Mass media

Mass media situation in Latvia evaluated as not sufficient regarding to accessible and understandable information as well with competence and activity from NGOs side. Media, as the translator of information to the public, stressed that they have to be objective and therefore needs to get first clear for themselves and more to research on GMOs issue. Strong interests on has been shown from all important media organisations, including national television, radio and press organisations e.g. magazine "Environmental News", TV programs producers "Environmental Film Studio", national newspaper "Diena", "Independent Newspaper" and regional media. The different information sources for mass media are science, industry, authorities and NGOs, easiest way for getting information were suggested interviews with scientists. Discussing public concerns of GMOs, it was pointed out that only media have been approaching public administration in Latvia so far and asking mostly general questions. Seems that mass media and NGOs beside the interpretation and actualisation of information should have a "watch dog" role doing supervision to the state institutions, industry, trade structures and scientists for checking their being in compliance with provisions of laws and socio-ethical norms. The public relies on journalists' competency much more than confidence to politicians still.

NGOs

Within discussions have been identified and involved at several stages at Regulations drafting different stakeholders from NGOs sector having interest regarding operations with GMOs such as:

- *trade organisations* responsible for agriculture and food industry - Federation of Food Producers, Latvian Trade Association etc.,
- *consumer bodies* dealing with food, public health and environmental protection - Centre of Protection of Consumer Rights Protection, Children Rights Protection Society, Environmental Protection Club, Latvian Nature Fund, Green Library and others who sometimes function as pressure groups during the course of the approximation process to EU etc.

At NGOs opinion the consumer should be introduced to simple questions like: which food contains potentially GMOs, what can a person do to avoid its consumption and what is important for the environment to control and avoid release.

Industry and trade

Currently Latvia is not producing commercially GMO's or their metabolites, but there is a potential for research institutes industry, trade and business structures in future. From industry should be given information on what kind of GMOs are in food and what kind of GMOs is used in production. Benefits of biotechnology should be made also public and information about safety from health and environmental aspects should be available. Media, advertising, labelling, consumer leaflets etc. were pointed out to be the means of the information flow, but important is to ensure objective information. GMOs-free label could serve as means for the advertising campaigning.

Science

By scientists basic knowledge of gene technology should be given to public and the difference of GMOs used in food production and in medical production has to be made clear. The question about necessity of GMOs use for food production has been interpreted and is very disputable still. Information pro and contra GMOs is needed also for scientists who tend to be not openly concerned about the risks. Scientist should combine the different opinions after joint discussions with involvement of NGOs, industry and governmental institutions. As main instruments for information supply should be media, independent research institutions and scientific journals, the results of any research should be easily accessible and understandable for public. Problems can be foreseen regarding establishment of independent authority because Latvia is rather small country and the scientist who would

advise the authority also should be the ones who interested in the permissions for contained use.

Therefore concluding described activities, the public awareness on GMOs related issues have strong tendency to increase, discussions have been started and definitely needs further development in future. Still there is a danger of misleading information to the public because the GMOs issue is so complicate and still unknown. Fact that not all information has been prepared and delivered by journalists at articles of newspapers, TV and radio programs was correct and objective showed it clearly. The form how specialists present information probably sometimes is too detailed and specific for journalists and general public.

Summarising current experience on providing of access to information and public participation on decision making on operations related GMOs in Latvia, there is clear need for further promotion launched activities, explanation and discussion them in details. Free and easy accessible information is a crucial point and needs to be introduced more actively and user friendly. Share of responsibilities on operations related GMOs among the various institutions should be confusing and complicate for public.

There is necessity to continue discussions at mass media, seminars, workshops, round tables with involving representatives from interested parties - politicians, representatives from state institutions, scientific institutes, trade, business and industry structures, mass media and different NGOs - environmental, human and consumers' rights organisations, professional associations etc. Important is to involve experts working both at national and international level. Important seems involvement of experts from countries where GMOs have raised a lot of discussions and conflicts for introducing and analysing of existing experience and prevention uncontrolled operations and failures in Latvia. Publishing discussions' results for wide public in mass media is very important for keeping public informed and aware on GMOs issues. Promotion of discussions among specialists working with GMOs related issues in CEE and particularly in Baltic countries. There are similar tendencies for development of the legislation and historical background serving good base for constructive discussions and looking for best available solutions in concrete situation.

There is need for further preparation and issuing of ***different informative printed materials*** (leaflets, brochures, postures etc.) explaining GMOs related issues at easy understandable way, achievements and tendencies of biotechnology and gene engineery as well as potential threats to environment and human health raised by GMOs, possibilities for avoiding them and securing of objective information and free choice to consumers regarding products in trade, adopted to local situation and local consumers.

Information availability and accessibility by ***electronical means*** should be used more widely. Due to fast development of use ***electronical means*** for gathering and securing information this can be considered as an effective tool for introduction of easy accessible database on related operations with GMOs at national level. There is need for establishing a ***clearing house mechanism*** securing good and effective information exchange using all possible means such as networking, data bases, e-mails connection, INTERNET and web pages, share of know-how, actual information and materials etc. Regular reporting by competent authorities would serve a base for public understanding of situation and information regarding current situation.

Information campaigning including various concrete, co-ordinated, consequent, consistent and continuous activities on related issue might be very effective tool for rising public awareness. In this case held activities should serve synergetic effect from different separate activities. From other side there is threat to partial information and not enough capacity and resources (skills and knowledge, human, time, material) for such complex activities.

There is need for ***training, education and capacity building*** for different target groups such as journalists, consumers, housekeepers, representatives from state institutions and municipalities, NGOs etc. Explanation and education on GMOs related issues from different

aspects would rise people understanding and knowledge and at the same time would be a base for proposing constructive and objective suggestions for further legal and institutional framework development. It would serve a guarantee for transmission of the correct and better-explained information to the different target groups, stakeholders and general public. From other side there is clear need for specialists from different target groups, especially state administration, have to be more trained on issues for development of effective public relations and consultations with different target groups at different stages of decision-making processes, working with target-group oriented information, planning and implementation more effective public participation at elaboration of plans and programs, legislative acts.

Finally, there is need for looking to different opportunities for attracting ***funds and resources***, information marketing and advertising.

14 NETHERLANDS

Existing regulatory framework in the Netherlands in the area of deliberate release into the environment, and contained use, of genetically modified organisms (GMOs):

Over the years the Netherlands has adopted and amended regulations relating to GMO's. Different areas and subject matters are covered by different laws, addressing environmental safety, medical/ethical concerns, animal welfare, product safety and quality of products.

Both EC-GMO directives are implemented through the GMO-decree, based on the Environmentally Hazardous Substances Act and the Environmental Management Act. The objective of this decree is the protection of human beings and the environment.

The primary Competent Authority (CA) in the field of GMOs is the Minister of Housing, Spatial Planning and the Environment (VROM). The GMO decree lays down notification procedures for **contained use** activities carried out within an installation. The procedure for gaining a permit for the installation itself is regulated through the Environmental Management Act (EMA)

The minister of VROM decides on requests for **releases** of GMOs into the environment in agreement with the minister of Agriculture, Nature Management and Fisheries in so far it concerns those aspects of environmental protection for which this minister is responsible. The notifier carries out risk analysis in advance.

Both in the case of contained use an deliberate release, the minister of VROM may seek advice from an independent scientific advisory body , the Committee on Genetic Modification (COGEM) This advisory committee may also advise the minister when it deems this to be appropriate. The meetings of the COGEM[1] are open to the public.

Provisions on passive and active access to information and public participation in decision making in the area of deliberate release and contained use of GMOs:

Most provisions on active and passive access to information to the public in environmental affairs in the Netherlands are covered by general laws. The *lex specialis/lex generalis* rule applies, which means that provisions in general laws apply unless otherwise provided for in specific (environmental) legislation. This is only so if the special legislation is exhaustive, however. Whenever this is not the case, joint application is called for.

The general law on access to governmental information is the Government Information (Public Access) Act (GIA). The provisions on access to information specifically in environmental matters are found in (chapter 19 of) the Environmental Management Act (EMA). Procedures for public participation in decision making in environmental matters are laid down in (chapter 3 of) the General Administrative Act (GAA) and (chapter 13 of) the EMA. Access to justice provisions are found in the GAA, chapters 6 and 8, and the EMA, chapter 20. Specific regulations which in several instances contain more detailed provisions on access to information & public participation in the area of GMOs are the Environmentally Hazardous Substances Act (EHSA). And the Genetically Modified Organisms Decree, pursuant to the EHSA

The following provisions are of importance for GMO-related access to information.

[1] The committee is assigned by the CA. The CA appoints members, several of them on the recommendation of Councils such as the Health Council and the Nature Conservation Council.

1.General Information Act (GIA)

Passive access to information:

- *Any person may apply to an administrative authority for information contained in documents concerning an administrative matter.*
- *An application for information shall be granted with due regard for exceptions and restrictions (grounds for refusal).*

- As the Aarhus Convention is being implemented, certain amendments are being proposed to bring Netherlands law in line with the convention. Currently the GIA states that information shall not be disclosed if it concerns data on companies or manufacturing processes which were furnished to the government in confidence. A restriction will be added that this ground for refusal will only apply if publication will harm legitimate economic interests.
- Another amendment concerns the time limit within which information should be disclosed. For environmental information this time limit will be brought back to 4 weeks in the GIA

Active access to information (collection and dissemination of information):

- *The public authority shall provide of its own accord information on its policy and the implementations and preparation thereof, whenever the provisions of such information is in the interest of effective democratic administration.*
- *Public authorities shall ensure that policy recommendations which the authority receives from independent advisory committees, shall be made public.*

The refusal grounds are equally applicable to the provisions on active access to information in the GIA.

2. General Administrative Act (GAA)

Public participation

For public participation in decision making concerning decisions on GMOs, the GAA applies. The GAA , like the GIA, is a general act.

The GAA contains detailed public preparatory procedures for governmental policy making.[2] Among other reason this has been done to ensure special participation procedures for information relating to the environment. The goal of the procedures in the GAA is *"to reach the public concerned so it can participate in decision making"*

Access to justice:

Most general access to justice provisions are found in the GAA.

- *provisions for objecting to and appealing against actions of administrative authorities. (GAA)*
- *an interested party may appeal to the district court against an order (GAA)*

The provisions apply any actions by administrative authorities unless stated otherwise in other specific provisions.

[2] The table two pages later covers the provisions of the GAA as they apply to decisions in the field of GMOs

3. Environmental Management Act (EMA)

Passive information: (chapter 19 of the EMA)

Under the EMA access to information generally concerns access to documents submitted for inspection during application for a permit. Deposit for inspection of documents relating to permits concurs with the time given to third parties for participation and comments, thus ensuring a connection between public participation in decision making and access to information. Passive access resumes after the period of participation and deposit for inspection.

An applicant may request secrecy when commercial interests are at stake. The exceptions and restrictions in the EMA are narrower than the GIA. For example whenever a request for secrecy is granted a *second letter* must be made accessible which leaves out the secret information but based upon which a third party may still be able to participate in the decision making.

Amendment to the grounds for refusal in this Act has also been proposed in the light of the Aarhus convention. To the provision; *The competent authority shall make use of this power (to permit omission of information in a second letter) with respect to trade secrets and security information only.* A restriction will be added that this will only apply if full publication will harm legitimate economic interests.

*Requests for other information: When requests concern information that is information other than documents submitted for inspection during application for a permit, e.g. internal governmental information, external advice etc., the GIA applies.

Active access to information (dissemination of information at own accord)

Active access to information is provided for in the EMA for environmental plans reports and environmental impact assessments.

Access to justice Chapter 20 states that

- *An appeal may be lodged with the Administrative Law Division of the Council of State against a decision based on this Act*

4. Environmentally Hazardous Substances Act (EHSA)

Passive access to information

The GMO-decree is based on the EHSA, which contains the following secrecy provision:

- *If a document, with respect to which this act imposes an obligation to allow public access to it, contains information the secrecy with respect to trade secrets may justifiably be maintained, the Competent Authority shall decide not to allow public access to the said information*.

In some instances the ESHA -secrecy provision could apply to access to information on GMO's.

Public participation in the preparation of decrees:

Article 61 of the ESHA states the following regarding the preparation of decrees (such as the GMO-decree)

- *A draft decree shall be submitted for inspection to Parliament and published in the Government Gazette. Anyone may submit reservations to the competent authority within four weeks of the date on which the draft is published*.

5. The GMO-Decree

Passive access to information, active access to information and public participation in decision making

Passive access to information, active access to information and public participation in decision making concerning GMO's is provided for by the legislation which has been explained above.:

Public participation in the preparation of further rules:

In the preparation of further rules for the division of GMO's in groups 1, 2 and 3 the decree states:

- The draft rules shall be published by the Competent authority in the Government Gazette. Anyone may submit written reservations to the competent authority within a time-period after which the draft is published.

Provisions on passive and active access to information and public participation in decision making in the area of deliberate release and contained use of GMOs (Table):

The table below gives an overview of the most important information provisions that apply to decisions and policies on GMO's.

Passive information.	-Any person may apply to an administrative authority for information contained in documents concerning an administrative matter. (GIA)
	-An application for information shall be granted with due regard for exceptions and restrictions (grounds for refusal). (GIA)
Active information	-The public authority shall provide of its own accord information on its policy and the implementations and preparation thereof, whenever the provisions of such information is in the interest of effective democratic administration(GIA).
	-Public authorities shall ensure that policy recommendations which the authority receives from independent advisory committees, shall be made public. (GIA)
Public participation(in decisions on specific activities)	a draft order shall be -deposited for public inspection -communicated in one or more newspapers and the Government Gazette. (GAA)
	Criteria for what should at least be stated in the communication (e.g. substance and purport of application.)(GAA)
	Criteria for additional information (beside draft order) to be deposited for public inspection (e.g. accompanying documents, reports)(GAA)
	Information is to be made publicly available for a certain period, there is an obligation to provide oral explanation free of charge.(GAA)
	Anyone may submit written reservations to the administrative authority within four weeks of the date on which the draft is deposited for inspection.(GAA)
	Anyone shall be given the opportunity to exchange ideas on the draft order and submit reservation orally. A record shall be kept of reservations submitted (GAA)
	If a category of persons is selected for public participation it must in any event include the interested parties (GAA)
	When notifying the order the public authority shall state its considerations on the reservations submitted (GAA)
	Public participation and active access to information must be provided for when an order is altered or repealed (GAA)
	An order shall not take effect until it has been -sent to interested parties -published in one or more news papers. -deposited for inspection (GAA)
	If an objection may be made or an appeal may be lodged this shall be stated, communicating by whom, what time limit and with which authority.(GAA)

Public participation(in preparation of legally binding instruments):	A draft decree shall be submitted for inspection to Parliament and published in the Government Gazette. Anyone may submit reservations to the competent authority within four weeks of the date on which the draft is published (ESHA)
	The draft rules shall be published by the Competent authority in the Government Gazette. Anyone may submit written reservations to the competent authority within a time-period after the date on which the draft is published (GMO-decree)
Access to justice	-An appeal may be lodged with the Administrative Law Division of the Council of State against a decision based on this Act (EMA)
	-provisions for objecting to and appealing against actions of administrative authorities. (GAA) -an interested party may appeal to the district court against an order (GAA)

Further legal and other instruments of public information and public participation in the GMO that exist or are planned.

The general policy making and decision making processes are open and members of the public and NGO's are regularly consulted and participate in discussion groups and meetings. A supplementary policy line that is often chosen is to support initiatives from public organisations, such as consumer organisations, and communicate through them. For example since 1990 a public information foundation regularly produced leaflets on biotechnology and organised small scale public debates with the support of several ministries.

Currently preparations are made to organise a public debate on the issue of GMOs and food production. In this the Dutch government works together with NGO's. The government actively takes part in debates on the issue of GMOs in the independent media.

All legislation, policy documents and decisions on GMOs (including permits) are published on the internet site of the Ministry of VROM.

The Public Communication department of the Ministry of Housing , Spatial Planning and the Environment will include GMO-issues in a trial communication strategy , which is aimed at subjects that have the potential to create unrest and public crises. This so called "issue management" consists of two major activities. The first is receiving social signals, the second is to developing an organisational structure to translate these signals into communication activities.

