Biotechnology regulations

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Introduction

On 22-23 September, 1994, in Vienna, the Biosafety Information Network and Advisory Service (BINAS) represented by Dr. George Tzotzos organized under the auspices of UNIDO, the meeting: "Harmonization of biotechnology regulations in Central and Eastern Europe". The participants of this meeting from Bulgaria, Czech Republik, Hungary, Lithuania, Poland, Russia, Slovakia and Slovenia, and the observers from OECD, ICGEB, UNIDO, EC, Austria, Canada, Germany reviewed international regulatory frameworks and their applicability for Central and Eastern Europe.

The invited representatives from Central and Eastern Europe discussed the current situation and legal aspects of biotechnology in their countries. We will be presenting short reviews describing rules and regulations relating to biotechnology in Central and Eastern Europe as soon as available. In this issue of "Biotechnologia" we present the following reports:

1) Austria,
2) Hungary,
3) Slovenia,
4) Slovakia,
5) Poland.

The "Voluntary Code of Conduct for the Release of Organisms into the Environment" prepared by the UNIDO Secretariat is reprinted.

Based on the participants' common initiative, the Task Force of Regulatory Oversight in Central and Eastern Europe in Biotechnology (ROCEEB) was established. "Biotechnologia" will present the activities and progress of this project.

Development of Biotechnology Regulations in Austria

- Before 1990: NIH Guidelines translated and adapted to Austria:
— 1990: Study "Genetic engineering" in the Austrian Law, published by the Austrian Ministry of Science and Research;
— 1990: Federal Ministerial Law — Ministry of Health is responsible for working out a law;
— March 1991: First draft, based on the EC Directives 90/219/EEC and 90/220/EEC;
— Interministerial Discussions;
— Discussions with interested groups;
— December 1992: Second draft, 2 months "comments-period";
— November 1992 — June 1993: Parliamentary Committee "Technology Assessment — taking biotechnology as an example", final report published, contains recommendations of the Austrian Parliament;
— Autumn 1993: Third draft, presented to the Council of Ministers, rejected;
— January 1994: Council of Ministers accepted the draft law;
— March 1994: Two sessions of a Parliamentary Subcommittee, small changes;
— June 1994: Plenary of the Austrian Parliament adopted "Law on Genetic engineering";
— January 1995: Law will come into force, regulations will have to be elaborated.

An overview of the Austrian Law on Genetic Engineering

— Framework Law;
— Scope: contained use, deliberate release, human genome analysis and human gene therapy;
— Aim: human health and environmental safety, promotion of the technology.

Sections:

- Definitions
- Contained Use
- Deliberate Release and Marketing
- Human Genome Analysis and Gene Therapy
- Advisory Committees
- Competent Authorities, Supervision
- Biosafety Research
- Confidentiality of data
- Penalties

Competent Authoritees:

- Contained Use: Ministry of Health, Ministry of Science and Research
- Deliberate Release: Ministry of Health, Ministry of Science and Research, Ministry of the Environment
- Human Genome Analysis and Gene Therapy: Ministry of Health

Advisory Committees:

- Advisory Committee on Gene Technology: Political body and scientists
- Subcommittees: scientific bodies
- Contained Use
- Deliberate release
- Human Genome Analysis and Genome Therapy

Public Participation:

When? Contained Use (large scale, higher safety categories) Deliberate Release.

How? Comments, Public Hearing with Competent Authorities, Advisory Committee, Applicant and Institutional Biosafety Committees.

Socioeconomic Aspects:

When? Marketing applications of products containing or consisting of GMOs.

How? Austrian Government can prohibit products on the basis of a socioeconomic evaluation.

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A report on the present biotechnology safety regulations in Hungary

1. There are no mandatory biotechnology safety regulations in Hungary.

2. A research on genetically modified organisms is carried out in Hungary, particularly for agricultural and pharmaceutical purposes.

3. Hungary became a member of the European Parliament. Thus, the decisions of the Parliament are binding also for Hungary which means that Hungary has to adapt the Parliament's regulations with regard to research on GMOs.

The national Committee for Technological Development is preparing a pro-

posal of the Government in order, to fulfil the prescriptions of the EP Directive. The Ministries involved include: Ministry of Health, Ministry of Agriculture, Ministry of Industry and Ministry of Environmental Protection.

