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VOLUNTARY CODE OF CONDUCT FOR THE RELEASE OF ORGANISMS INTO THE ENVIRONMENT

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

in IDA?

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VOLUNTARY CODE OF CONDUCT FOR THE RELEASE OF ORGANISMS INTO THE ENVIRONMENT

I. PREAMBLE

A. Genetically modified microorganisms, plants and animals offer new technological possibilities to improve quality and production. Improved crops and food products, drugs and health care products, vaccines, feeds, industrial chemicals and products, new diagnostic agents and environmental agents are being developed via new biotechnological processes. Throughout the centuries, traditional breeding programs have produced new and improved varieties and brought products to markets. The products of biotechnology can be considered to be part of this continuum.

B. The advent of new molecular and cellular techniques of genetic modification has led to the continuing emergence of products (including organisms) of biotechnology that promise substantial benefits and improvements to the quality of life. These techniques are available now, but to be safely and effectively used, they must be applied according to a number of principles, such as those described below, and with the support of an international biosafety information network and advisory service.

C. The proposed document contains all the elements of a code of conduct for the release of genetically modified organisms (GMOs) into the environment. It aims to set forth the minimum acceptable components necessary for international cooperation. While not calling for a change in national regulatory provisions, it is intended as a general model that could be adopted in countries that have no regulations at present. Aiming to draw on existing experience rather than to frame new principles, it contains a list of selected reference documents in an annex (Annex I).

D. Since newly introduced organisms have the potential for transfrontier impacts, there is a need to develop an international code of conduct/practice and establish a general framework and guidelines that will ensure their safety in research, development, production, trade and use. This would facilitate safe applications of biotechnology in an orderly manner. Alongside high expectations from the application of biotechnology, questions regarding public health and environmental safety, development, and use need to be addressed.

E. Of particular relevance to international cooperation is the introduction of organisms to the environment. It is anticipated that

the code will provide help to governments in developing their own regulatory infrastructure and in establishing standards for the safe development, manufacture, use and release of GMOs to the environment, or in obtaining appropriate advice and support in those cases where a country recognises the need for improvement in its review, national assessment or decision making structures. The principles outlined in this document deal primarily with GMOs. They may not always provide an adequate framework to assess the risks posed by the introduction of other organisms such as organisms not indigenous to the introduction site. Therefore, there is a need for a similar effort to develop principles and codes of practice to deal with this category of introductions.

Furthermore, the document is not intended to deal with issues related to the contained industrial application of GMOs. Whereas there is a substantial body of knowledge regarding contained uses of microorganisms, there is still the need to further address safety considerations that pertain to industrial uses of pathogenic organisms, to internationalize the principles underlying safety and to develop codes of conduct to deal with this category of applications.

F. To ensure the safe management of biotechnology including research, development, use, and associated environmental introductions of GMOs, member countries need;

- •appropriate scientific and technical expertise;
- •national assessment and decision making structure(s);
- •specific scientific advisory bodies;
- •mechanisms to gather information on local agronomic and environmental conditions;
- •systems for the provision of information to, and education of, the public.

G. a. To respond to these needs, a number of approaches are available to member countries. In this regard, virtually all countries have quarantine procedures or similar mechanisms for managing the import of new plants, animals or microorganisms. An adaptation of these mechanisms through specific organism-related scientific advisory bodies could provide a means of handling new biotechnology products. In addition, such procedures could be extended to include review of new domestically produced GMOs.

b. Governments may in other cases require assistance in the form of information or advice in order to make a proper scientific assessment. Even where a researcher supplies full

documentation, expert advice may be needed to enable an adequate assessment to be made.

c. In the simplest case support to access existing information may be all that is needed to assist the product assessment. Beyond this, there will be a wide range of needs.

d. For some countries, the only need will be for expert advice to help in the assessment of a particular project or product. Other countries may wish to draw on external sources to provide all the skills needed to form a national review or risk assessment body; and yet other countries may request a full risk assessment team from another country, regional grouping or international body. Such advice could be provided through an external service which should also encourage the development of national expertise by inviting qualified local scientists to participate in the review process.

e. No matter which option is selected by a country, it is necessary to build confidence in the system established and the results obtained.