Public perception of use of GMOs and the level of public debate

Compared to other countries in the EU, the level of public knowledge on the subject of GMOs is high. It is not easy to assess the general **public perception** of use of GMOs, as it is shaped by many factors, such as education, the debate between NGO's, industry and government, the media and general (food related) developments. A recent consumer survey has revealed that a significant proportion of consumers in the Netherlands is eager to learn more about GMOs and their effect upon health and the environment, which indicates a perception of slight concern.

The **level of public debate** has been more or less constant over a period of 10 years. Regular discussions between NGO's, industry and the government started in the middle of the 1980's and continue to be held. This discussion has been low-profile, constructive, well organised and generally does not involve the public at large. In recent years the debate in the media has increased, which has had an effect upon the public at large. Public debate involving the general public consists of scattered initiatives, such as debates on the internet and above mentioned discussions with members of the public

The feasibility and usefulness of round-table discussions, consensus conferences, technology assessment and the role of stake holders in these instruments.

Round table discussions, consensus conferences and technology assessments are tools that are an integral part of so called “interactive policy making”. In environmental matters interactive policy making, which means involving as many stake holders as possible in an early stage of policy preparations, is important for effective policy making. In the Netherlands this approach is regularly taken in the preparation of plans, programmes and policies as well as during the preparation of new legislation. Experience has shown the usefulness and feasibility of this approach in the field of GMOs as well as other subject matters.

Further proposals regarding the implementation of Art 6.11 of the Aarhus Convention.

The experience of the Netherlands is that openness, either active or passive, and public participation in decision making have led to a better informed public, more effective decision making and more consensus on the subject of GMO’s. The Netherlands Government proposes that Art 6.11 should be implemented in such a way that the public participation in decision making provisions of article 6 of the Aarhus Convention apply to decisions on GMOs as they apply to subjects listed in the annex to article 6.

15 NORWAY

Regulatory framework

Norway and the other EFTA countries are through the EEA agreement committed to incorporating into their national legislation the EU directives concerning contained use (dir. 90/219) and deliberate release of GMOs (dir. 90/220). Norway has fulfilled this requirement through the Act relating to the production and use of genetically modified organisms (Gene Technology Act) which was adopted in 1993 (Act No.38 of 2 April 1993). The purpose of the Act is to ensure that the production and use of genetically modified organisms takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment.

The following regulations are adopted in addition to the Gene Technology Act:

- 1997.10.01 : Regulation prohibiting release in Norway of GM vaccine against rabies
- 1997.10.01: Regulation prohibiting release in Norway of GM vaccine against pseudorabies
- 1997.10.01: Regulation prohibiting release in Norway of GM maize
- 1997.10.01: Regulation prohibiting release in Norway of GM seed from sikori salad
- 1997.10.01: Regulation prohibiting release in Norway of GM oil seed rape

Some special adaptations are laid down in the EEA agreement in order to balance the fact that Norway has no legal influence on decisions taken on GMO products in the EU. According to the adapted art.16, Norway can prohibit GMO products on a permanent basis.

Deliberate release of genetically modified organisms may only occur subject to approval by the Ministry of environment. A notification has to be sent to the competent authority, which has to make a decision within 90 days. Applications for approval of deliberate release shall contain an impact (risk) assessment. Deliberate release of GMOs may only be approved when there is no risk of detrimental effect on health or the environment. In deciding whether or not to grant the application significant emphasis shall according to the Act also be put on whether the deliberate release represents a benefit to the community and a contribution to sustainable development.

Contained use shall take place in laboratories and installations that are approved by the Ministry of Health and Social Affairs. The contained use of GMOs shall be reported or approved in accordance with regulations issued by the Ministry.

By the end of March 2000 thirty-two applications for placing on the market have been received from the EU. Six decisions are taken. Only one tobacco plant has been accepted, the other five applications have been refused. The reason for this is *inter alia* a Parliamentary Decision of 1997 according to which "The Government will prohibit production, import and marketing of genetically modified food and feed containing antibiotic resistant marker genes." In addition four field releases have been approved.

Regulations on public participation/information to the public

The Gene Technology Act states that in cases where approval is required under the Act, the competent authority may decide that a public consultation is to be carried out. Such consultation shall take place in good time before the decision on the case is made. The decision to carry out a public consultation is publicly announced in an official newspaper. In practice all applications are sent out for a public hearing to relevant ministries, industry, research organisations, environment- and consumer organisations. These are all allowed to put forward written opinions/statements on the application usually within a time frame of 25-30 days. Any person can put forward opinions/statements in a consultation that is publicly announced.

Opinions put forward in public hearings are taken into account in the proposal for decision from the Directorate for Nature Management which is sent to the Ministry of environment for the final decision. All critical voices have been taken into account in the decisions since all the applications dealt with so far with the exception of one have been refused.

Freedom of Information Act

The Freedom of Information Act (Act of 19 June 1970 as amended by Act of 10 January 1997) applies to cases under the Gene Technology Act. The following information shall always be public regardless of the duty of secrecy:

- the description of the GMO, the user's name and address, the purpose of the use and the location of use
- methods and plans for monitoring and emergency response
- assessments of the foreseeable consequences.

According to the Freedom of Information Act a request for access to information held by a public authority shall be decided without undue delay. Such a request can be made without providing any interest in the case. If the request is refused by an administrative agency, it shall indicate the right of appeal and the time limit for making an appeal. A person whose request has been refused may appeal to the administrative agency that is superior to the authority that has made the decision. The appeal shall be decided without undue delay. In practice, decisions with regard to requests on access to information and appeals have been decided within time limits of less than one month which is the requirement in the Aarhus Convention.

Public Administration Act

According to the Public Administration Act (Act of 10 February 1967 as amended by Act of 9 January 1998) which is also applicable for decisions under the Gene Technology Act administrative decisions may be appealed by a Party or another person having a legal interest in appealing the case, to the administrative agency which is the immediate superior of the administrative agency that made the administrative decision. The time limit for lodging an appeal is three weeks from the date on which notification of the administrative decision has reached the party concerned. If the notification is made by public announcement, the time limit for an appeal runs from the date on which the administrative decision was first published.

Usefulness of Consensus conferences, round-table discussions etc.

We consider the use of round-table discussions and consensus conferences as important means to improve public participation in matters related to GMOs. The public perception of GMOs, in particular for food consumption is high. In 1996 the Norwegian Biotechnology Board together with the National Committees for Research Ethics organised a layman's conference on genetically modified food. The Biotechnology Advisory Board functions as an official independent advisory body appointed by the Government. The Board shall evaluate general issues related to biotechnology, and put forward proposals for ethical guidelines for biotechnology activities. The Board shall also inform the public of matters related to biotechnology.

At the consensus conference a panel of non-professionals used a group of experts to answer a number of questions. The aim of the conference was to give co-ordinated advice on genetically modified food to politicians, authorities and the industry, to establish a forum for dialogue between experts and non-experts, and to contribute to a well informed public discussion on the subject. The conclusion of the panel was that there is no need for GM food in Norway today, because the selection, availability and quality of ordinary food is satisfactory.

Information to the public

The final decisions with regard to GMO applications are published in two official newspapers and in a press release.

The Norwegian policy with regard to labelling is that the consumer shall be properly informed of the presence of GMOs in a product or that the product consists of GMOs. All genetically modified food products are labelled as such in Norway.

Possible revisions

A possible revision of these provisions will wait until the new EU directive 90/220 is adopted and until any necessary changes resulting from the Cartagena Protocol on Biosafety are identified.

The Norwegian Government wants to strengthen the public right to environmental information and appointed a Commission to Report on Legislation Relating to Environmental Information in 1998 to consider whether new legislation was necessary in this area. The aim is to give better access to environmental information and to improve the quality of the information provided. The Commission will among other things survey the relevant existing legislation and Norway's international obligations. The Commission will present its report by the end of the year 2000.

Implementation of Article 6.11. of the Aarhus Convention

The further discussions could focus on *inter alia:*

- Comparison of regulatory decision-making in biotechnology with regard to public information/participation in the various countries
- Identification of restrictions with regard to public information/participation
- Proposals for improving public information/participation
- How is this issue dealt with in other agreements e.g. the Cartagena Protocol on Biosafety (article 23).

16 SLOVENIA

Modern biotechnology in Slovenia is one of the most important technology in the economic and technological enforcement. At the same time we aware very much that through implementation of the national biosafety framework conforms international obligations is imperative. Although, at present national biosafety framework is in its infancy. Fortunately, there a number of instruments and initiatives to manage that area such as:

Environmental Protection Act (Ministry of the Environment and Spatial Planning) lays down general principles, which are implemented by decrees, regulations and other legally binding secondary legislation. This act will have to be modified and some new acts also to be adopted to ensure full transposition of the *acquis communitaire*. Regarding the above Slovenia intends to fully transpose Directive 90/313/EEC on access to environmental information by March 2001. Slovenia also intends to set up an *"integrated environmental protection information system"* by 31 December 2002. Reporting obligations according to Directive 91/692/EEC, foreseen under most sectoral directives, still need to be fully aligned with Community standards and the relevant implementing decrees will be in place.

Act on Nature Protection (Ministry of the Environment and Spatial Planning) includes provisions following international compatibility of substantive elements of nature protection such are protection of habitats, protection of gene resources usage, introduction of plant or animals of non-indigenous species and etc.. Act implements Convention on Biological Diversity ratified in 1996 and some EU directives. Slovenia intends to sign the Protocol on Biosafety in May this year.

Existing conditions for plant protection in Slovenia are enable through Act on Plant Health Protection (Ministry of Agriculture). Act involves control over testing commercialisation of new plant products including new transgenic plants. Act on Seed and Plant Variety Protection adopted in June 1999 follows provisions from UPOV Convention. Provisions from EU Animal experiments directive are including in Act on Animal Experiments (Ministry of Agriculture).

Slovenian Industrial Property Act (Ministry of Science and Technology) adequately modifies our regulation and follows the international compatibility of substantive elements of protection of biotechnological inventions and the recent developments concerning WIPO Convention and GATT Agreement (TRIPS) have been taken into account. In concordance to EU directive on biotechnological invention from 1998 and its provisions to patentability of biotechnological inventions new amendments to the Act was prepared. Agreement on International Recognition of the Microorganisms Deposits for Patent Procedure ratified in 1998 assures depositing of all kinds of biological material related to patent applications.

In March 2000, Ministry of Health has been prepared GLP legislation which is now under Governmental procedure.

In June 1995 Ministry of Scienece and Technology nominated the Commission for supervision of manipulation with genetic engineering research and production practise.

Intergovernmental Commission for Biotechnology adopted 30 biotechnology standards associated to EU directives (90/219/EC and 90/220/EC), to large scale processes and equipment in accordance with the biological risk.

Ministry of the Environment and Spatial Planning is coordinator for the project Implementation of National Biosafety Frameworks in co-operation with the Dutch Government. The main aim of the project is tailor-made training programme for all stake-holders, including NGO's, public, academia and industry. The Ministry already organised two workshops in January and in March 2000. The aim was to initiate a discussion on the subject before the first application for transgenic plants will be done.

Responsibility for the development and implementation of legislation and policy in the field of GMO's (including micro-organisms, transgenic plants and animals) is in the competence of the Ministry of Environment and Spatial Planning. A comprehensive draft Act on the use of GMO's is currently under governmental discussion. The main aim of the draft is to transpose EU directive 98/81/EC and 90/220/EC in Slovenian legal system and to establish legal guaranties to protect human health and environment from potential harmful impacts of GMO's. It proposed the establishment of a Committee of experts which main purpose would be to ensure professional opinion in authority decision on the applications for permits and/or consents for contained use, deliberate release and placing on the market GMO's or products contained them. The Competent Authority, according the draft Act should be Nature Protection Authority of the Republic of Slovenia within the Ministry, shall oversee the implementation of the legislation and examine the conformity of the notifications with the requirements referred to the legislation. In the case of the contained use of GMO's and deliberate release as well, Ministry shall issue permission. Permission for placing on the market shall be issued by the Ministry in agreement with the competent ministries such as Ministry for Health, for Agriculture and for Economic Affairs. Implementation of the legislation shall be carried out by the Inspectorate of the Environment and Spatial Planning, Inspectorate for Agriculture, Forestry, Hunting and Fisheries, Veterinary Administration, Health Inspectorate, Market Inspectorate and Inspectorate for Traffic in compliance with their competence. EIONET (environment information system) within the Ministry shall be upgraded and available to public and use for information exchange too.

Draft Act ensures an active and passive information to the public, public participation and access to justice as follows:

- in the procedure of issuing the permission for each deliberate release of GMO's the notification data ,except the information indicated as confidental, including the risk assessment and the opinion of the Committee shall be available to the public for a time period of 60 days,
- notification or application of permit for contained use of GMO's, except the information indicated as confidential, including the risk assessment and the opinion of the Committee, shall be made available to the public for a time period of 45 days,
- detailed procedure about public participation and access to justice is regulate by General Administrative Procedure.

By reason that biotechnology, particularly new biotechnology, is too often discussed only from narrow, technical viewpoint, public information and participation of deliberate release and contained use is not workable enough in Slovenia. Last Biotechnology conference held in March in Ljubljana showed us that the Government should perform its duties in open communication with the public in closely co-operation with the science and inversibly.

Therewith we aware very much that the participation of public in the discussion and decision making procedure should be improve in Slovenia. Workable and usefulness system should make steps towards to measurements that are needed to minimise risk for the environment and consumer.

Hereafter we strongly support co-operation between governments and NGOs/public based on open discussion on the contribution of gene technology towards to sustainable development and to pontential risk as well.

17 SWITZERLAND

Switzerland has regulated the handling of genetically modified organisms by an Ordinance on the Contained Use of Organisms (Containment Ordinance) and an Ordinance on the Release of Organisms into the environment (Release Ordinance). There are only draft translations existing at the moment.

We are answering your questions as follows:

2a:

Contained use: The receipt of notifications and licence applications are announced in the Federal Law Gazette and are made public so long as they are not confidential (article 15 para 2 let. d).

Release: The receipt of application is announced in the Federal Law Gazette and the non-confidential documents are displayed for 30 days for examination (article 18 para 2 for the release; article 23 para 2 for the distribution).

2b and c:

Contained use: The general administrative procedural law provides public participation in decision making similarly to article 6 of the Aarhus-Convention. It also provides access to justice similarly to article 9 of the Aarhus-Convention. Additionally, NGOs too are allowed to participate in decision making and have access to justice, because installations for handling of GMO (class 3 and 4) in containment are regulated in the ordinance of the environmental impact assessment.

The general administrative procedural law provides public participation in decision making similarly to article 6 of the Aarhus-Convention. It also provides access to justice similarly to article 9 of the Aarhus-Convention. Since the Ordinance of environmental impact assessment does not regulate release of GMO, NGOs therefore do not have a right to public participation in decision making and access to justice.

4:

At present time there is a new regulation about the public access to information conceming GMOs on the agenda of the parliament. The goal is to integrate article 4 of the Aarhus- Convention concerning GMOs into the Swiss Legislation.

18 UNITED KINGDOM

In line with Article 6.11 of the Convention, this statement covers the situation in relation to the deliberate release of GMOs.

1. Please describe any existing or planned regulatory framework in your country in the area of deliberate release into the environment, and/or contained use, of genetically modified organisms (GMOs).

1.1 The broad regulatory framework for the release and marketing of GMOs in Great Britain and Northern Ireland is based on, and structured in conformity with, EC Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms. The Directive was implemented in Great Britain by Part VI of the Environmental Protection Act 1990 and the Genetically Modified Organisms (Deliberate Release) Regulations 1992 (as amended in 1995 and 1997), made under the 1990 Act.

1.2 The main features of this framework are:

- all experimental releases of GMOs require a consent from the national competent authority;
- proposed releases are advertised and information about them placed on a public register, giving the opportunity for the public to comment;
- the issue of any consent by the competent authority can only proceed after certain minimum, science-based, information requirements have been satisfied;
- all EU member states have the opportunity to comment on information notified to the competent authority in connection with release consent applications;
- all release consents issued by the competent authority may include general or specific conditions, including requirements for post release monitoring and reports;
- a consent to market products consisting of or including GMOs may only be issued by the competent authority following Community wide clearance; and
- any product for which a marketing consent is issued by the competent authority in accordance with the Directive may be sold and used throughout the EU.