A committee of 5 members was established. It has the right and obligation to approve of and monitor the research on GMOs. A data-bank shall be established, where the relevant data will be stored and communicated to the relevant international authorities.

We hope that this bill will soon be passed by the Government that could comply with EC regulations.The present situation is as follows:

— small scale field trials are carried out with 5 crops: potato, tobacco, corn, rape and alfalfa, monitoring the distribution of foreign genes under field conditions. The foreign gene is the kanamycin resistance gene. The experiment will be closed and evaluated this year.

— the production of Hirudin in *Sacharomyces* is at the transition stage between the laboratory and production phase.

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A review of recent situation in Slovak Republic

The situation in the biotechnology and biosafety regulations in the Slovak Republic is specific due to the validity of former Czechoslovak laws, norms and standards.

Recently there is no commission for the biotechnology regulation and the arising problems are solved mainly by authorities in frame of Ministry of Health, Ministry of Agriculture and Ministry of Environment.

The application of genetically manipulated microorganisms is practically not permitted and for the use of nontraditionally prepared products are required certificates issued by Ministry of Health.

Taking into consideration present socio-economic aspects in Slovakia and the level of biotechnology education, it can be anticipated opposition and contraversions of the part of public opinion concerning introduction of modern biotechnology products into the praxis.

On the other hand, it is advantage for our legislation that all new laws passed by Slovak Parliament have to be in accordance with the EU conceptions.

Nevertheless, for the process of creation of biosafety regulations the recommendations and help of European authorities and experts will be very important.

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A review of recent situation in Slovenia

In Slovenia biotechnology mainly develops in the pharmaceutical industry, veterinary industry, agriculture and food industry. Biotechnological research and its products are subject to the legislation concerning human health, hygiene, agriculture and forestry, foodstuff industry and environment protection.

Safety regulations should guarantee safe research, production and products as well as close international cooperation such. Regulations should be a result of a consensus between the regulators law-makers and industry also taking into consideration the attitude of the public.

The following types of legal acts and other documents are valid in Slovenia:

1. State standards.
2. Procedual decrees and directives of particular ministries in Slovenia.
3. Law on Industrial Property — Slovenia has no regulations specifically concerned with GMOs and their safe use, yet these organisms have not been excluded from the scope of any particular statute. Thus, the establishment intending to use genetically modified organisms will accordingly fall under the laws relating to environment protection, public health or labour protection.

The law on Industrial Property has been adapted by the Republic of Slovenia in March, 1991 and it covers among others the aspects of legal protection of intellectual property in the field of biotechnology. The Industrial Property Protection Office of the Republic of Slovenia is a govermental body responisible for the implementation of the above mentioned law.

The adaptation of the Agreement on International Recognition of Microorganism Deposit for Patent Procedure (the Budapest Agreement) will asure the depositing of all kinds of microorganisms as biological material related to patent applications. The legal procedure necessary for signing of the above mentioned Budapest Agreement is in its final phase. When the procedure is over an institution will have to be appointed to perform the function of a depository institution and to acquire a corresponding status of an internationally recognized institution.

In June 1994, the Ministry of Science and Technology established the Commission for Supervision of the genetic engineering techniques, research and production practice. In the near future a schedule for the Commission (including ethical and legal aspects) will be prepared. In order to develop domestic research and promote international cooperation in the field of biotechnology, efforts have been made to involve Slovenia into relevant biotechnology regulation and international cooperation. We are sure that success will not be overdue.

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A Review of Recent Situation in Poland

1. Current situation and the legal aspects of Polish biotechnology*

For the cooperation and integration with the European Community legal aspects are particularly important. In the last 5 years we have observed significant modification of the Polish law towards West European standards and legal norms. The following milestones are strictly connected with several aspects of biotechnology and are of special interest:

1. Protection of biodiversity of species and genetic resources (Polish official journal announcing current legislation: Dziennik Ustaw, October 16, 1991, no 114), and signing of the Biodiversity Convention.

2. Protection by patents: drugs, chemical compounds, food and food additives, techniques of isolation and identification of natural compounds, gene technology (modification and transfer), new biological systems, cf. microorganisms (Polish official journal announcing current legislation: Dziennik Ustaw, October 30, 1993, no 4).