H. The UN is an obvious system through which to co-ordinate a worldwide effort to ensure that all such work is preceded by an appropriate assessment of risks. The subject receives continuous attention in the various UN agencies and more specifically from the Informal UNIDO/UNEP/WHO/FAO Working Group on Biotechnology Safety.

II. CODE OF CONDUCT

A. Purpose and Objectives

1. The objective of the code is to:

a. 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;

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

c. 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;

d. 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;

e. stimulate the development of mechanisms for co-operation 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;

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

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

2. The document addresses the shared responsibility of many sectors of society, including individual governments, regional, supranational and international 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.

3. 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.

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

5. 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 accommodate 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.

B. Scope

1. 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.

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

3. This document covers safety issues regarding public health and the environment.

C. The Code

1. General Principles

a. 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.

b. 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.

c. The level of potential risk identified based on the biological properties of the modified organisms and its receiving environment will determine the type and the detail of the information required from the researcher/proposer.

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

e. 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.

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

g. 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.

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

i. 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.*

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

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

l. Information on anticipated consequences, which may extend 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. Actions and Responsibilities for Governments

a. 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.

b. 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.

c. 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, multi-disciplinary 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.

d. 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.

e. The national authority(ies) should establish mechanisms to facilitate the collection, storage and dissemination of data on local conditions such as agronomic and environmental data.

f. 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.

g. 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 necessary as part of the experimental protocol.

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

i. 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.

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

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

l. 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.

m. 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.

3. Responsibilities of the Researcher/Proposer

a. 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 appropriate.

b. The researcher/proposer has the responsibility of conducting evaluations of potential risks at appropriate stages of

research and development of an organism prior to its formal review or assessment.

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

d. 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 a GMO.

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

f. The researcher/proposer should disclose all relevant information to the responsible national authority, or authoritites. 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.

g. 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 which have 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.

A recommendation for a mechanism to this effect in the form of establishment of an international biosafety information network and advisory service is set out in Annex II. Once this service or an equivalent international mechanism is in place, the researcher/proposer should, in consultation with the government involved, may contact the service for appropriate advice.

D. Existing Regulatory Provisions and Guidelines

To facilitate international cooperation in biosafety and to help countries that do not have regulatory mechanisms, a list of a number of documents reflecting existing approaches is attached as the Bibliography in Annex I.

ANNEX I

BIBLIOGRAPHY OF AUTHORITATIVE STATUTES AND GUIDELINES

To facilitate international cooperation in biosafety and to help countries which do not have regulatory mechanisms, the following list of applicable statutes and guidelines is set out below.The list is intended to be illustrative and is not comprehensive.

Guidelines, Recommendations and Rules on Genetic Engineering

Australia

Genetic Engineering

- Guidelines for the preparation and presentation of applications for general marketing of monoclonal antibodies for use in humans, May 1988
- Procedures for assessment of the planned release of recombinants DNA organisms, May 1987
- Guidelines for large scale work with genetically manipulated organisms, 1990
- Guidelines for small scale genetic manipulation work, 1989
- Guidelines for the preparation and presentation ofapplications for general marketing of monoclonal antibodies for use in humans, May 1988, Australian Drug Evaluation Committee, Department of Community Servicesand Health, GPO Box 9848, Canberra ACT 2601
- Australian Code of Good Manufacturing Practice for Therapeutic Goods
- Medicinal Products, draft of January 1990, Therapeutic Goods Administration, Department of Community Services and Health, PO Box 100, Woden ACT 2606
- NDF 4 guidelines for preparing applications for the general marketing or clinical investigational use of atherapeutic substance, Therapeutic GoodsAdministration, Department of Community Services andHealth, PO Box 100, Woden ACT 2606
- Code of good manufacturing practice for therapeutic goods, May 1983, National Biological StandardsLaboratory, PO Box 462, Canberra ACT 2601
- The Australian code of practice for the care and useof animals for scientific purposes (1990), National Health and Medical Research Organisation, and Australian Agricultural Council, Australian GovernmentPublishing Service, Canberra ISBN 0-644-03737-7