1.3 In Great Britain, the Department of the Environment Transport and the Regions (DETR) co-ordinates statutory and operational requirements in relation to the release and marketing of all GMOs, including plants, animals and microorganisms, or preparations or products containing or consisting of GMOs. Similar requirements apply in Northern Ireland, but are controlled under separate legislation.

1.4 DETR's role in Great Britain is exercised, as appropriate, in co-operation with the devolved administrations in Scotland and Wales, the Ministry of Agriculture, Fisheries and Food (in relation to agricultural issues), and the Health and Safety Executive (in relation to human health and safety issues). The devolved administrations are responsible for issuing their own consents in appropriate cases. Expert scientific and other advice is provided by the independent Advisory Committee on Releases to the Environment (ACRE) which is supported by a secretariat of scientifically qualified officials.

2. Does or will this regulatory framework contain provisions on the following matters in the area of deliberate release and/or contained use of GMOs:

a) active and passive information to the public?

2.1 Yes.

b) public participation in decision making?

2.3 Yes.

c) access to justice in environmental matters?

2.4 Yes.

3. What are or will be the contents of these provisions?

3.1 To inform the public and to allow an opportunity for comment, specified information in relation to GMO release consents applied for and granted must be placed on a public register. Such information includes, for example, the location of the experimental release sites, the environmental risk assessment, and the advice of the Government's independent expert body, ACRE (see paragraph 1.4)

3.2 Applications for consents to release GMOs must also be advertised in the press and be and notified to certain public bodies. Advertisements must include information on the name and address of the applicant for consent to release a GMO, the general description of the organisms to be released, the location and general purpose of the release, and the foreseen dates of release.

3.3 These requirements are subject to the limitation that the Secretary of State may decide, on representation from the applicant, that certain information should not be made available because its disclosure would affect the protection of commercial confidentiality (for example, patent rights). The Secretary of State may also limit information disclosure on grounds of national security or the need to prevent damage to the environment.

3.4 A public register of all GMO release consent applications and decisions is kept centrally by DETR in London, and in regional offices. An electronic index of this information, including a summary of the main items of the register entries, is kept on a web-site maintained by the DETR (http://www.environment.detr.gov.uk/acre/pdf/exper.pdf.) The index includes information on applications received by the Secretary of State for experimental releases in the United Kingdom as well as information relating to applications to the UK competent authority for consent to market GMOs in Europe made in conformity with Directive 90/220. In addition, the web-site includes a list of active sites where experimental releases are expected to take place plus the agendas and reports of ACRE meetings, including copies of the minutes of meetings in which decisions on advice in relation to release consent applications are made.

3.5 The decisions of the Secretary of State in relation to GMO release consent applications are subject to judicial review through the national courts.

4. Which further legal and other instruments of public information and public participation in the GMO area exist or are planned in your country?

4.1 Information not already made public by being placed on the register will be made available in accordance with the Environmental Information Regulations 1992, which implement EC Directive 90/313/EEC on the freedom of access to information on the environment. In practice, however, all information on release consent applications is likely to be available via the register referred to in the answer to question 3.

5. How is the public perception of deliberate release and/or contained use of GMOs in your country? What is the level of public debate on this issue?

5.1 There is considerable public interest in the release of GMOs in the United Kingdom, with a high level of public debate. This applies particularly to the release of GM crops. Largely in response to public concern, the Government has recently launched a series of farm scale evaluations of the effects on biodiversity of the management of certain GM crops as compared with their non-GM counterparts. In order to explain its purpose and to allow the opportunity for the public to express views, part of this programme includes a schedule of public meetings with local people in the areas where the trials are to take place.

5.3 The farm scale trials are part of a voluntary agreement with industry that there will be no general commercial planting of GMO crops in the UK before 2003.

6. What is your opinion about the feasibility and usefulness of round-table discussions, consensus conferences, technology assessment and the role that government, industry and NGOs/public should play in these instruments?

6.1 As demonstrated by our public register system and the farm scale evaluations, the UK believes that wide-ranging consultations and co-operation with all sections of society with an interest in GMO releases are both feasible and useful in the formulation of policy in this area. Other examples of regular consultations with NGOs and others on specific issues include the revision of Directive 90/220 on the deliberate release and marketing of GMOs and the development of the UK position in relation to the Biosafety Protocol to the Convention on Biological Diversity.

7. Do you have any further proposals regarding the implementation of Art 6.11 of the Aarhus Convention?

7.1 The UK intends to continue to develop the features of the system of public participation in decisions on GMO releases described above. This applies particularly with regard to the provision of increased information by electronic means via the internet (for example, by placing the whole of the public register, not just summary details, on our web site).

19 EUROPEAN COMMISSION

1.Description of the existing and future regulatory frameworks concerning the deliberate release in the environment genetically modified organisms (GMOs) and contained use of genetically modified micro- organisms (GMMs)

The existing regulatory framework comprises two fundamental legal instruments:

- Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (GMOs)
- Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms (GMMs).

These horizontal Directives set out the minimum regulatory requirements in relation to work with genetically modified organisms and genetically modified micro-organisms in order to protect human health and the environment. This framework for biotechnology in the EU was adopted in 1990 and came into force in October 1991.

Directive 90/219/EEC on the contained use of genetically modified micro-organisms (GMMs)

Directive 90/219/EEC on the contained use of GMMs was founded on scientific knowledge available in the early 1980s and entered into force on 23 October 1991, when experience of industrial applications was limited. The Directive sets out the requirements for the classification of contained use activities, the containment requirements and the administration procedures to be applied for the classes of GMMs defined in the Directive.

On the basis of the continued safe use of genetic modification techniques, a growing body of scientific knowledge and experience, the Commission in 1994/5 undertook an extensive and systematic review of the provisions and operation of Directive 90/219/EEC. Following this review, which involved an extensive consultation with Member States and other interested parties, the Commission proposed an amendment that addressed a number of issues, notably:

- the administration procedures and notification requirements were not linked to the real risk of activities
- there was insufficient guidance as to the containment and control measures to be applied to protect human health and the environment
- the classification system for GMMs was not in line with current international practice.

Directive 98/81/EEC amending Directive 90/219/EEC entered into force on 5 December 1998 and Member States should bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 5 June 2000. The revised Directive is based on the risk arising from work activities rather than process although size and scale of the process is still considered in the risk assessment.

The Commission has to establish, through a Regulatory Committee composed of representatives from Member States, guidance on risk assessment to further assist a harmonised approach to the central component of the Directive by the Member States. In addition, an annex listing the criteria for establishing whether a GMM is safe for human health and the environment and would be suitable for inclusion into Annex IIC of the Directive has to be adopted by the Council prior to 5 December 2000.

Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (GMOs)

The 'horizontal' Directive 90/220/EEC harmonises the laws, regulations and administrative provisions of the Member States for the protection of human health and the environment when carrying out deliberate releases of the GMOs. It regulates the deliberate release of GMOs for research and development purposes (Part B) and the placing on the market of products containing or consisting of GMOs (Part C).

The Directive does, however, contain provisions that allow for 'verticalisation' of the authorisation procedure for certain products. This means that the procedural requirements of Directive 90/220/EEC for the placing on the market of products do not apply to products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in the Directive. This procedure has been established for the product legislation governing Medicinal Products and Novel Food as well as the Directive concerning additives in feeding-stuffs.

Following a review of the regulatory framework of Directive 90/220/EEC, the Commission adopted a proposal to amend the Directive. The review identified a number of issues that required attention and recognised the importance of a regulatory horizontal framework sufficiently flexible and specific to ensure a high level of environmental and human health safety and transparency. The Commission adopted the proposal for an amendment of Directive 90/220/EEC on 23 February 1998.

After the first reading in the European Parliament, the amended Proposal was forwarded to the Council and a Common Position adopted on 9 December 1999. The Common Position maintains the basic structure of the Commission Proposal and builds on specific elements to provide for a more stringent and transparent regulatory framework. It clarifies a number of operational aspects of the current Directive 90/220/EEC including the scope, definitions and administrative procedures.

More specifically, the Common Position introduces the following new elements:

- A comprehensive environmental risk assessment based on common principles to be carried out before Part B (experimental releases) or Part C (placing on the market) authorisation procedures are initiated
- In the case of placing on the market of GMOs, consent to be given for a maximum period of 10 years for the initial consent; in the case of renewal of consent time limitation is optional and may be limited as appropriate
- Part C requirements will not apply to products authorised by other Community legislation which is at least equivalent as regards risk assessment, risk management, monitoring as appropriate, labelling, information to the public and safeguard clause to this Directive; by way of exemption only the risk assessment requirements will apply in the case of Regulation 2309/93 on medicinal products
- Mandatory monitoring and labelling requirements and the possibility of establishing threshold levels for products where adventitious or technically unavoidable traces cannot be excluded
- A mandatory consultation of the public for Part B and Part C releases
- Mandatory consultation of the Scientific Committees for Part C releases
- An obligation for the Member States to ensure traceability at all stages of placing on the market of GMOs authorised under the Directive and in accordance with the precautionary principle, that all appropriate measures are taken to avoid adverse effects on human health and the environment

- The possibility for Member States and the Commission to consult Committees on ethics concerning general matters related to the release of GMOs, while not allowing the consultation to affect the administrative procedures.

The Common Position has been transmitted to the European Parliament for a 2nd reading, which has been scheduled for Tuesday 11th April. The new regulatory system will not, however, be fully implemented for at least eighteen months after the second reading or even later than this depending on whether the second reading leads to conciliation. This is difficult to predict at the present time.

2. Does or will this regulatory framework contain provisions on the following matters in the area of deliberate release and/or contained use of GMOs:

(a) active or passive information to the public ?

(b) public participation in decision making ?

(c) access to justice in environment matters ?

and

3. What are or will be the contents of these provisions ?

Directive 98/81/EEC amending Directive 90/219/EEC on the Contained Use of GMMs includes provisions for the involvement of the public in a recital. According to the Directive, the public may be consulted on the contained use of genetically modified organisms when it is considered to be appropriate.

A similar provision is included in the existing Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms. These obligations have been substantially strengthened in the Common Position where public participation was addressed as one of the major issues during the revision process.

Several recitals in the Common Position refer to the provision of information to and consultation of the public. As a means to improve and strengthen public participation in the decision making process, obligations to provide information have been included in the General Provisions of the Directive. Such provisions have been included in stages of the authorisation procedures for experimental releases under Part B of the Directive and also for the commercial release of GMOs under Part C.

For experimental releases, Member States are required to consult the public within a certain time period and make available the public information on all Part B releases in their territory. For commercial releases under Part C, the Commission is obliged to make available to the public a summary of a notification together with an assessment report.

Access to justice in environmental matters is in principle, provided by the Aarhus Convention.

4. Which further legal and other instruments of public information and public participation in the GMO area exist or are planned in your country ?

The involvement of the public with respect to the deliberate release of GMOs and contained use of GMMs as detailed above is integrated in Directives 90/219/EEC and Directive 90/220/EEC, which regulate the use of such organisms. The final adoption of the revised Directive 90/220/EEC will considerably improve the provision of information to the public and public participation with regard to the deliberate release of GMOs.

5. What is the public perception of deliberate release and/or contained use of GMOs in your country? What is the level of public debate on the issue?

Genetically modified organisms (GMOs) and in particular their commercial release are currently the focus of intense public and political debate with particular reference to the long-term effects on the environment and the issue of food safety, and more recently, ethical, cultural and faith issues. Following the recent BSE and dioxin crises, the credibility of science, industry and governments in Europe has declined and as a result, public confidence has been eroded with regard to food safety. Public perception remains one of major concern as was stressed in the declarations of Member States at the June Environment Council of 25 June 1999 where the need to restore public and market confidence was also highlighted. It is important to point out that public perception of products for medicinal purposes and bio-remediation is supportive. The major problems appear to exist only where GMOs are approved for use in food or feed.

The Commission cannot ignore the increasing public concern of European consumers, particularly in the light of recent food safety crises, and is taking steps to address the issues that have been highlighted. It is clear that in the future, biotechnology as a whole will only be accepted in Europe with public support.

Against this background, a number of initiatives are under consideration. First and foremost, the rapid adoption of the Commission Proposal to amend Directive 90/220/EEC should deliver an effective, efficient and transparent regulatory framework and provide the necessary certainty. It is also necessary to give full consideration to related issues that require specific attention including new labelling requirements, traceability and monitoring. Initiatives of the Commission should contribute to the ongoing debate that is being fuelled by the media.

6. What is your opinion about the feasibility and usefulness of round-table discussions, consensus conferences, technology assessment and the role that government, industry and NGO/public should play in these instruments ?

The Commission welcomes any initiative to discuss issues that facilitate the restoration of public confidence in biotechnology and GMO-products. In order to restore public confidence open dialogues between all stakeholders should lead to a better understanding of the problems, challenges and concerns of all citizens with regard to GMOs. In that sense the Commission is willing to give its support to initiatives aiming to achieve a better public understanding and perception. It also intends to actively contribute to this dialogue.

20 ECO-FORUM – NGO COALITION

Public Concerns

In the two years since the adoption of the Aarhus Convention, concerns about the lack of democracy with respect to use of GMOs have increased rather than decreased. There is huge public concern about the possible impact on food safety, consumer choice, biodiversity and sustainable agriculture. Yet in many countries information is hard to come by or unavailable, and opportunities for public participation range from none to minimal. This is despite rapid research and development of this new technology and the huge pressure for increasing the commercial exploitation of GMOs. For example, over 1500 field trials have been authorised in the EU alone, representing an advance of intense activity by the GMO industry. The revision of the EU Deliberate Release Directive 90/220 is partly aimed at strengthening access to information and public participation.

As much as we are generally concerned about access to information and public participation in decision-making on GMOs, we are particularly concerned that many CEE/NIS countries fall even further behind in these respects. In many countries there is no regulation whatsoever, leading to a legal and policy vacuum within which trans-national companies may operate to their own benefit, free of wider considerations. Decisions – if needed even - about deliberate release and use of GMOs are sometimes made in secrecy, without public involvement and participation. There are reports of bad practice emerging – such as a genetic engineer drafting laws on releases. This is completely unacceptable. Lack of public involvement and awareness of the debate could lead to inappropriate changes in agricultural practices before consideration of the wider implications of gene technologies is possible. There is potential for not just environmental, but social and economic damage. For example, market demand for GM food has collapsed in at least some EU countries, and it would be hugely inequitable if CEE/NIS countries were seen as an easy option for commercial growth because of the lack of public involvement. Ultimately, the Convention could play a key role in promoting the harmonisation of laws across the region.

Action in this area should be swift and we call upon Signatories (and other governments) -

- **immediately to apply the public participation provisions of Article 6** to GMO releases and other uses of GMOs;
- **in the interim to work on standards and guidelines** for information (including labelling and related information under Article 5.8) and public participation**;**
- **to develop explicit guaranteed rights** for citizens to be effectively involved in decision-making in this area.

Against this backdrop, we welcome the opportunity for this Task Force to contribute to strengthening the Aarhus Convention. We should build on

i) the **preamble** to the Convention – which recognises “the concern of the public about the deliberate release of genetically modified organisms into the environment and the need for increased transparency and greater public participation in decision-making in this field”;

ii) the **Resolution** of the Signatories – which recognises “the importance of the application of the provisions of the Convention to deliberate releases of genetically modified organisms into the environment” and request[ed] “the Parties, at their first meeting, to further develop the application of the Convention.”

iii) **Article 6.1(b)** which states that each Party “shall, in accordance with its national law, also apply the provisions of this article to decisions…not listed in annex I which may have a significant effect on the environment”;

iv) the **Cartagena Biosafety Protocol**, which

- by its very existence now acknowledges the special nature of GMOs;
- notes that Parties "are aware of the rapid expansion of modern biotechnology and the growing public concern…" ;
- takes into account "the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks…"; and
- has an objective "in accordance with the **precautionary approach** contained in Principle 15 of the Rio Declaration on Environment and Development" (Article 1) (our emphasis).