3. Signing of the Budapest Treaty concerning the deposition of microorganisms (September 22, 1993).

4. Poland's application to the European Union (April 1994).

5. Protection of authorship rights (May 23, 1994).

6. Poland's application for OECD membership (June 1, 1994).

In Poland we are not in a position to discuss commercialisation. Except for some agriculture products (e.g. diagnostic of animals and plants viruses, flower production) our biotech industry have not entered the market.

1.1. Patent law

New Polish patent law (October 30, 1992) satisfactorily modifies our regulations and makes them similar to those of the countries of the United Europe and USA. Following the new regulations, it is possible to protect drugs, chemical compounds and food products with patents. Similar to other countries the following are patentable in Poland: techniques of isolation and identification (including gene technology), modified genes, technology of gene transfer and organism modification, new biological systems (cf. microorganisms), human genome (totally or in fragments) and the deposition of microorganisms.

1.2. Patenting in agriculture

A plant variety is eligible for protection if it is characterized by: distinctiveness, uniformity and stability. The producer (e.g. a farmer) has the pri-

* Biotechnology refers to the use of contemporary technologies, specifically recombinant—DNA and related techniques.

vilege of selling the reproductive plant material of a given plant variety and to save seeds from the current crop for sowing next season. Protection of plant breeders rights is fully catered under the Plant Varieties Protection Law. The classical technologies of plant and animal breeding are not suitable for modern patent protection. However, genetic engineering technologies have created a new situation from technological as well as legal points of view — the plants and animals created by genetic engineering can be protected by **patents.**

1.3. Protection of natural genomic resources

In Poland, in October 16, 1991 (Dz.U. no 114) **new** legal regulations concerning protection of nature also determined the protection of national genomic resources. §21.1. states the following: "[...]protection of biodiversity of species and genetic resources[...]". The local state authorities are responsible for nature protection. All the national parks are treated as "gene banks" — sources of "genomic resources" and "biodiversity is protected by law and supported by the state". Genetic resources are common human heritage of humankind.

We are working on: biosafety regulation and bio-laboratories registration aiming to correlate Polish regulations with the rules and recommendations of UE.

2. Questions

The following problems — among many others — are worth being highlighted:

- Protection of local genomic resources (particularly in the 3rd world).
  - — How could the 3rd world countries collect profit originating from their natural genomic resources?
  - — How to support and how to protect against damage the natural and man — made collections of germplasm?
  - — How to define and prove the property of a gene occuring in nature or in a germplasm collection?
- Rights of access to information concerning future experimental projects and their expected perspective effect(s) on the environment.
- Rights to protect confidentiality of results, particularly of the preliminary ones with high level of uncertainty concerning humankind.
- Rights to unlink the data from the names of persons; protection of confidentiality of the suspects and results.
- Ownership rights to the analytical and particularly genomic data concerning people.

The researchers (particularly medical doctors) are obliged to protect the confidentiality of medical subjects. Medical treatment and analytical data are protected by law. Evidently, some general rules have to apply:

— data are strictly confidential,
— data are owned by the tested people,
— data are not available for insurance or employment purposes.

- Scientists and industrialists rights to perform an experiment and to take reasonable and substantial risk as well as freedom to refuse doing a research, experiment or being an object of an experiment.
- Public opinion plays a significant role in the determination of limitations for science and technology. This is the obligation of the scientific society to explain and to popularize the real, scientific picture of biotechnology. The main goal should be to evaluate the reasonable and acceptable for the society risk associated with the progress of science.

3. Perspectives

Technology transfer may be defined as the movement of technical information and/or materials used for developing a product or process from one sector to another. In this particular case mostly from the West to the East. Both sides (donor as well as acceptor) should be familiar with the state of the art not exclusively from the technological position but also in sociological and legal terms.

The recent development of modern biotechnology in Poland is connected with political, economic and sociological changes brought to our country in the last 5 years. We have to take into account the conversion to the market economy, the government program of privatization and the long — distance goal of joining the United Europe.

In view of significant changes in geopolitics and tremendous development of biotechnology as technology of the 21st century the information on new regulations is fundamental for the scientific community. The new regulation will affect the transfer of products and technologies, freedom and transfer of information as well as the society.