Strengthening the Aarhus Convention

In summary, the Convention should adopt explicit procedures for strengthening the right to know and public participation. It should provide for:

- an obligation for governments to provide public information regarding the environmental, health, biodiversity, social and economic impacts of uses and releases of GMOs and their products,
- public participation in consent procedures
- public participation in all risk assessments for immediate and delayed, and direct and indirect impacts, and including risk assessments covering health and socio-economic impacts
- public participation in construction of programmes to monitor immediate and delayed, and direct and indirect, impacts.

The Task Force should also share information on and consider the use of committees which include citizen representation (Hungary has such a biosafety committee) and lay persons' conferences established to consider the implications of GM technology.

The Right to Know

GMOs are included in the definition of environmental information. As a result, all provisions of the first pillar (access to information) of the Convention apply to GMOs. Nevertheless, it is important to highlight some specific ways in which information should be provided about GMOs. We also note that participants in the recent meeting of the Aarhus Convention Task Force on Pollutant Release and Transfer Registers (PRTRs) considered that GMOs might be a substance for inclusion in a PRTR type system.

The Public should have an explicit right to know about:

- all releases and uses of GMOs, including contained use, handling, transport, transfer, field trials, commercial cultivation, and placing on the market of GMOs intended for deliberate release as well as for food, feed, for processing, and processed foodstuffs;
- risk assessment reports, monitoring plans, environmental reviews, socio-economic studies and reviews, and information on emergency response plans;
- unintended releases of GMOs, including when an emergency situation arises from a release that may have significant adverse effect on the conservation and sustainable use of biological diversity, including risks to human health;
- notification and approval of export and import of GMOs.

Practical arrangements could also be specified – e.g. the establishment of public registers. Use of electronic data methods should be promoted. We note that the Biosafety Clearing-House to be established under the Biosafety Protocol will be Internet based by all accounts (although this is not specified in the protocol).

Furthermore, Article 5.8 should be elaborated to specify clear and unambiguous labelling of GMOs to ensure that consumers are able *"to make informed environmental choices"*.

The Right to Participate

By virtue of Article 6.11 and the lack of inclusion of GMO decision-making in Annex 1, the public participation provisions of the Convention do not treat GMOs as they do other activities with potential for significant effect on the environment. Few countries have laws that guarantee the public its proper role of participation in decision-making. The principles of the Convention should – quite logically – extend to GMO decision-making.

The public should have the right to participate at an early stage of decision-making on:

- -the issuing of permits for all releases and uses of GMOs, including contained use, handling, transport, transfer, field trials, commercial cultivation, and placing on the market of GMOs intended for deliberate release as well as for food, feed, for processing, and processed foodstuffs;
- risk assessments, monitoring plans, environmental reviews, socio-economic studies and reviews, and emergency response plans
- notification and approval of export and import of GMOs.

Ways forward

1. The NGO community is anxious that the Convention be strengthened without undue delay. Earlier in the paper we have called for **the establishment of a working group to develop standards and guidelines** which could make swift progress towards setting standards for labelling and public involvement in GMO decision-making.
2. Further amendment of the Convention could occur by **amending Annex 1** of the Convention and including:

   (a) advanced informed agreement procedures on import and export of GMOs

   (b) approval of field trials

   (c) approval of commercial scale cultivation and releases

   (d) placing on the market of GMOs intended for deliberate release as well as for food, feed, for processing, and processed foodstuffs

   (e) the approval of contained uses of GMOs.
3. Whilst we have concerns about the length of time it would take, a further alternative is to **adopt a protocol** on GMO decision-making:

   (a) to define important terminology;

   (b) to specify further the type of information available to the public on GMOs and forms of access;

   (c) to provide for public participation in risk assessments and in decisions involving releases and uses of GMOs, including contained use, handling, transport, transfer, field trials, commercial cultivation, and placing on the market of GMOs intended for deliberate release as well as for food, feed, for processing, and processed foodstuffs.

PART C BACKGROUND MATERIAL

1 LIST OF PARTICIPANTS

Armenia

Ms. Margarita Korkhmazyan
Ministry of Nature Protection
Dep. of International Co-operation
35 Moskovyan Street
Yerevan 375002, Armenia
Tel./Fax +37-42-53.18.61
e-mail: iterdpt@freenet.am
kormag@freenet.am

Austria

Mr. Helmut Gaugitsch
Federal Environment Agency
Spittelauer Lände 5
A-1090 Wien
Tel. +43-1-31304-3710
Fax +43-1-31304-3700
e-mail: gaugitsch@ubavie.gv.at

Mr.Johannes Mayer
Federal Environment Agency
Spittelauer Lände 5
A-1090 Wien
Tel. +43-1-31304-3240
Fax +43-1-31304-3211
e-mail: mayer@ubavie.gv.at

Ms. Silvia Pultz
Federal Ministry for Agriculture, Forestry,
Environment and Water Management
Stubenbastei 5
A-1010 Wien
Tel. +43-1-51522-3732
Fax +43-1-51522-7331
e-mail: silvia.pultz@bmu.gv.at

Mr. Georg Zimmermann
Arbeitsgemeinschaft
Schöpfungsverantwortung
Spiegelgasse 3/2,
A-1010 Vienna
Tel. +43-1-51552-3667
Fax +43-1-51552-3663
e-mail: argeschoepfung@xpoint.at

Ms. Lilia Kirova
Federal Environment Agency
Spittelauer Lände 5
A-1090 Wien
Tel. +43-1-31304-3261
Fax +43-1-31304-3211
e-mail: kirova@ubavie.gv.at

Belgium

Ms. Lieze Cloots
Ministry of the Flemish Community
AMINAL (Environment, Nature, Land
and Water Management Administration)
Koning Albert II Laan 20
B-1000 Brussel
Tel. +32-2-553.81.76
Fax +32-2-553.81.65
e-mail: lieze.cloots@lin.vlaanderen.be

Mr. Marc Smaers
AMINAL (Environment, Nature, Land
and Water Management Administration)
Koning Albert II-Laan 20
B-1000 Brussel
Tel. +32-2-553.81.26
Fax +32-2-553.81.65
e-mail: marc.smaers@lin.vlaanderen.be

Mr. Jan Heyman
Flemish Environment Agency
A. Van de Maelestraat 96
B-9320 Erembodegem
Tel. +32-53-726.634
Fax +32-53-726.630
e-mail: j.heyman@vmm.be

Bulgaria

Ms. Evdokia Maneva
Minister of Environment and Waters
67, William Gladstone str.
BG-1000 Sofia
Tel. +359-2-88.25.77
Fax +359-2-986.25.33

Mr. Atanas Kaimaktchiev
Seceretary General
Ministry of Environment and Waters
67, William Gladstone str.
BG-1000 Sofia
Tel. +359-2-87.10.43, 980.09.05
Fax +359-2-981.11.85
e-mail: akaimaktchiev@moew.govrn.bg

Ms. Nelly Ilieva
Ministry of Environment and Waters
Information Unit
67, William Gladstone str.
BG-1000 Sofia
Tel. +359-2-940.6.299
e-mail: ilievanelly@moew.govrn.bg

Ms. Denitsa Nedeva
Ministry of Environment and Waters
European Integration Directorate
67, William Gladstone str.
BG-1000 Sofia
Tel. +359-2-940.6.282
Fax +359-2-986.48.48
e-mail: dnedeva@moew.govrn.bg

Mr. Gantcho Armianov
Council for Biosafety of Genetically
Modified Higher Plants
IGE - Kostinbrod
Tel. +359-7-21.25.52
e-mail: geneng@mtel.net

Ms Nedka Shivarova
Bulgarian Academy of Sciences
Institute for Microbiology
BG-Sofia 1113
Tel. +359-2-979.31.14
e-mail: netty@microbio.bas.bg

Denmark

Ms. Camilla Mathiesen
National Forest and Nature Agency
Dept. of Agriculture and Biotechnology
Haraldsgade 53
DK-2100 Copenhagen Ø
Tel. +45-39.47.20.00
Fax +45-39.47.27.65
e-mail: cmm @sns.dk

Finland

Ms. Tuula Pehu
Ministry of the Environment
Environmental Protection Dept.
P.O.Box 380
FIN - 00131 Helsinki
Tel. ++358-9-160.9310
Fax ++358-9-160.9630
e-mail: Tuula.Pehu@vyh.fi

Ms. Helena von Troil
National Advisory Board for Biotechnology
Rikhard Nymantie 9 B
FIN - 00370 Helsinki
Tel. +358-40-544.9981
Fax +358-9-556.383
e-mail: helena.troil@clarinet.fi

Georgia

Ms Tamar Gobejishvili
Ministry of Environment and Natural
Resources
Dep. of Public Relations and Envt.
Education
68a Kostava str.
Tbilisi 380015, Georgia
Tel./Fax +995-32-33.40.82
e-mail: gmep@caucasus.net

Nato Kirvalidze
Environmental Information and
Sustainable Development Centre „Rio“
Saburtalo Street 57A/48
Tbilisi 380077, Georgia
Tel. +995-32-966.956
Fax +995-32-967.971
e-mail: rio@caucasus.net

Germany

Mr. Thomas Rolf
Federal Ministry for the Environment,
Nature Conservation and Nuclear Safety
Alexanderplatz 6
D-10178 Berlin
Tel. +49-1888/305-2361
Fax +49-1888/305-3331
e-mail: Rolf.Thomas@bmu.de

Mr. Hansgeorg Sengewein
Federal Ministry for the Environment,
Nature Conservation and Nuclear Safety
Postfach 12 06 29

D-53048 Bonn
Tel. +49-228-305.2662
Fax +49-228-305.2695
e-mail: Sengewein.Hansgeorg@bmu.de

Netherlands

Ms. Katja Lasseur
Ministry of Housing, Spatial Planning
and the Environment
PO BOX 670
2500 GX The Hague
Tel. ++31-70-33.91.981
Fax ++31-70-33.91.306
e-mail:
Katja.Lasseur@dimz.dgm.minvrom.nl

Mr. Piet van der Meer
(Project: Implementation of national biosafety frameworks in pre-accession countries in Central and Eastern Europe)
Agricultural Biotechnology Center
P.O.Box 411
H-2101 Gödöllö
e-mail: 100302.1420@compuserve.com

Norway

Ms. Birthe Ivars
Ministry of the Environment
P.O.Box 8013 Dep.
0030 Oslo, Norway
Tel. +32-2-351.52.98
Fax +47-22-24.27.56
e-mail: birthe.ivars@skynet.be

The former Yugoslav Republic of Macedonia

Ms. Maria Dirlevska-Caloska
Ministry of Environment
Drezdenska 52
91000 Skopje
Tel. +389-91-366.930 ext. 122,154
Fax +389-91-366-931
e-mail: pcal@stat.gov.mk

United Kingdom

David Steele
Biotechnology Safety Unit
Department of the Environment,
Transport and the Regions
Ashdown House
123 Victoria Street
London SW1 5DU
Tel. +44-171-890.5916
Fax +44-171-890.5229
e-mail: david_steele@detr.gsi.gov.uk

NGOs

Friends of the Earth
Mary Taylor
26-28 Underwood Str.
London NI 7JQ, UK
Tel. +44-20-7566.1687
Fax +44-20-7490.0881
e-mail: maryt@foe.co.uk

EcoForum NGO Coalition
Public Participation Campaign Committee
Svitlana Kravchenko
Ecopravo-Lviv
2, Krushelnitska Str.
Lviv 290000, Ukraine
Tel. +38-0322-72.27.46
Fax +38-0322-97.14.46
e-mail: slana@icmp.lviv.ua

Information Center „Green Dossier"
Ms. Tamara Malkowa
P.O.B. 201
Kiev 01025, Ukraine
Tel./Fax: +38-044-476.84.28
e-mail: tamara@akcecc.kiev.ua

Friends of the Earth Europe
Mr. Dan Leskien
29, rue Blanche
B-1060 Bruxelles
Tel. +32-2-542.61.01
Fax +32-2-537.55.96
e-mail: Dan.Leskien@gmx.net

Borrowed Nature
Mr. Kliment Mindjov
20-B, Al.Stamboliyski Blvd.
BG-1000 Sofia
Tel. +359-2-981.66.15
Fax +359-2-986.45.74
e-mail: kmindjov@mbox.cit.bg
Demeter
Alexander Kodjabashev
Bld Skobelev, 16, vhod 2
BG-1463 Sofia

Tel. +359-2-526.956
Fax +359-2-986.45.74
e-mail: demetra@iterra.net

ANPED
Ms. Iza Kruszewska
P.O.Box 12201
London SW17 9ZL, UK
Tel.&Fax +44-20-867.34.54
e-mail: iza@cpa-iza.u-net.com

Regional Environmental Center for Central and Eastern Europe (REC)

Ms. Magda Toth Nagy
Ady E. u. 9-11
H-2000 Szentendre
Tel. +36-26-311.199-115
Fax +36-26-311.294
e-mail: tmagdi@rec.org

Mr. Stephen Stec
REC
Ady E. u. 9-11
H-2000 Szentendre
Tel. +36-26-311.199-101
Fax +36-26-311.294
e-mail: sstec@rec.org

UN-ECE

Mr. Jeremy Wates
Secretary / Aarhus Convention
Environment and Human Settlements Division
Economic Commission for Europe
Palais de Nations
CH-1211 Geneva 10
Tel. +41-22-917.2384
Fax +41-22-907.0107
jeremy.wates@unece.org

Ms. Mariya Kostytska
Tel. +41-22-789.5007
e-mail: mariya.kostytska@unece.org
mkostyts@hotmail.com

1.1 Written Contributions

Estonia

Ms Liina Eek
Department of Nature Protection
Ministry of the Environment
Toompuiestee 24
Tallinn 15172
Estonia
Tel. + 372 6262 877
Fax + 372 6262 801
e-mail leek@ut.ee

Hungary

Ms Eva Szopper
Hungarian Ministry for Environment
e-mail: szopper.eva@ktmdom2.ktm.hu
or: benko.gyongyi@ktmdom2.ktm.hu

Iceland

Mr Sigridur Stefansdottir
Ministry for the Environment
Vonarstraeti 4
IS – 150 Reykjavik, Iceland
Tel. +354-560.9600
Fax +354-562.4566
e-mail: postur@umh.stjr.is

Italy

Mr. Carlo Zaghi
Ministry for the Environment
Via C.Colombo, 44
00147 Roma - Italia
Tel. +39-06-57.22.5161
Fax +39-06-57.22.5097
e-mail:
francesco.lacamera@via.minambiente.it

Latvia

Ms Dace Dravniece
Ministry of Environmental Protection and Regional Development
Environmental Protection Department
Street Peldu 25, Riga, LV-1494
Latvia
Tel. +371 7026512
Fax +371 7820442
e-mail rasa@varam.gov.lv

Slovenia

Ms Biserka Strel
Counsellor to the Government
Ministry of Environment and Physical Planning
Nature Protection Department
Dunajska c.48, 1000 Ljubljana
Slovenia
Tel.+386 61 1787 338
Fax.+386 61 1787 422

European Commission

Mr Daniele Franzone
DG Environment
E1. Industrial installations and hazards, biotechnology
200 rue de la Loi
B – 1049 Bruxelles
Tel. +32-2-295.04.76
Fax: +32-2-296.62.33
Daniele.Franzone@cec.eu.int

2 AARHUS CONVENTION

Distr.
GENERAL
ECE/CEP/43
21 April 1998
ORIGINAL : ENGLISH

ECONOMIC COMMISSION FOR EUROPE

COMMITTEE ON ENVIRONMENTAL POLICY

Fourth Ministerial Conference
„Environment for Europe“,
Aarhus, Denmark, 23-25 June 1998

CONVENTION ON ACCESS TO INFORMATION, PUBLIC PARTICIPATION IN DECISION-MAKING AND ACCESS TO JUSTICE IN ENVIRONMENTAL MATTERS */

The Parties to this Convention,

Recalling principle l of the Stockholm Declaration on the Human Environment,

Recalling also principle 10 of the Rio Declaration on Environment and Development,

Recalling further General Assembly resolutions 37/7 of 28 October 1982 on the World Charter for Nature and 45/94 of 14 December 1990 on the need to ensure a healthy environment for the well-being of individuals,

Recalling the European Charter on Environment and Health adopted at the First European Conference on Environment and Health of the World Health Organization in Frankfurt-am-Main, Germany, on 8 December 1989,

*/ Final text endorsed by the Committee on Environmental Policy at its special session on 16-18 March 1998 for adoption at the Ministerial Conference „Environment for Europe“.

Affirming the need to protect, preserve and improve the state of the environment and to ensure sustainable and environmentally sound development,

Recognizing that adequate protection of the environment is essential to human well-being and the enjoyment of basic human rights, including the right to life itself,

Recognizing also that every person has the right to live in an environment adequate to his or her health and well-being, and the duty, both individually and in association with others, to protect and improve the environment for the benefit of present and future generations,

Considering that, to be able to assert this right and observe this duty, citizens must have access to information, be entitled to participate in decision-making and have access to justice in environmental matters, and acknowledging in this regard that citizens may need assistance in order to exercise their rights,

Recognizing that, in the field of the environment, improved access to information and public participation in decision-making enhance the quality and the implementation of decisions, contribute to public awareness of environmental issues, give the public the opportunity to express its concerns and enable public authorities to take due account of such concerns,

Aiming thereby to further the accountability of and transparency in decision-making and to strengthen public support for decisions on the environment,

Recognizing the desirability of transparency in all branches of government and inviting legislative bodies to implement the principles of this Convention in their proceedings,

Recognizing also that the public needs to be aware of the procedures for participation in environmental decision-making, have free access to them and know how to use them,

Recognizing further the importance of the respective roles that individual citizens, non-governmental organizations and the private sector can play in environmental protection,

Desiring to promote environmental education to further the understanding of the environment and sustainable development and to encourage widespread public awareness of, and participation in, decisions affecting the environment and sustainable development,

Noting, in this context, the importance of making use of the media and of electronic or other, future forms of communication,

Recognizing the importance of fully integrating environmental considerations in governmental decision-making and the consequent need for public authorities to be in possession of accurate, comprehensive and up-to-date environmental information,

Acknowledging that public authorities hold environmental information in the public interest,

Concerned that effective judicial mechanisms should be accessible to the public, including organizations, so that its legitimate interests are protected and the law is enforced,

Noting the importance of adequate product information being provided to consumers to enable them to make informed environmental choices,

Recognizing the concern of the public about the deliberate release of genetically modified organisms into the environment and the need for increased transparency and greater public participation in decision-making in this field,

Convinced that the implementation of this Convention will contribute to strengthening democracy in the region of the United Nations Economic Commission for Europe (ECE),

Conscious of the role played in this respect by ECE and recalling, inter alia, the ECE Guidelines on Access to Environmental Information and Public Participation in Environmental Decision-making endorsed in the Ministerial Declaration adopted at the Third Ministerial Conference "Environment for Europe" in Sofia, Bulgaria, on 25 October 1995,

Bearing in mind the relevant provisions in the Convention on Environmental Impact Assessment in a Transboundary Context, done at Espoo, Finland, on 25 February 1991, and the Convention on the Transboundary Effects of Industrial Accidents and the Convention on the Protection and Use of Transboundary Watercourses and International Lakes, both done at Helsinki on 17 March 1992, and other regional conventions,

Conscious that the adoption of this Convention will have contributed to the further strengthening of the "Environment for Europe" process and to the results of the Fourth Ministerial Conference in Aarhus, Denmark, in June 1998,

Have agreed as follows:

Article 1

OBJECTIVE

In order to contribute to the protection of the right of every person of present and future generations to live in an environment adequate to his or her health and well-being, each Party shall guarantee the rights of access to information, public participation in decision-making, and access to justice in environmental matters in accordance with the provisions of this Convention.

Article 2

DEFINITIONS

For the purposes of this Convention,

1. „Party“ means, unless the text otherwise indicates, a Contracting Party to this Convention;

2. „Public authority“ means:

(a) Government at national, regional and other level;

(b) Natural or legal persons performing public administrative functions under national law, including specific duties, activities or services in relation to the environment;

(c) Any other natural or legal persons having public responsibilities or functions, or providing public services, in relation to the environment, under the control of a body or person falling within subparagraphs (a) or (b) above;

(d) (d)The institutions of any regional economic integration organization referred to in article 17 which is a Party to this Convention.

This definition does not include bodies or institutions acting in a judicial or legislative capacity;

3. „Environmental information“ means any information in written, visual, aural, electronic or any other material form on:

(a) The state of elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites, biological diversity and its components, including genetically modified organisms, and the interaction among these elements;

(b) Factors, such as substances, energy, noise and radiation, and activities or measures, including administrative measures, environmental agreements, policies, legislation, plans and programmes, affecting or likely to affect the elements of the environment within the scope of subparagraph (a) above, and cost-benefit and other economic analyses and assumptions used in environmental decision-making;

(c) The state of human health and safety, conditions of human life, cultural sites and built structures, inasmuch as they are or may be affected by the state of the elements of the environment or,

through these elements, by the factors, activities or measures referred to in subparagraph (b) above;

4. „The public“ means one or more natural or legal persons, and, in accordance with national legislation or practice, their associations, organizations or groups;

5. „The public concerned“ means the public affected or likely to be affected by, or having an interest in, the environmental decision-making; for the purposes of this definition, non-governmental organizations promoting environmental protection and meeting any requirements under national law shall be deemed to have an interest.

Article 3

GENERAL PROVISIONS

1. Each Party shall take the necessary legislative, regulatory and other measures, including measures to achieve compatibility between the provisions implementing the information, public participation and access-to-justice provisions in this Convention, as well as proper enforcement measures, to establish and maintain a clear, transparent and consistent framework to implement the provisions of this Convention.

2. Each Party shall endeavour to ensure that officials and authorities assist and provide guidance to the public in seeking access to information, in facilitating participation in decision-making and in seeking access to justice in environmental matters.

3. Each Party shall promote environmental education and environmental awareness among the public, especially on how to obtain access to information, to participate in decision-making and to obtain access to justice in environmental matters.

4. Each Party shall provide for appropriate recognition of and support to associations, organizations or groups promoting environmental protection and ensure that its national legal system is consistent with this obligation.

5. The provisions of this Convention shall not affect the right of a Party to maintain or introduce measures providing for broader access to information, more extensive public participation in decision-making and wider access to justice in environmental matters than required by this Convention.

6. This Convention shall not require any derogation from existing rights of access to information, public participation in decision-making and access to justice in environmental matters.

7. Each Party shall promote the application of the principles of this Convention in international environmental decision-making processes and within the framework of international organizations in matters relating to the environment.

8. Each Party shall ensure that persons exercising their rights in conformity with the provisions of this Convention shall not be penalized, persecuted or harassed in any way for their involvement. This provision shall not affect the powers of national courts to award reasonable costs in judicial proceedings.

9. Within the scope of the relevant provisions of this Convention, the public shall have access to information, have the possibility to participate in decision-making and have access to justice in environmental matters without discrimination as to citizenship, nationality or domicile and, in the case of a legal person, without discrimination as to where it has its registered seat or an effective centre of its activities.

Article 4

ACCESS TO ENVIRONMENTAL INFORMATION

1. Each Party shall ensure that, subject to the following paragraphs of this article, public authorities, in response to a request for environmental information, make such information available to the public, within the framework of national legislation, including, where requested and subject to subparagraph (b) below, copies of the actual documentation containing or comprising such information:

(a) Without an interest having to be stated;

(b) In the form requested unless:

(i) It is reasonable for the public authority to make it available in another form, in which case reasons shall be given for making it available in that form; or

(ii) The information is already publicly available in another form.

2. The environmental information referred to in paragraph 1 above shall be made available as soon as possible and at the latest within one month after the request has been submitted, unless the volume and the complexity of the information justify an extension of this period up to two months after the request. The applicant shall be informed of any extension and of the reasons justifying it.

3. A request for environmental information may be refused if:

(a) The public authority to which the request is addressed does not hold the environmental information requested;

(b) The request is manifestly unreasonable or formulated in too general a manner; or

(c) The request concerns material in the course of completion or concerns internal communications of public authorities where such an exemption is provided for in national law or customary practice, taking into account the public interest served by disclosure.

4. A request for environmental information may be refused if the disclosure would adversely affect:

(a) The confidentiality of the proceedings of public authorities, where such confidentiality is provided for under national law;

(b) International relations, national defence or public security;

(c) The course of justice, the ability of a person to receive a fair trial or the ability of a public authority to conduct an enquiry of a criminal or disciplinary nature;

(d) The confidentiality of commercial and industrial information, where such confidentiality is protected by law in order to protect a legitimate economic interest. Within this framework, information on emissions which is relevant for the protection of the environment shall be disclosed;

(e) Intellectual property rights;

(f) The confidentiality of personal data and/or files relating to a natural person where that person has not consented to the disclosure of the information to the public, where such confidentiality is provided for in national law;

(g) The interests of a third party which has supplied the information requested without that party being under or capable of being put under a legal obligation to do so, and where that party does not consent to the release of the material; or

(h) The environment to which the information relates, such as the breeding sites of rare species.

The aforementioned grounds for refusal shall be interpreted in a restrictive way, taking into account the public interest served by disclosure and taking into account whether the information requested relates to emissions into the environment.

5. Where a public authority does not hold the environmental information requested, this public authority shall, as promptly as possible, inform the applicant of the public authority to which it believes it is possible to apply for the information requested or transfer the request to that authority and inform the applicant accordingly.

6. Each Party shall ensure that, if information exempted from disclosure under paragraphs 3 (c) and 4 above can be separated out without prejudice to the confidentiality of the information exempted, public authorities make available the remainder of the environmental information that has been requested.

7. A refusal of a request shall be in writing if the request was in writing or the applicant so requests. A refusal shall state the reasons for the refusal and give information on access to the review procedure provided for in accordance with article 9. The refusal shall be made as soon as possible and at the latest within one month, unless the complexity of the information justifies an extension of this period up to two months after the request. The applicant shall be informed of any extension and of the reasons justifying it.

8. Each Party may allow its public authorities to make a charge for supplying information, but such charge shall not exceed a reasonable amount. Public authorities intending to make such a charge for supplying information shall make available to applicants a schedule of charges which may be levied, indicating the circumstances in which they may be levied or waived and when the supply of information is conditional on the advance payment of such a charge.

Article 5

COLLECTION AND DISSEMINATION OF ENVIRONMENTAL INFORMATION

1. Each Party shall ensure that:

(a) Public authorities possess and update environmental information which is relevant to their functions;

(b) Mandatory systems are established so that there is an adequate flow of information to public authorities about proposed and existing activities which may significantly affect the environment;

(c) In the event of any imminent threat to human health or the environment, whether caused by human activities or due to natural causes, all information which could enable the public to take measures to prevent or mitigate harm arising from the threat and is held by a public authority is disseminated immediately and without delay to members of the public who may be affected.

2. Each Party shall ensure that, within the framework of national legislation, the way in which public authorities make environmental information available to the public is transparent and that environmental information is effectively accessible, inter alia, by:

(a) Providing sufficient information to the public about the type and scope of environmental information held by the relevant public authorities, the basic terms and conditions under which such information is made available and accessible, and the process by which it can be obtained;

(b) Establishing and maintaining practical arrangements, such as:

(i) Publicly accessible lists, registers or files;

(ii) Requiring officials to support the public in seeking access to information under this Convention; and

(iii) The identification of points of contact; and

(c) Providing access to the environmental information contained in lists, registers or files as referred to in subparagraph (b) (i) above free of charge.

3. Each Party shall ensure that environmental information progressively becomes available in electronic databases which are easily accessible to the public through public telecommunications networks. Information accessible in this form should include:

(a) Reports on the state of the environment, as referred to in paragraph 4 below;

(b) Texts of legislation on or relating to the environment;

(c) As appropriate, policies, plans and programmes on or relating to the environment, and environmental agreements; and

(d) Other information, to the extent that the availability of such information in this form would facilitate the application of national law implementing this Convention,

provided that such information is already available in electronic form.

4. Each Party shall, at regular intervals not exceeding three or four years, publish and disseminate a national report on the state of the environment, including information on the quality of the environment and information on pressures on the environment.

5. Each Party shall take measures within the framework of its legislation for the purpose of disseminating, inter alia:

(a) Legislation and policy documents such as documents on strategies, policies, programmes and action plans relating to the environment, and progress reports on their implementation, prepared at various levels of government;

(b) International treaties, conventions and agreements on environmental issues; and

(c) Other significant international documents on environmental issues, as appropriate.

6. Each Party shall encourage operators whose activities have a significant impact on the environment to inform the public regularly of the environmental impact of their activities and products, where appropriate within the framework of voluntary eco-labelling or eco-auditing schemes or by other means.

7. Each Party shall:

(a) Publish the facts and analyses of facts which it considers relevant and important in framing major environmental policy proposals;

(b) Publish, or otherwise make accessible, available explanatory material on its dealings with the public in matters falling within the scope of this Convention; and

(c) Provide in an appropriate form information on the performance of public functions or the provision of public services relating to the environment by government at all levels.

8. Each Party shall develop mechanisms with a view to ensuring that sufficient product information is made available to the public in a manner which enables consumers to make informed environmental choices.

9. Each Party shall take steps to establish progressively, taking into account international processes where appropriate, a coherent, nationwide system of pollution inventories or registers on a structured, computerized and publicly accessible database compiled through standardized reporting. Such a system may include inputs, releases and transfers of a specified range of substances and products, including water, energy and resource use, from a specified range of activities to environmental media and to on-site and off-site treatment and disposal sites.

10. Nothing in this article may prejudice the right of Parties to refuse to disclose certain environmental information in accordance with article 4, paragraphs 3 and 4.

Article 6

PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES

1. Each Party:

(a) Shall apply the provisions of this article with respect to decisions on whether to permit proposed activities listed in annex I;

(b) Shall, in accordance with its national law, also apply the provisions of this article to decisions on proposed activities not listed in annex I which may have a significant effect on the environment. To this end, Parties shall determine whether such a proposed activity is subject to these provisions; and

(c) May decide, on a case-by-case basis if so provided under national law, not to apply the provisions of this article to proposed activities serving national defence purposes, if that Party deems that such application would have an adverse effect on these purposes.

2. The public concerned shall be informed, either by public notice or individually as appropriate, early in an environmental decision-making procedure, and in an adequate, timely and effective manner, inter alia, of:

(a) The proposed activity and the application on which a decision will be taken;

(b) The nature of possible decisions or the draft decision;

(c) The public authority responsible for making the decision;

(d) The envisaged procedure, including, as and when this information can be provided:

  (i) The commencement of the procedure;

  (ii) The opportunities for the public to participate;

  (iii) The time and venue of any envisaged public hearing;

  (iv) An indication of the public authority from which relevant information can be obtained and where the relevant information has been deposited for examination by the public;

  (v) An indication of the relevant public authority or any other official body to which comments or questions can be submitted and of the time schedule for transmittal of comments or questions; and

  (vi) An indication of what environmental information relevant to the proposed activity is available; and

(e) The fact that the activity is subject to a national or transboundary environmental impact assessment procedure.

3. The public participation procedures shall include reasonable timeframes for the different phases, allowing sufficient time for informing the public in accordance with paragraph 2 above and for the public to prepare and participate effectively during the environmental decision-making.

4. Each Party shall provide for early public participation, when all options are open and effective public participation can take place.

5. Each Party should, where appropriate, encourage prospective applicants to identify the public concerned, to enter into discussions, and to provide information regarding the objectives of their application before applying for a permit.

6. Each Party shall require the competent public authorities to give the public concerned access for examination, upon request where so required under national law, free of charge and as soon as it becomes available, to all information relevant to the decision-making referred to in this article that is available at the time of the public participation procedure, without prejudice to the right of Parties to refuse to disclose certain information in accordance with article 4, paragraphs 3 and 4. The relevant information shall include at least, and without prejudice to the provisions of article 4:

(a) A description of the site and the physical and technical characteristics of the proposed activity, including an estimate of the expected residues and emissions;

(b) A description of the significant effects of the proposed activity on the environment;

(c) A description of the measures envisaged to prevent and/or reduce the effects, including emissions;

(d) A non-technical summary of the above;

(e) An outline of the main alternatives studied by the applicant; and

(f) In accordance with national legislation, the main reports and advice issued to the public authority at the time when the public concerned shall be informed in accordance with paragraph 2 above.