Biotechnology in Poland is developing mainly in agriculture, food industry and veterinary and medical diagnostic. The Polish Government through the State Committee for Scientific Research supports funding of new laboratory facilities and research projects, formation of networks and cooperation with European organizations (e.g. UNESCO Network for Molecular Biology, UNIDO FACE Network, UNIDO ICGEB).

At the moment, we do not have in Poland the consumer movement for or against biotechnology or, particularly, genetic engineering. Through education correlated with a public perception research we have a good chance to avoid several serious problems already observed in the western hemisphere.

We have to remember, that first of all the researchers are responsible for providing reliable data. The scientific community has to think how the results of their research will be used. However, the scientists cannot take respon-

sibility for the final application and usage of their methods, technologies and results interpretation.

4. Conclusions

At the moment (August 1994) there are no formal regulations which specifically concern biotechnology. Intellectual property rights, patents' law, bioethics, biohazard and bioinformatics in Polish biotechnology are covered in the frame of general rules and regulations. In relation to European Community this situation offers a possibility to avoid difficulties and troubles of our western partners (e.g. UK and Germany).

It is the opinion of the Biotechnology Committee that the general formula of the (Polish) law is broad enough to accept and solve problems of biotechnology.

Specific problems, e.g. ethics of medical research, are given for the consideration of expert committee, and evaluated on the case – by – case base.

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About "Voluntary International Code of Conduct"

Humans have practiced biotechnology for millennia through traditional breeding methods. Most of the present day domesticated animals and plants are the result of such practices. These involved the transfer of genetic material from one organism to another with the ensuing expression of new biological properties.

The revolutionary advancements of the last fifteen years in molecular and cell biology have similarly enabled scientists to transfer genetic material amongst widely unrelated organisms in unique ways. The power of "new" biotechnology to cross species barriers in ways that no "conventional" breeding technology could do generated considerable public concern regarding the probability of proliferation of transgenic organisms with undesirable genetic characteristics. Although the major controversial scientific aspects have been resolved though our better understanding of the processes involved in the introduction and expression of foreign genetic material, the issue of biotechnological safety still possesses a prominent position in international debate. Such fears are not to be taken lightly. Public perception is key to the acceptability of biotechnological products and any concerns over safety, warranted or not, will have an impact on the biotechnology industry.

In scientific terms, a lot has been demystified and it has been amply demonstrated that nature itselfs effects transfers of genetic material amongst unrelated organisms and across species boundaries in much the same way

as modern biotechnology. This does not mean that no adverse environmental effects are ever likely to occur as a result of biotechnological applications. For example, major academic and industrial efforts are directed toward the development of herbicide resistant crops. Such crops are valuable in ensuring increased productivity through reduced losses to disease and are considerably more environment-friendly as they minimics the application of chemical herbicides. Transfer of herbicide resistance genes from such transgenic crops to their weedy relatives is possible and has been experimentally demonstrated on a number of occasions, the result being herbicide resistant weeds. Similarly, the ease of transfer of genetic material in soil microorganism populations may have adverse ecological repercussions. Having said this, however, it is important to stress that potentially adverse impacts are likely to be danger for populations and the environments. To be more specific, organisms with "bad" genes may persist in insignificant populations for long periods, years or decades, until some environmental change (e.g. presence of chemicals) leads to a population explosion.

Legislators have provided for a number of monitoring approaches that aim at minimizing the chance of such effects going unnoticed. It is common practice in industrial countries to conduct small scale field trials in which all potential eventualities are eliminated through scientific scrutiny and practical observation. Such trials are demanding on personnel resources and money. For example, field testing of transgenic plants costs up to 100 times more than for new plant varieties developed by traditional breeding methods. They are, nevertheless, useful for improving our understanding of the interaction of introduced transgenic organisms with their environment. This is important as the expression of the new genetic traits is environmentally controlled.

In the case of the developing world and Eastern Europe, however, there is an almost total lack of regulation and of monitoring mechanisms for releases of transgenic organisms into the environment.

Individual countries are confronted with the choice between legally binding instruments (regulations) or softer, non-binding legislation (guidelines). There are good arguments in support of the latter, namely, their greater flexiblity in responding to the evolution of scientific knowledge through case of amendment. The disadvantage is that, although legal liability may arise as a result of non-compliance with guidelines, legal institutions and enforcement mechanisms are not in place in many countries.