7. Procedures for public participation shall allow the public to submit, in writing or, as appropriate, at a public hearing or inquiry with the applicant, any comments, information, analyses or opinions that it considers relevant to the proposed activity.

8. Each Party shall ensure that in the decision due account is taken of the outcome of the public participation.

9. Each Party shall ensure that, when the decision has been taken by the public authority, the public is promptly informed of the decision in accordance with the appropriate procedures. Each Party shall make accessible to the public the text of the decision along with the reasons and considerations on which the decision is based.

10. Each Party shall ensure that, when a public authority reconsiders or updates the operating conditions for an activity referred to in paragraph 1, the provisions of paragraphs 2 to 9 of this article are applied mutatis mutandis, and where appropriate.

11. Each Party shall, within the framework of its national law, apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment.

Article 7

PUBLIC PARTICIPATION CONCERNING PLANS, PROGRAMMES AND POLICIES RELATING TO THE ENVIRONMENT

Each Party shall make appropriate practical and/or other provisions for the public to participate during the preparation of plans and programmes relating to the environment, within a transparent and fair framework, having provided the necessary information to the public. Within this framework, article 6, paragraphs 3, 4 and 8, shall be applied. The public which may participate shall be identified by the relevant public authority, taking into account the objectives of this Convention. To the extent appropriate, each Party shall endeavour to provide opportunities for public participation in the preparation of policies relating to the environment.

Article 8

PUBLIC PARTICIPATION DURING THE PREPARATION OF EXECUTIVE REGULATIONS AND/OR GENERALLY APPLICABLE LEGALLY BINDING NORMATIVE INSTRUMENTS

Each Party shall strive to promote effective public participation at an appropriate stage, and while options are still open, during the preparation by public authorities of executive regulations and other generally applicable legally binding rules that may have a significant effect on the environment. To this end, the following steps should be taken:

(a) Time-frames sufficient for effective participation should be fixed;

(b) Draft rules should be published or otherwise made publicly available; and

(c) The public should be given the opportunity to comment, directly or through representative consultative bodies.

The result of the public participation shall be taken into account as far as possible.

Article 9

ACCESS TO JUSTICE

1. Each Party shall, within the framework of its national legislation, ensure that any person who considers that his or her request for information under article 4 has been ignored, wrongfully refused, whether in part or in full, inadequately answered, or otherwise not dealt with in accordance with the provisions of that article, has access to a review procedure before a court of law or another independent and impartial body established by law.

In the circumstances where a Party provides for such a review by a court of law, it shall ensure that such a person also has access to an expeditious procedure established by law that is free of charge or inexpensive for reconsideration by a public authority or review by an independent and impartial body other than a court of law.

Final decisions under this paragraph 1 shall be binding on the public authority holding the information. Reasons shall be stated in wri-

ting, at least where access to information is refused under this paragraph.

2. Each Party shall, within the framework of its national legislation, ensure that members of the public concerned

(a) Having a sufficient interest

or, alternatively,

(b) Maintaining impairment of a right, where the administrative procedural law of a Party requires this as a precondition,

have access to a review procedure before a court of law and/or another independent and impartial body established by law, to challenge the substantive and procedural legality of any decision, act or omission subject to the provisions of article 6 and, where so provided for under national law and without prejudice to paragraph 3 below, of other relevant provisions of this Convention.

What constitutes a sufficient interest and impairment of a right shall be determined in accordance with the requirements of national law and consistently with the objective of giving the public concerned wide access to justice within the scope of this Convention. To this end, the interest of any non-governmental organization meeting the requirements referred to in article 2, paragraph 5, shall be deemed sufficient for the purpose of subparagraph (a) above. Such organizations shall also be deemed to have rights capable of being impaired for the purpose of subparagraph (b) above.

The provisions of this paragraph 2 shall not exclude the possibility of a preliminary review procedure before an administrative authority and shall not affect the requirement of exhaustion of administrative review procedures prior to recourse to judicial review procedures, where such a requirement exists under national law.

3. In addition and without prejudice to the review procedures referred to in paragraphs 1 and 2 above, each Party shall ensure that, where they meet the criteria, if any, laid down in its national law, members of the public have access to administrative or judicial procedures to challenge acts and omissions by private persons and public authorities which contravene provisions of its national law relating to the environment.

4. In addition and without prejudice to paragraph 1 above, the procedures referred to in paragraphs 1, 2 and 3 above shall provide adequate and effective remedies, including injunctive relief as appropriate, and be fair, equitable, timely and not prohibitively expensive. Decisions under this article shall be given or recorded in writing. Decisions of courts, and whenever possible of other bodies, shall be publicly accessible.

5. In order to further the effectiveness of the provisions of this article, each Party shall ensure that information is provided to the public on access to administrative and judicial review procedures and shall consider the establishment of appropriate assistance mechanisms to remove or reduce financial and other barriers to access to justice.

Article 10

MEETING OF THE PARTIES

1. The first meeting of the Parties shall be convened no later than one year after the date of the entry into force of this Convention. Thereafter, an ordinary meeting of the Parties shall be held at least once every two years, unless otherwise decided by the Parties, or at the written request of any Party, provided that, within six months of the request being communicated to all Parties by the Executive Secretary of the Economic Commission for Europe, the said request is supported by at least one third of the Parties.

2. At their meetings, the Parties shall keep under continuous review the implementation of this Convention on the basis of regular reporting by the Parties, and, with this purpose in mind, shall:

(a) Review the policies for and legal and methodological approaches to access to information, public participation in decision-making and access to justice in environmental matters, with a view to further improving them;

(b) Exchange information regarding experience gained in concluding and implementing bilateral and multilateral agreements or other arrangements having relevance to the purposes of this Convention and to which one or more of the Parties are a party;

(c) Seek, where appropriate, the services of relevant ECE bodies and other competent international bodies and specific committees in all aspects pertinent to the achievement of the purposes of this Convention;

(d) Establish any subsidiary bodies as they deem necessary;

(e) Prepare, where appropriate, protocols to this Convention;

(f) Consider and adopt proposals for amendments to this Convention in accordance with the provisions of article 14;

(g) Consider and undertake any additional action that may be required for the achievement of the purposes of this Convention;

(h) At their first meeting, consider and by consensus adopt rules of procedure for their meetings and the meetings of subsidiary bodies;

(i) At their first meeting, review their experience in implementing the provisions of article 5, paragraph 9, and consider what steps are necessary to develop further the system referred to in that paragraph, taking into account international processes and developments, including the elaboration of an appropriate instrument concerning pollution release and transfer registers or inventories which could be annexed to this Convention.

3. The Meeting of the Parties may, as necessary, consider establishing financial arrangements on a consensus basis.

4. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State or regional economic integration organization entitled under article 17 to sign this Convention but which is not a Party to this Convention, and any intergovernmental organization qualified in the fields to which

this Convention relates, shall be entitled to participate as observers in the meetings of the Parties.

5. Any non-governmental organization, qualified in the fields to which this Convention relates, which has informed the Executive Secretary of the Economic Commission for Europe of its wish to be represented at a meeting of the Parties shall be entitled to participate as an observer unless at least one third of the Parties present in the meeting raise objections.

6. For the purposes of paragraphs 4 and 5 above, the rules of procedure referred to in paragraph 2 (h) above shall provide for practical arrangements for the admittance procedure and other relevant terms.

Article 11

RIGHT TO VOTE

1. Except as provided for in paragraph 2 below, each Party to this Convention shall have one vote.

2. Regional economic integration organizations, in matters within their competence, shall exercise their right to vote with a number of votes equal to the number of their member States which are Parties to this Convention. Such organizations shall not exercise their right to vote if their member States exercise theirs, and vice versa.

Article 12

SECRETARIAT

The Executive Secretary of the Economic Commission for Europe shall carry out the following secretariat functions:

(a) The convening and preparing of meetings of the Parties;

(b) The transmission to the Parties of reports and other information received in accordance with the provisions of this Convention; and

(c) Such other functions as may be determined by the Parties.

Article 13

ANNEXES

The annexes to this Convention shall constitute an integral part thereof.

Article 14

AMENDMENTS TO THE CONVENTION

1. Any Party may propose amendments to this Convention.
2. The text of any proposed amendment to this Convention shall be submitted in writing to the Executive Secretary of the Economic Commission for Europe, who shall communicate it to all Parties at least ninety days before the meeting of the Parties at which it is proposed for adoption.
3. The Parties shall make every effort to reach agreement on any proposed amendment to this Convention by consensus. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a three-fourths majority vote of the Parties present and voting at the meeting.
4. Amendments to this Convention adopted in accordance with paragraph 3 above shall be communicated by the Depositary to all Parties for ratification, approval or acceptance. Amendments to this Convention other than those to an annex shall enter into force for Parties having ratified, approved or accepted them on the ninetieth day after the receipt by the Depositary of notification of their ratification, approval or acceptance by at least three fourths of these Parties. Thereafter they shall enter into force for any other Party on the ninetieth day after that Party deposits its instrument of ratification, approval or acceptance of the amendments.
5. Any Party that is unable to approve an amendment to an annex to this Convention shall so notify the Depositary in writing within twelve months from the date of the communication of the adoption. The Depositary shall without delay notify all Parties of any such notification received. A Party may at any time substitute an acceptance for its previous notification and, upon deposit of an instrument of acceptance with the Depositary, the amendments to such an annex shall become effective for that Party.
6. On the expiry of twelve months from the date of its communication by the Depositary as provided for in paragraph 4 above an amendment to an annex shall become effective for those Parties which have not submitted a notification to the Depositary in accordance with the provisions of paragraph 5 above, provided that not more than one third of the Parties have submitted such a notification.
7. For the purposes of this article, "Parties present and voting" means Parties present and casting an affirmative or negative vote.

Article 15

REVIEW OF COMPLIANCE

The Meeting of the Parties shall establish, on a consensus basis, optional arrangements of a non-confrontational, non-judicial and consultative nature for reviewing compliance with the provisions of this Convention. These arrangements shall allow for appropriate public involvement and may include the option of considering communications from members of the public on matters related to this Convention.

Article 16

SETTLEMENT OF DISPUTES

1. If a dispute arises between two or more Parties about the interpretation or application of this Convention, they shall seek a solution by negotiation or by any other means of dispute settlement acceptable to the parties to the dispute.

2. When signing, ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a Party may declare in writing to the Depositary that, for a dispute not resolved in accordance with paragraph 1 above, it accepts one or both of the following means of dispute settlement as compulsory in relation to any Party accepting the same obligation:

(a) Submission of the dispute to the International Court of Justice;

(b) Arbitration in accordance with the procedure set out in annex II.

3. If the parties to the dispute have accepted both means of dispute settlement referred to in paragraph 2 above, the dispute may be submitted only to the International Court of Justice, unless the parties agree otherwise.

Article 17

SIGNATURE

This Convention shall be open for signature at Aarhus (Denmark) on 25 June 1998, and thereafter at United Nations Headquarters in New York until 21 December 1998, by States members of the Economic Commission for Europe as well as States having consultative status with the Economic Commission for Europe pursuant to paragraphs 8 and 11 of Economic and Social Council resolution 36 (IV) of 28 March 1947, and by regional economic integration organizations constituted by sovereign States members of the Economic Commission for Europe to which their member States have transferred competence over matters governed by this Convention, including the competence to enter into treaties in respect of these matters.

Article 18

DEPOSITARY

The Secretary-General of the United Nations shall act as the Depositary of this Convention.

Article 19

RATIFICATION, ACCEPTANCE, APPROVAL AND ACCESSION

1. This Convention shall be subject to ratification, acceptance or approval by signatory States and regional economic integration organizations.

2. This Convention shall be open for accession as from 22 December 1998 by the States and regional economic integration organizations referred to in article 17.

3. Any other State, not referred to in paragraph 2 above, that is a Member of the United Nations may accede to the Convention upon approval by the Meeting of the Parties.
4. Any organization referred to in article 17 which becomes a Party to this Convention without any of its member States being a Party shall be bound by all the obligations under this Convention. If one or more of such an organization's member States is a Party to this Convention, the organization and its member States shall decide on their respective responsibilities for the performance of their obligations under this Convention. In such cases, the organization and the member States shall not be entitled to exercise rights under this Convention concurrently.
5. In their instruments of ratification, acceptance, approval or accession, the regional economic integration organizations referred to in article 17 shall declare the extent of their competence with respect to the matters governed by this Convention. These organizations shall also inform the Depositary of any substantial modification to the extent of their competence.

Article 20

ENTRY INTO FORCE

1. This Convention shall enter into force on the ninetieth day after the date of deposit of the sixteenth instrument of ratification, acceptance, approval or accession.
2. For the purposes of paragraph 1 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by States members of such an organization.
3. For each State or organization referred to in article 17 which ratifies, accepts or approves this Convention or accedes thereto after the deposit of the sixteenth instrument of ratification, acceptance, approval or accession, the Convention shall enter into force on the ninetieth day after the date of deposit by such State or organization of its instrument of ratification, acceptance, approval or accession.

Article 21

WITHDRAWAL

At any time after three years from the date on which this Convention has come into force with respect to a Party, that Party may withdraw from the Convention by giving written notification to the Depositary. Any such withdrawal shall take effect on the ninetieth day after the date of its receipt by the Depositary.

Article 22

AUTHENTIC TEXTS

The original of this Convention, of which the English, French and Russian texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized thereto, have signed this Convention.

DONE at Aarhus (Denmark), this twenty-fifth day of June, one thousand nine hundred and ninety-eight.

Annex I

LIST OF ACTIVITIES REFERRED TO IN ARTICLE 6, PARAGRAPH 1 (a)

1. Energy sector:

- Mineral oil and gas refineries;
- Installations for gasification and liquefaction;
- Thermal power stations and other combustion installations with a heat input of 50 megawatts (MW) or more;
- Coke ovens;
- Nuclear power stations and other nuclear reactors including the dismantling or decommissioning of such power stations or reactors 1/ (except research installations for the production and conversion of fissionable and fertile materials whose maximum power does not exceed 1 kW continuous thermal load);
- Installations for the reprocessing of irradiated nuclear fuel;
- Installations designed:
    - For the production or enrichment of nuclear fuel;
    - For the processing of irradiated nuclear fuel or high-level radioactive waste;
    - For the final disposal of irradiated nuclear fuel;
    - Solely for the final disposal of radioactive waste;
    - Solely for the storage (planned for more than 10 years) of irradiated nuclear fuels or radioactive waste in a different site than the production site.

2. Production and processing of metals:

- Metal ore (including sulphide ore) roasting or sintering
- installations;
- Installations for the production of pig-iron or steel (primary or secondary fusion) including continuous casting, with a capacity exceeding 2.5 tons per hour;
- Installations for the processing of ferrous metals:

(i) Hot-rolling mills with a capacity exceeding 20 tons of crude steel per hour;

(ii) Smitheries with hammers the energy of which exceeds 50 kilojoules per hammer, where the calorific power used exceeds 20 MW;

(iii) Application of protective fused metal coats with an input exceeding 2 tons of crude steel per hour;

- Ferrous metal foundries with a production capacity exceeding 20 tons per day;
- Installations:

(i) For the production of non-ferrous crude metals from ore, concentrates or secondary raw materials by metallurgical, chemical or electrolytic processes;

(ii) For the smelting, including the alloying, of non-ferrous metals, including recovered products (refining, foundry casting, etc.), with a melting capacity exceeding 4 tons per day for lead and cadmium or 20 tons per day for all other metals;

- Installations for surface treatment of metals and plastic materials using an electrolytic or chemical process where the volume of the treatment vats exceeds 30 m^3.

3. Mineral industry:

- Installations for the production of cement clinker in rotary kilns with a production capacity exceeding 500 tons per day or lime in rotary kilns with a production capacity exceeding 50 tons per day or in other furnaces with a production capacity exceeding 50 tons per day;
- Installations for the production of asbestos and the manufacture of asbestos-based products;
- Installations for the manufacture of glass including glass fibre with a melting capacity exceeding 20 tons per day;
- Installations for melting mineral substances including the production of mineral fibres with a melting capacity exceeding 20 tons per day;
- Installations for the manufacture of ceramic products by firing, in particular roofing tiles, bricks, refractory bricks, tiles, stoneware or porcelain, with a production capacity exceeding 75 tons per day, and/or with a kiln capacity exceeding 4 m^3 and with a setting density per kiln exceeding 300 kg/m^3.

4. Chemical industry: Production within the meaning of the categories of activities contained in this paragraph means the production on an industrial scale by chemical processing of substances or groups of substances listed in subparagraphs (a) to (g):

(a) Chemical installations for the production of basic organic chemicals, such as:

- (i) Simple hydrocarbons (linear or cyclic, saturated or unsaturated, aliphatic or aromatic);
- (ii) Oxygen-containing hydrocarbons such as alcohols, aldehydes, ketones, carboxylic acids, esters, acetates, ethers, peroxides, epoxy resins;
- (iii) Sulphurous hydrocarbons;
- (iv) Nitrogenous hydrocarbons such as amines, amides, nitrous compounds, nitro compounds or nitrate compounds, nitriles, cyanates, isocyanates;
- (v) Phosphorus-containing hydrocarbons;
- (vi) Halogenic hydrocarbons;
- (vii) Organometallic compounds;
- (viii) Basic plastic materials (polymers, synthetic fibres and cellulose-based fibres);
- (ix) Synthetic rubbers;
- (x) Dyes and pigments;
- (xi) Surface-active agents and surfactants;

(b) Chemical installations for the production of basic inorganic chemicals, such as:

- (i) Gases, such as ammonia, chlorine or hydrogen chloride, fluorine or hydrogen fluoride, carbon oxides, sulphur compounds, nitrogen oxides, hydrogen, sulphur dioxide, carbonyl chloride;
- (ii) Acids, such as chromic acid, hydrofluoric acid, phosphoric acid, nitric acid, hydrochloric acid, sulphuric acid, oleum, sulphurous acids;
- (iii) Bases, such as ammonium hydroxide, potassium hydroxide, sodium hydroxide;
- (iv) Salts, such as ammonium chloride, potassium chlorate, potassium carbonate, sodium carbonate, perborate, silver nitrate;
- (v) Non-metals, metal oxides or other inorganic compounds such as calcium carbide, silicon, silicon carbide;

(c) Chemical installations for the production of phosphorous-, nitrogen- or potassium-based fertilizers (simple or compound fertilizers);

(d) Chemical installations for the production of basic plant health products and of biocides;

(e) Installations using a chemical or biological process for the production of basic pharmaceutical products;

(f) Chemical installations for the production of explosives;

(g) Chemical installations in which chemical or biological processing is used for the production of protein feed additives, ferments and other protein substances.

5. Waste management:

- Installations for the incineration, recovery, chemical treatment or landfill of hazardous waste;
- Installations for the incineration of municipal waste with a capacity exceeding 3 tons per hour;
- Installations for the disposal of non-hazardous waste with a capacity exceeding 50 tons per day;
- Landfills receiving more than 10 tons per day or with a total capacity exceeding 25 000 tons, excluding landfills of inert waste.

6. Waste-water treatment plants with a capacity exceeding 150 000 population equivalent.

7. Industrial plants for the:

(a) Production of pulp from timber or similar fibrous materials;

(b) Production of paper and board with a production capacity exceeding 20 tons per day.

8.

(a) Construction of lines for long-distance railway traffic and of airports 2/ with a basic runway length of 2 100 m or more;

(b) Construction of motorways and express roads; 3/

(c) Construction of a new road of four or more lanes, or realignment and/or widening of an existing road of two lanes or less so as to provide four or more lanes, where such new road, or realigned and/or widened section of road, would be 10 km or more in a continuous length.

9.

(a) Inland waterways and ports for inland-waterway traffic which permit the passage of vessels of over 1 350 tons;

(b) Trading ports, piers for loading and unloading connected to land and outside ports (excluding ferry piers) which can take vessels of over 1 350 tons.

10. Groundwater abstraction or artificial groundwater recharge schemes where the annual volume of water abstracted or recharged is equivalent to or exceeds 10 million cubic metres.

11.

(a) Works for the transfer of water resources between river basins where this transfer aims at preventing possible shortages of water and where the amount of water transferred exceeds 100 million cubic metres/year;

(b) In all other cases, works for the transfer of water resources between river basins where the multiannual average flow of the basin of abstraction exceeds 2 000 million cubic metres/year and where the amount of water transferred exceeds 5% of this flow.

In both cases transfers of piped drinking water are excluded.

12. Extraction of petroleum and natural gas for commercial purposes where the amount extracted exceeds 500 tons/day in the case of petroleum and 500 000 cubic metres/day in the case of gas.

13. Dams and other installations designed for the holding back or permanent storage of water, where a new or additional amount of water held back or stored exceeds 10 million cubic metres.

14. Pipelines for the transport of gas, oil or chemicals with a diameter of more than 800 mm and a length of more than 40 km.

15. Installations for the intensive rearing of poultry or pigs with more than:

(a) 40 000 places for poultry;

(b) 2 000 places for production pigs (over 30 kg); or

(c) 750 places for sows.

16. Quarries and opencast mining where the surface of the site exceeds 25 hectares, or peat extraction, where the surface of the site exceeds 150 hectares.

17. Construction of overhead electrical power lines with a voltage of 220 kV or more and a length of more than 15 km.

18. Installations for the storage of petroleum, petrochemical, or chemical products with a capacity of 200 000 tons or more.

19. Other activities:

- Plants for the pretreatment (operations such as washing, bleaching, mercerization) or dyeing of fibres or textiles where the treatment capacity exceeds 10 tons per day;
- Plants for the tanning of hides and skins where the treatment capacity exceeds 12 tons of finished products per day;
-
    (a) Slaughterhouses with a carcass production capacity greater than 50 tons per day;
    (b) Treatment and processing intended for the production of food products from:
        (i) Animal raw materials (other than milk) with a finished product production capacity greater than 75 tons per day;
        (ii) Vegetable raw materials with a finished product production capacity greater than 300 tons per day (average value on a quarterly basis);
    (c) Treatment and processing of milk, the quantity of milk received being greater than 200 tons per day (average value on an annual basis);
- Installations for the disposal or recycling of animal carcasses and animal waste with a treatment capacity exceeding 10 tons per day;

- Installations for the surface treatment of substances, objects or products using organic solvents, in particular for dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning or impregnating, with a consumption capacity of more than 150 kg per hour or more than 200 tons per year;
- Installations for the production of carbon (hard-burnt coal) or electrographite by means of incineration or graphitization.

20. Any activity not covered by paragraphs 1-19 above where public participation is provided for under an environmental impact assessment procedure in accordance with national legislation.

21. The provision of article 6, paragraph 1 (a) of this Convention, does not apply to any of the above projects undertaken exclusively or mainly for research, development and testing of new methods or products for less than two years unless they would be likely to cause a significant adverse effect on environment or health.

22. Any change to or extension of activities, where such a change or extension in itself meets the criteria/thresholds set out in this annex, shall be subject to article 6, paragraph 1 (a) of this Convention. Any other change or extension of activities shall be subject to article 6, paragraph 1 (b) of this Convention.

Notes

1/ Nuclear power stations and other nuclear reactors cease to be such an installation when all nuclear fuel and other radioactively contaminated elements have been removed permanently from the installation site.

2/ For the purposes of this Convention, "airport" means an airport which complies with the definition in the 1944 Chicago Convention setting up the International Civil Aviation Organization (Annex 14).

3/ For the purposes of this Convention, "express road" means a road which complies with the definition in the European Agreement on Main International Traffic Arteries of 15 November 1975.

Annex II

ARBITRATION

1. In the event of a dispute being submitted for arbitration pursuant to article 16, paragraph 2, of this Convention, a party or parties shall notify the secretariat of the subject matter of arbitration and indicate, in particular, the articles of this Convention whose interpretation or application is at issue. The secretariat shall forward the information received to all Parties to this Convention.

2. The arbitral tribunal shall consist of three members. Both the claimant party or parties and the other party or parties to the dispute shall appoint an arbitrator, and the two arbitrators so appointed shall designate by common agreement the third arbitra-

tor, who shall be the president of the arbitral tribunal. The latter shall not be a national of one of the parties to the dispute, nor have his or her usual place of residence in the territory of one of these parties, nor be employed by any of them, nor have dealt with the case in any other capacity.

3. If the president of the arbitral tribunal has not been designated within two months of the appointment of the second arbitrator, the Executive Secretary of the Economic Commission for Europe shall, at the request of either party to the dispute, designate the president within a further two-month period.

4. If one of the parties to the dispute does not appoint an arbitrator within two months of the receipt of the request, the other party may so inform the Executive Secretary of the Economic Commission for Europe, who shall designate the president of the arbitral tribunal within a further two-month period. Upon designation, the president of the arbitral tribunal shall request the party which has not appointed an arbitrator to do so within two months. If it fails to do so within that period, the president shall so inform the Executive Secretary of the Economic Commission for Europe, who shall make this appointment within a further two-month period.

5. The arbitral tribunal shall render its decision in accordance with international law and the provisions of this Convention.

6. Any arbitral tribunal constituted under the provisions set out in this annex shall draw up its own rules of procedure.

7. The decisions of the arbitral tribunal, both on procedure and on substance, shall be taken by majority vote of its members.

8. The tribunal may take all appropriate measures to establish the facts.

9. The parties to the dispute shall facilitate the work of the arbitral tribunal and, in particular, using all means at their disposal, shall:

(a) Provide it with all relevant documents, facilities and information;

(b) Enable it, where necessary, to call witnesses or experts and receive their evidence.

10. The parties and the arbitrators shall protect the confidentiality of any information that they receive in confidence during the proceedings of the arbitral tribunal.

11. The arbitral tribunal may, at the request of one of the parties, recommend interim measures of protection.

12. If one of the parties to the dispute does not appear before the arbitral tribunal or fails to defend its case, the other party may request the tribunal to continue the proceedings and to render its final decision. Absence of a party or failure of a party to defend its case shall not constitute a bar to the proceedings.

13. The arbitral tribunal may hear and determine counter-claims arising directly out of the subject matter of the dispute.

14. Unless the arbitral tribunal determines otherwise because of the particular circumstances of the case, the expenses of the tribu-

nal, including the remuneration of its members, shall be borne by the parties to the dispute in equal shares. The tribunal shall keep a record of all its expenses, and shall furnish a final statement thereof to the parties.

15. 15.Any Party to this Convention which has an interest of a legal nature in the subject matter of the dispute, and which may be affected by a decision in the case, may intervene in the proceedings with the consent of the tribunal.

16. The arbitral tribunal shall render its award within five months of the date on which it is established, unless it finds it necessary to extend the time limit for a period which should not exceed five months.

17. The award of the arbitral tribunal shall be accompanied by a statement of reasons. It shall be final and binding upon all parties to the dispute. The award will be transmitted by the arbitral tribunal to the parties to the dispute and to the secretariat. The secretariat will forward the information received to all Parties to this Convention.

18. Any dispute which may arise between the parties concerning the interpretation or execution of the award may be submitted by either party to the arbitral tribunal which made the award or, if the latter cannot be seized thereof, to another tribunal constituted for this purpose in the same manner as the first.

3 CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,

Have agreed as follows:

Article 1

OBJECTIVE

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article 2

GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article 3

USE OF TERMS

For the purposes of this Protocol:

(a) "Conference of the Parties" means the Conference of the Parties to the Convention;

(b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) "Export" means intentional transboundary movement from one Party to another Party;

(d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) "Import" means intentional transboundary movement into one Party from another Party;

(f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) "Living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) "Modern biotechnology" means the application of:

a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article 4

SCOPE

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 5

PHARMACEUTICALS

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

Article 6

TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article 7

APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8

NOTIFICATION

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article 9

ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

   (a) The date of receipt of the notification;

   (b) Whether the notification, prima facie, contains the information referred to in Article 8;

   (c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article 10

DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

   (a) Only after the Party of import has given its written consent; or

   (b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

   (a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

   (b) Prohibiting the import;

   (c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

   (d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedu-

res and mechanisms to facilitate decision-making by Parties of import.

Article 11

PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

   (a) A risk assessment undertaken in accordance with Annex III; and

   (b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.
9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12

REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.
2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:
   (a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or
   (b) Additional relevant scientific or technical information has become available.
3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.
4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article 13

SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article 14

BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.
2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.
3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.
4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article 15

RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.
3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16

RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.
2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.
3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.
4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.
5. Parties shall cooperate with a view to:
   (a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
   (b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.
2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.
3. Any notification arising from paragraph 1 above, should include:
   (a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article 18

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characte-

ristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article 19

COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.
2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.
3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article 20

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:
   (a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and
   (b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among

them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

   (a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

   (b) Any bilateral, regional and multilateral agreements and arrangements;

   (c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

   (d) Its final decisions regarding the importation or release of living modified organisms; and

   (e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 21

CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.
4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.
5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.
6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:
   (a) The name and address of the notifier;
   (b) A general description of the living modified organism or organisms;
   (c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
   (d) Any methods and plans for emergency response.

Article 22

CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.
2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition

shall also be taken fully into account for such capacity-building in biosafety.

Article 23

PUBLIC AWARENESS AND PARTICIPATION

1. The Parties shall:
   (a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;
   (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.
2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.
3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Article 24

NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.
2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25

ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.
2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article 26

SOCIO-ECONOMIC CONSIDERATIONS

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.
2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article 27

LIABILITY AND REDRESS

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Article 28

FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.
2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.
3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.
4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-

building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 29

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

   (a) Make recommendations on any matters necessary for the implementation of this Protocol;

   (b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

   (c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

   (d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

   (e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Pro-

tocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 30

SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.
3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 31

SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.
2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.
3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 32

RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 33

MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article 34

COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 35

ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36

SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article 37

ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.
2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.
3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 38

RESERVATIONS

No reservations may be made to this Protocol.

Article 39

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article 40

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

ANNEX II

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Annex III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

   (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

   (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

   (c) An evaluation of the consequences should these adverse effects be realized;

   (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

   (e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

   (f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

   (a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known,

and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

4 EU-DIRECTIVE 90/220/EEC – DELIBERATE RELEASE

PART A General provisions

Article 1

1. 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:
   - when carrying out the deliberate release of genetically modified organisms into the environment,
   - when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment.
2. This Directive shall not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.

Article 2

For the purposes of this Directive:
1. 'organism' is any biological entity capable of replication or of transferring genetic material;
2. 'genetically modified organism (GMO)' means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
   Within the terms of this definition:
   i. genetic modification occurs at least through the use of the techniques listed in Annex I A Part 1;
   ii. the techniques listed in Annex I A Part 2 are not considered to result in genetic modification;
3. 'deliberate release' means any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment;
4. 'product' means a preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market;
5. 'placing on the market' means supplying or making available to third parties;
6. 'notification' means the presentation of documents containing the requisite information to the competent authority of a Member State. The person making the presentation shall be referred to as 'the notifier';
7. 'use' means the deliberate release of a product which has been placed on the market. The persons carrying out this use will be referred to as 'users';
8. 'environmental risk assessment' means the evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOs.

Article 3

This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

Article 4

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs.
2. Member States shall designate the competent authority or authorities responsible for carrying out the requirements of this Directive and its Annexes.
3. Member States shall ensure that the competent authority organizes inspections and other control measures as appropriate, to ensure compliance with this Directive.