Developing an oversight capability is crucial for facilitating technology transfer and allaying public concerns. Moreover, regional approaches may be considered in order to overcome resource limitations.

The United Nations Development Organization (UNIDO) and the International Centre of Genetic Engineering and Biotechnology (ICGEB) have been trying to address the dual task of harmonizing international guidelines, strengthening member country cooperation and established through interagency (UNIDO/UNEP/WHO/FAO) working group a "Voluntary International Code of Conduct for the Release of Genetically Modified Organisms to the

Environment". The Code was prepared with the help of over 40 experts from developing and industrial countries. It compiles the consensus elements of national regulations/guidelines into a coherent whole, without attempting to introduce new regulatory considerations. It thus provides a good basis for developing national guidelines where they are deemed necessary.

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Voluntary Code of Conduct for the Release of Organisms into the Environment

1. Code of Conduct

1.1. Purpose and Objectives

The objective of the Code is to:

— outline the general principles governing standards of practice for all parties involved in the introduction of organisms or their products/metabolites to the environment. Some sections of the Code may also be applicable to other phases of research and development;

— encourage and assist the establishment of appropriate national regulatory frameworks, particularly where no adequate infrastructure presently exists;

— ensure that appropriate national authorities and institutions, distributors and users are informed or have access to information, thereby facilitating the safe use and handling of biotechnology products;

— encourage international governmental and non-governmental institutions, including funding organizations that provide incentives for the use of new biotechnology for development purposes, to require researchers or producers to follow the principles set out in this document;

— stimulate the development of mechanisms for cooperation and consultation between governments to ensure safe research, development, use including environmental application, compliance with international transport laws, and movement in commerce of the products of biotechnology;

— assist countries to ensure the safety of research, development, use and introduction by providing mechanisms to obtain consultation and advice as needed;

— stimulate the development of mechanisms for obtaining and disseminating information in a timely and efficient manner.

The document addresses the shared responsibility of many sectors of society, including idividual governments, regional, supranational and interna-

tional organizations, scientific researchers, institutions and societies, trade associations, industry including manufacturers, formulators and distributors, users, and non-governmental organizations such as environmental groups, consumers and trade unions, and funding institutions.

The document is designed to help industries, organizations and scientists seeking to facilitate, develop and apply biotechnology for social and economic improvement to be aware that their judgements and actions involving GMOs, if taken with adequate review and notification, will ensure public health and environmental safety and thereby promote, and not jeopardize, the long-term development of the technology.

The document emphasizes the need and responsibility of all national authorities and other parties involved to ensure that the public is well informed.

It is intended that the Code will be broad-based, sufficiently comprehensive and transparent so that it will be widely acceptable. It should be sufficiently flexible to allow evolution over time to accomodate new advances, expertise and requirements. In addition to the existing general regulations for agricultural and pharmaceutical products, experience will also demonstrate whether there is a need for amendments to the regulatory approach specifically aimed at biotechnology products.

1.2. Scope

The scope of this document covers GMOs at all stages of research, development, use and disposal, while focusing on release to the environment. It covers, but is not limited to, genetically modified plants, animals (including, for example, insects, molluscs and fish), and microorganisms and their products and by-products.

The document is addressed to all those researching, developing, regulating or using the products of biotechnology in all countries.

This covers safety issues regarding public health and the environment.

2. The Code

2.1. General Principles

1. Regulatory oversight and risk assessment should focus on the characteristics of the product rather than the molecular or cellular techniques used to produce it. While knowledge of the techniques is useful as it relates to properties conferred to the GMO, it is the GMO or related product to which humans, animals and the environment are exposed.

2. A primary research goal should be to work with well-characterized nucleic acid sequences and to know to the extent feasible all sequences transferred to the modified organisms to be released to the environment.

3. The level of potential risk identified based on the biological properties

of the modified organisms and its receiving environment will determine the type and detail of the information required from the researcher/proposer.

4. The safety precautions and monitoring procedures specified should be appropriate to the level of assessed risk.

5. National authorities, industry and researchers have a responsibility to disclose or make available safety information to the public. Acceptance of biotechnology products will be enhanced if the information is disclosed and made available to the public, especially the community where the test will occur. There is a need for openness in this process.

6. Unexpected or adverse public health or environmental impacts related to the release of a GMO should be reported to the appropriate national and international authorities.

7. Key aspects of risk assessment should include the biological and reproductive properties of the organism, the characteristics imparted by the genetic modification and the relevant attributes of the site where the organism is to be used.

8. Risk assessment/evaluation must be based on sound scientific principles, requiring participation of experts from appropriate disciplines.

9. Evaluations of risk should be conducted at each step of development from the research laboratory to small-scale and large-scale release for production and testing, and finally to commercial use. Evaluations at each stage should be built on those made at prior stages, and need not always be conducted *de novo*.

10. The systems developed for review of proposal applications must remain flexible and capable of being adapted in accordance with the latest scientific information.

11. While national authorities have primary responsibility for ensuring review and making decisions concerning biotechnology activities carried out within their countries, regional cooperation will be desirable and sometimes essential.

12. Information on anticipated consequences, which may beyond the country immediately involved, will need to be provided. In this case formal notification and relevant information should be provided to the country or countries which may be affected.

2.2. Actions and Responsibilities for Governments

1. Every member country should designate a national authority, or authorities, to be responsible for handling enquiries and proposals, i.e., all contacts concerning the use and introductions of GMOs. More than one authority may be appropriate to cover specific areas of use of biotechnology; for example, pharmaceuticals, foods, agriculture and pesticides.

2. As a starting point in implementing this code countries should examine their existing mechanisms for review and risk assessment to determine if they are suitable for ensuring the safe use of GMOs, both for human health and the environment.

3. Risk assessment and scientific reviews should be carried out by scientifically competent bodies independent of the researcher/proposer. Competent review bodies should be established on a national basis by the designated authority or authorities. Since risk assessment requires high level, multidisciplinary scientific competence, it may be necessary to call on expertise from outside the country. Nonetheless, decisions regarding the safety of GMOs are the responsibility of the country involved.

4. Case-by-case evaluation should be the rule unless sufficient experience and an adequate body of knowledge is gathered to allow classifications and generalizations based on experience and conclusions regarding the behaviour of GMOs.

5. The national authority or authorities should establish mechanisms to facilitate the collection, storage and dissemination of data on local conditions, such as agronomic and environmental data.

6. The national authority or authorities should ensure that for each proposed use or release there is appropriate compliance with the safety conditions set down as a result of the risk assessment. This should include any appropriate control or mitigation procedures as well as procedures for termination of the experiment and waste disposal.

7. The national authority or authorities should ensure that the researcher/proposer has suitable monitoring protocols in place. In addition, the national authority may wish to undertake additional monitoring of the GMO, the site or the surrounding environment beyond that which is necessary as part of the experimental protocol.

8. While ensuring maximum disclosure of information necessary for risk assessment and safety, the recognition of, and respect for, confidential business information is essential.

9. When an introduction of an organism is planned, the national authority or authorities should ensure that the local community is informed prior to the release. In addition, the national authority or authorities in collaboration with its (their) scientific advisory bodies and the researcher/proposer should provide appropriate educational material.

10. The national authority or authorities should ensure public access to information on which decisions regarding the use or release of organisms are taken.

11. Member countries should establish mechanisms for exchanging information with other interested countries, particularly those in their geographic region.

12. The designated authority or authorities should also be responsible for ensuring that the principles set out in this document are being implemented. As a confidence building procedure, countries may wish to seek outside review of their implementation of the principles set out in this document.

13. When informed about an unexpected or adverse public health or environmental impact related to the release of a GMO, the national authority or authorities should report relevant information to the appropriate international organizations.

2.3. Responsibilities of the Researcher/Proposer

1. Researchers should take into account for environmental introduction of GMOs:
- the characteristics of the organism(s) used, including the introduced gene, genetic materials and gene products;
- the characteristics of the site and the surrounding environment;
- appropriate conditions of the release, including confinement, control, mitigation, termination and disposal procedures as required.

2. The researcher/proposer has the responsibility for conducting of potential risks at appropriate stages of research and development of an organism prior to its formal review or assessment.

3. Records should be kept and securely maintained on all activities involving GMOs. Documentation should include the description and location of each activity, protocols for carrying them out, the results, monitoring data and any other pertinent information.