PART B Deliberate release of GMOs into the environment for research and development purposes or for any other purpose than for placing on the market

Article 5

Member States shall adopt the provisions necessary to ensure that:
1. any person, before undertaking a deliberate release of a GMO or a combination of GMOs for the purpose of research and development, or for any other purpose than for placing on the market, must submit a notification to the competent authority referred to in Article 4 (2) of the Member State within whose territory the release is to take place;
2. the notification shall include:
   (a) a technical dossier supplying the information specified in Annex II necessary for evaluating the foreseeable risks, whether immediate or delayed, which the GMO or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them and covering, in particular:
      (i) general information including information on personnel and training,
      (ii) information relating to the GMO(s),
      (iii) information relating to the conditions of release and the receiving environment,
      (iv) information on the interactions between the GMO(s) and the environment,
      (v) information on monitoring, control, waste treatment and emergency response plans;
   (b) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;
3. the competent authority may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period may be notified in a single notification;
4. the notifier shall include in the notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by him either inside or outside the Community.The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing;
5. in the case of a subsequent release of the same GMO or combination of GMOs previously notified as part of the same research programme, the notifier shall be required to submit a new notification. In this case, the notifier may refer to data from previous notifications or results from previous releases;
6. in the event of any modification of the deliberate release of GMOs or a combination of GMOs which could have consequences with regard to the risks for human health or the environment or if new information has become available on such risks, either while the notification is being examined by the competent authority or after that authority has given its written consent, the notifier shall immediately:
   (a) revise the measures specified in the notification,
   (b) inform the competent authority in advance of any modification or as soon as the new information is available,
   (c) take the measures necessary to protect human health and the environment.

Article 6

1. On receipt and after acknowledgment of the notification the competent authority shall:
   - examine it for compliance with this Directive,
   - evaluate the risks posed by the release,
   - record its conclusions in writing, and, if necessary,
   - carry out tests or inspections as may be necessary for control purposes.
2. The competent authority, having considered, where appropriate, any comments by other Member States made in accordance with Article 9, shall respond in writing to the notifier within 90 days of receipt of the notification by either:
   (a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed, or
   (b) indicating that the release does not fulfil the conditions of this Directive and the notification is therefore rejected.
3. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority:
   - is awaiting further information which it may have requested from the notifier,

or

   - is carrying out a public inquiry or consultation in accordance with Article 7

shall not be taken into account.
4. The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.
5. If the competent authority considers that sufficient experience has been obtained of releases of certain GMOs, it may submit to the Commission a request for the application of simplified procedures for releases of such types of GMOs. The Commission shall, in accordance with the procedures laid down in Article 21, establish appropriate criteria and take a decision accordingly on each application. The criteria shall be based on safety to human health and the environment and on the evidence available on such safety.
6. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

Article 7

Where a Member State considers it appropriate, it may provide that groups or the public shall be consulted on any aspect of the proposed deliberate release.

Article 8

After completion of a release, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product that the notifier intends to notify at a later stage.

Article 9

1. The Commission shall set up a system of exchange of the information contained in the notifications. The competent authorities shall send to the Commission, within 30 days of its receipt, a summary of each notification received. The format of this summary will be established by the Commission in accordance with the procedure laid down in Article 21.
2. The Commission shall immediately forward these summaries to the other Member States, which may, within 30 days, ask for further information or present observations through the Commission or directly.

3. The competent authorities shall inform the other Member States and the Commission of the final decisions taken in compliance with Article 6 (2).

PART C Placing on the market of products containing GMOs

Article 10

1. Consent may only be given for the placing on the market of products containing, or consisting of, GMOs, provided that:
   - written consent has been given to a notification under Part B or if a risk analysis has been carried out based on the elements outlined in that Part;
   - the products comply with the relevant Community product legislation;
   - the products comply with the requirements of this Part of this Directive, concerning the environmental risk assessment.
2. Articles 11 to 18 shall not apply to any products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive.
3. Not later than 12 months after notification of this Directive, the Commission, in accordance with the procedure laid down in Article 21, shall establish a list of Community legislation covering the products referred to in paragraph 2. This list will be re-examined periodically and, as necessary, revised in accordance with the said procedure.

Article 11

1. Before a GMO or a combination of GMOs are placed on the market as or in a product, the manufacturer or the importer to the Community shall submit a notification to the competent authority of the Member State where such a product is to be placed on the market for the first time. This notification shall contain:
   - the information required in Annex II, extended as necessary to take into account the diversity of sites of use of the product, including information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product and an assessent of any risks for human health and the environment related to the GMOs or a combination of GMOs contained in the product, including information obtained from the research and development stage on the impact of the release on human health and the environment;
   - the conditions for the placing on the market of the product, including specific conditions of use and handling and a proposal for labelling and packaging which should comprise at least the requirements laid down in Annex III.

If on the basis of the results of any release notified under Part B of this Directive, or on substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a product do not pose a risk to human health and the environment, he may propose not to comply with one or more of the requirements of Annex III B.

2. The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community.
3. The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing.
4. Each new product which, containing or consisting of the same GMO or combination of GMOs, is intended for a different use, shall be notified separately.
5. The notifier may proceed with the release only when he has received the written consent of the competent authority in accordance with Article 13, and in conformity with any conditions, including reference to particular ecosystems/environments, required in that consent.

6. If new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier shall immediately:
   - revise the information and conditions specified in paragraph 1,
   - inform the competent authority, and
   - take the measures necessary to protect human health and the environment.

Article 12

1. On receipt and after acknowledgement of the notification referred to in Article 11, the competent authority shall examine it for compliance with this Directive, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.
2. At the latest 90 days after receipt of the notification, the competent authority shall either:
   (a) forward the dossier to the Commission with a favourable opinion, or
   (b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.
3. In the case referred to in paragraph 2 (a), the dossier forwarded to the Commission shall include a summary of the notification together with a statement of the conditions under which the competent authority proposes to consent to the placing on the market of the product.

The format of this summary shall be established by the Commission in accordance with the procedure laid down in Article 21.
In particular where the competent authority has acceded to the request of the notifier, under the terms of the last subparagraph of Article 11 (1), not to comply with some of the requirements of Annex III B, it shall at the same time inform the Commission thereof.

4. If the competent authority receives additional information pursuant to Article 11 (6), it shall immediately inform the Commission and the other Member States.
5. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account.

Article 13

1. On receipt of the dossier referred to in Article 12 (3), the Commission shall immediately forward it to the competent authorities of all Member States together with any other information it has collected pursuant to this Directive and advise the competent authority responsible for forwarding the document of the distribution date.
2. The competent authority, in the absence of any indication to the contrary from another Member State within 60 days following the distribution date referred to in paragraph 1, shall give its consent in writing to the notification so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.
3. In cases where the competent authority of another Member State raises an objection - for which the reasons must be stated - and should it not be possible for the competent authorities concerned to reach an agreement within the period specified in paragraph 2, the Commission shall take a decision in accordance with the procedure laid down in Article 21.
4. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market and shall inform the other Member States and the Commission thereof.

5. Once a product has received a written consent, it may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.
6. Member States shall take all necessary measures to ensure that users comply with the conditions of use specified in the written consent.

Article 14

Member States shall take all necessary measures to ensure that products containing, or consisting of, GMOs will be placed on the market only if their labelling and packaging is that specified in the written consent referred to in Articles 12 and 13.

Article 15

Member States may not, on grounds relating to the notification and written consent of a deliberate release under this Directive, prohibit, restrict or impede the placing on the market of products containing, or consisting of, GMOs which comply with the requirements of this Directive.

Article 16

1. Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.
2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.

Article 17

The Commission shall publish in the Official Journal of the European Communities a list of all the products receiving final written consent under this Directive. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

Article 18

1. Member States shall send to the Commission, at the end of each year, a brief factual report on the control of the use of all products placed on the market under this Directive.
2. The Commission shall send to the European Parliament and the Council, every three years, a report on the control by the Member States of the products placed on the market under this Directive.
3. When submitting this report for the first time, the Commission shall at the same time submit a specific report on the operation of this Part of this Directive including an assessment of all its implications.

PART D Final provisions

Article 19

1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received.
2. The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive position, that should therefore be treated as confidential. Verifiable justification must be given in such cases.
3. The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decisions.
4. In no case may the following information when submitted according to Articles 5 or 11 be kept confidential:
   - description of the GMO or GMOs, name and address of the notifier, purpose of the release and location of release;
   - methods and plans for monitoring of the GMO or GMOs and for emergency response;
   - the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.
5. If, for whatever reasons, the notifier withdraws the notification, the competent authorities and the Commission must respect the confidentiality of the information supplied.

Article 20

According to the procedure laid down in Article 21, the Commission shall adapt Annexes II and III to technical progress in particular by amending the notification requirements to take into account the potential hazard of the GMOs.

Article 21

The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.
The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.
If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.
If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 22

1. Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release of GMOs into the environment.
2. Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive, the first time being on 1 September 1992.
3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being in 1993.

Article 23

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 23 October 1991.
2. Member States shall immediately inform the Commission of all laws, regulations and administrative provisions adopted in implementation of this Directive.

Article 24

This Directive is addressed to the Member States.

Done at Luxembourg, 23 April 1990.
For the Council
The President
A. REYNOLDS

(1) OJ No C 198, 28. 7. 1988, p. 19 and (2) OJ No C 158, 26. 6. 1989, p. 225 and(3) OJ No C 23, 30. 1. 1989, p. 45.

ANNEX I

A TECHNIQUES REFERRED TO IN ARTICLE 2 (2)
PART 1
Techniques of genetic modification referred to in Article 2 (2) (i) are inter alia:
1. recombinant DNA techniques using vector systems as previously covered by Council Recommendation 82/472/EEC (;);
2. techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
3. cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2
Techniques referred to in Article 2 (2) (ii) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant DNA molecules or GMOs, are:
1. in vitro fertilization,
2. conjugation, transduction, transformation or any other natural process,
3. polyploidy induction.

ANNEX I

B TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques of genetic modification to be excluded from this Directive, on condition that they do not involve the use of GMOs as recipient or parental organisms, are:

1. mutagenesis,
2. cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods.

(¹) OJ NO L 213, 21. 7. 1982, p.15.

ANNEX II

INFORMATION REQUIRED IN THE NOTIFICATION

The notifications for a deliberate release referred to in Article 5 and for placing on the market referred to in Article 11 must provide the information set out below.

Not all the points included will apply to every case. It is to be expected, therefore, that individual notifications will address only the particular subset of considerations that are appropriate to individual situations. In each case where it is not technically possible or it does not appear necessary to give the information, the reasons shall be stated.

The level of detail required in response to each subset of considerations is also likely to vary according to the nature and the scale of the proposed release.

The description of the methods used or the reference to standardized or internationally recognized methods shall also be mentioned in the dossier, together with the name of the body or bodies responsible for carrying out the studies.

III. GENERAL INFORMATION

A. Name and address of the notifier

B. Information on personnel and training

1. Name of person(s) responsible for planning and carrying out the release including those responsible for supervision, monitoring and safety, in particular, name and qualifications of the responsible scientist;
2. Information on training and qualifications of personnel involved in carrying out the release.

III. INFORMATION RELATING TO THE GMO

A. Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):

1. scientific name;
2. taxonomy;
3. other names (usual name, strain name, cultivar name, etc.);
4. phenotypic and genetic markers;
5. degree of relatedness between donor and recipient or between parental organisms;
6. description of identification and detection techniques;
7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts;
9. potential for genetic transfer and exchange with other organisms;
10. verification of the genetic stability of the organisms and factors affecting it;
11. pathological, ecological and physiological traits:
    (a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;
    (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;

(c) information on survival, including seasonability and the ability to form survival structures e.g.: seeds, spores or sclerotia;
(d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonize other organisms;
(e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;
(f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

12. Nature of indigenous vectors:
(a) sequence;
(b) frequency of mobilization;
(c) specificity;
(d) presence of genes which confer resistance.

13. History of previous genetic modifications.

B. Characteristics of the vector:

1. nature and source of the vector;
2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function in the GMO;
3. frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination;
4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism:

1. Information relating to the genetic modification:
(a) methods used for the modification;
(b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;
(c) description of the insert and/or vector construction;
(d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;
(e) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence.
2. Information on the final GMO:
(a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
(b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;
(c) stability of the organism in terms of genetic traits;
(d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;
(e) activity of the expressed protein(s);
(f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;
(g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
(h) history of previous releases or uses of the GMO;
(i) health considerations:
(i) toxic or allergenic effects of the non-viable GMOs and/or their metabolic products;
(ii) product hazards;

(iii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;
(iv) capacity for colonization;
(v) if the organism is pathogenic to humans who are immunocompetent
- diseases caused and mechanism of pathogenicity including invasiveness and virulence,
- communicability,
- infective dose,
- host range, possibility of alteration,
- possibility of survival outside of human host,
- presence of vectors or means of dissemination,
- biological stability,
- antibiotic-resistance patterns,
- allergenicity,
- availability of appropriate therapies.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. Information on the release:
1. description of the proposed deliberate release, including the purpose(s) and foreseen products;
2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases;
3. preparation of the site previous to the release;
4. size of the site;
5. method(s) to be used for the release;
6. quantities of GMOs to be released;
7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities);
8. worker protection measures taken during the release;
9. post-release treatment of the site;
10. techniques foreseen for eliminatin or inactivation of the GMOs at the end of the experiment;
11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B. Information on the environment (both on the site and in the wider environment):
1. geographical location and grid reference of the site(s) (in case of notifications under Part C the site(s) of release will be the foreseen areas of use of the product);
2. physical or biological proximity to humans and other significant biota;
3. proximity to significant biotopes or protected areas;
4. size of local population;
5. economic activities of local populations which are based on the natural resources of the area;
6. distance to closest areas protected for drinking water and/or environmental purpose;
7. climatic characteristics of the region(s) likely to be affected;
8. geographical, geological and pedological characteristics;
9. flora and fauna, including crops, livestock and migratory species;
10. description of target and non-target ecosystems likely to be affected;
11. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
12. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination:
1. biological features which affect survival, multiplication and dispersal;
2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.);
3. sensitivity to specific agents.

B. Interactions with the environment:
1. predicted habitat of the GMOs;
2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses;
3. genetic transfer capability:
   (a) post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
   (b) post-release transfer of genetic material from indigenous organisms to the GMOs;
4. likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism;
5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal of genetic material. Methods to verify genetic stability;
6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.;
7. description of ecosystems to which the GMOs could be disseminated.

C. Potential environmental impact:
1. potential for excessive population increase in the environment;
2. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
3. identification and description of the target organisms;
4. anticipated mechanism and result of interaction between the released GMOs and the target organism;
5. identification and description of non-target organisms which may be affected unwittingly;
6. likelihood of post-release shifts in biological interactions or in host range;
7. known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbionts, predators, parasites and pathogens;
8. known or predicted involvement in biogeochemical processes;
9. other potentially significant interactions with the environment.

IV. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring techniques:
1. methods for tracing the GMOs, and for monitoring their effects;
2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques;
3. techniques for detecting transfer of the donated genetic material to other organisms;
4. duration and frequency of the monitoring.

B. Control of the release:
1. methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of release or the designated area for use;
2. methods and procedures to protect the site from intrusion by unauthorized individuals;
3. methods and procedures to prevent other organisms from entering the site.

C. Waste treatment:
1. type of waste generated;
2. expected amount of waste;
3. possible risks;
4. description of treatment envisaged.

D. Emergency response plans:
1. methods and procedures for controlling the GMOs in case of unexpected spread;
2. methods for decontamination of the areas affected, e.g. eradication of the GMOs;
3. methods for disposal or sanitation of plants, animals, soils, etc. that were exposed during or after the spread;
4. methods for the isolation of the area affected by the spread;
5. plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

ANNEX III

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING ON THE MARKET

A. The following information shall be provided in the notification for placing on the market of products, in addition to that of Annex II:
1. name of the product and names of GMOs contained therein;
2. name of the manufacturer or distributor and his address in the Community;
3. specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the Community for which the product is suited;
4. type of expected use: industry, agriculture and skilled trades, consumer use by public at large.

B. The following information shall be provided, when relevant, in addition to that of point A, in accordance with Article 11 of this Directive:
1. measures to take in case of unintended release or misuse;
2. specific instructions or recommendations for storage and handling;
3. estimated production in and/or imports to the Community;
4. proposed packaging. This must be appropriate so as to avoid unintended release of the GMOs during storage, or at a later stage;
5. proposed labelling. This must include, at least in summarized form, the information referred to in points A. 1, A. 2, A. 3, B. 1 and B. 2.