4. The researcher/proposer should notify or obtain approval from the responsible national authority or authorities prior to the conduct of an activity involving the release of the GMO.

5. If an unexpected or adverse public health or environmental impact occurs related to the release of the GMO the researcher/proposer should notify and provide relevant information to the appropriate national authority or authorities.

6. The researcher/proposer should disclose all relevant information to the responsible national authority or authorities. Details of specific approvals and refusals of all trials and applications, including those in other countries, granted or denied, should be included in any new application.

7. When a country does not yet have a designated national authority or a suitable scientific review body, the researcher/proposer has an obligation to inform the government authorities in the areas having the closest corresponding responsibilities, for example, health ministries for pharmaceutical applications and agriculture ministries for crops and livestock. The researcher/proposer should suggest alternative review mechanisms to enable the government involved to obtain access to competent and independent scientists able to provide unbiased and scientifically sound risk assessment. In this case the risk assessment effort should include consultation with the appropriate international organizations.

Annex I
Recommendation to Establish an International Biosafety Information Network and Advisory Service

Recognizing that an international mechanism is needed in the field of biosafety for advice to countries that may require it, it is proposed that the

UN system shall establish an international biosafety information network and advisory service. This will handle requests for advice and questions about the assessment of proposals as rapidly as possible and also arrange for appropriate help. Such a service will be of particular help to developing countries. An important area of its activities will be concerned with the release of organisms into the environment.

1. Role of the Service

The service shall, on request, provide advice to assist in working towards the setting up of a designated national authority/authorities, in each country to provide a national point of contact. All contact shall be through, or at least with the knowledge of, such authority/authorities. The service may also help countries on request to ensure that they have the means to conduct assessments. The national authority/authorities will make requests for whatever assistance is desired. In some cases, the national authority/authorities may wish to request assistance directly from certain experts or from another country or group of countries; when this is the case, the service will play a coordinating and facilitating role. It will be responsible for ensuring that products or projects are assessed and that its decisions based on these assessments, and any others, are enforced.

The service shall have access to sufficient multidisciplinary expertise to be accepted as competent to share information with national and international advisory and/or regulatory bodies. It shall have sufficient links with national authority/authorities and scientific advisory bodies. It shall gather information on what projects have been or are being assessed worldwide. Where possible, it should attempt to compile information on the assessment procedures used and the controls of experimental conditions imposed. Such information shall be made widely available in order to facilitate future assessments at the national, regional or international levels.

The service shall provide assistance to national authority/authorities on request to facilitate the implementation of the principles set out in this document.

As requested, advice and technical assistance shall be provided on monitoring the environmental impacts associated with the use of organisms.

The primary function of the advisory service is to provide assistance to assess health and environmental safety of a proposed applications. It is not to provide an assessment of need, cost effectiveness, or of risk/benefit.

The service shall take into account developments in new assessment methods or approaches, as well as the work of national, regional and international organizations aimed at harmonization.

2. Organization of the Service

A scientific steering commmittee. The function of the steering committee will be to facilitate access to the latest scientific and technological knowledge in the relevant fields. It will also provide overall quidance to the service. It should be made up of a panel of recognized scientists selected to represent appropriate disciplines and regional perspectives.

A small technical/administrative secretariat. It will be responsible for the day-to-day operation of the service. Its duties will include the servicing of the steering committee, liaising with different authorities, collecting and distributing relevant information, and with the advice of the steering committee, setting up ad hoc panels of experts as needed.

UNIDO should take the lead, in consultation with the Informal UNIDO/ /UNEP/WHO/FAO Working Group and other international organizations, in setting up an international biosafety information network and advisory service.

As a starting point, the service should conduct an international survey to identify existing expertise in the various scientific disciplines required for the safety assessment of biotechnology use. At a minimum, this should result in the development of an international directory of experts with names, areas of expertise, telephone and telefax numbers.

Sufficient funding will be necessary to enable the service to carry out these duties. Expenditures will include those associated with meetings of the scientific steering committee, the salaries and operational expenditures for the secretariat, and travel-related expenditure for experts.

Prepared by the UNIDO Secretariat for the Informal
UNIDO/UNEP/WHO/FAO
Working Group on Biosafety