• The NH & MRC statement on human experimentation and supplementary notes, 1987, National Health and MedicalResearch Council, Department of Community Services andHealth, Canberra ACT 2601
• Ethical aspects of research on human gene therapy.Report to the NH & MRC by the Medical Ethics Committee, 1987, National Health and Medical Research Council, Commonwealth of Australia ISBN 0-644-06623-7
• Laboratory biosafety guidelines, September 1986, AIDS Task Force, PC Box 100, Woden ACT 2606, ISBN 0-644-05315-1
• Infection control guidelines
• acquired immunedeficiency syndrome (AIDS) and related conditions, AIDS Task Force, PO Box 100, Woden ACT 2606, Commonwealth of Australia 1988, ISBN 0-644-05021-7
• Requirements for clearance of agricultural andveterinary drugs
• Regulatory control of veterinary drugs, document PB 2374A, 1983, Department of Primary Industry, Pesticides Section, Australian Government Publishing Service, Canberra
• Australian Standard 2243: Safety in laboratories -
Part 1, 1982 - General
Part 3, 1985 - Microbiology; plus 1990 appendix
• Australian Standard 2252: Biological safety cabinets -
Part 1, 1981 - Biological safety cabinets (class I)
Part 2, 1985 - Laminar flow biological safety cabinets (class II) for personnel and product protection
• Australian Standard 2647: "Biological Safety Cabinets - Installation and Use", 1983
• Australian Standard 1095: Micro'iological methods forthe dairy industry
• Australian Standard 1132-1973: Methods of test for air filters for use in air conditioning and general ventilation, ISBN 0-7262-0095-6
• Australian Standard 1386-1989: Cleanrooms and cleanworkstations, ISBN 0-7262-5689-7; 5691-9; 5692-7; 5693-5, 5694-3; 5695-1
• Australian Standard 1766: Methods fo: the micro-biological examination of food
• Australian Standard 1807-1989: Cleanrooms, workstations and safety cabinets - methods of testing
• Australian Standard 2013-1989: Cleanroom garments, ISBN 0-7262-5686-2 and 5687-0
• Australian Standard 2252 Part 2: 1985: Laminar-flow biological safety cabinets (class II) for personnel and product protection, ISBN 0-7262-3627-6

Secretary, Genetic Manipulation
Advisory Committee
Department of Administrative Services
PO Box 2183
Canberra ACT 2601

Austria

- NIH Guidelines translated and adapted for Austria
- Act on contained use and deliberate release of genetically modified organisms into the environment
(first draft April 1991)

Belgium

Applied and existing regulations in connection with Genetic Engineering

- Waste regulation, decree of 5.7.1985 (B.S.14.12.1985)
- Waste water regulation, decree of 26.3.1971
(B.S.1.5.1971)
- Air regulation under law of 28.12.1964 (B.S.14.1.1965)
(controlled by the National Health Authority)
- Royal regulation of 6 June 1960 on the production, distribution and marketing of drugs and their application, inclusive of all additional regulation until September 1988
- Regulation concerning plants at risk (Etablissement incommodes, dangereux, insalubres)
- Regional building regulations (also regulate waste water problems) (Code wallon d'urbanisme et d'amenagement du toirie)
- Construction regulations for construction companies in Brussels, 3000 pages volume (Union des entreprises de Bruxelles)
- Regulation for the protection of workers (Réglement général pour la protection du travail)
- General regulations concerning chemical plants, drugs group (Fédération des Industries Chimiques, Groupement Médicament)

Brazil

- Biosafety Guidelines for the national programme of science and technological development (PADCT/Biotechnology). The

programme is financed by a agreement between the Brazilian Government and the World Bank.

Canada

General Guidance Documents

- Guidelines for the registration of genetically modified micro-organisms (GMMs), in preparation for 1991.Agriculture Canada.
- Guidelines for the registration of naturally occurring micro-organisms (NOMs), 1990.Agriculture Canada.
- Requirements for field trials of naturally occurring microbial pest control agents, 1990.Agriculture Canada.
- Guidelines for field trials of genetically modified micro-organisms, registration of microbial pesticides and pest control agents, in preparation for 1991
- Guidelines for the handling of recombinant DNA molecules and animal viruses and cells.Medical Research Council of Canada, 1989.
- Guidelines for the production and testing of new drugs and biologicals produced by recombinant DNA technology. Health and Welfare, 1990.
- Guidelines for the regulation of veterinary biologics produced by biotechnology
- Regulation of plant biotechnology, part 2. Environmental release of genetically altered plant material

Applied and existing regulations in connection with Genetic Engineering

- Health of Animals Act and Regulations
- Fertilizer Act and Regulations
- Pest Control Products Act and Regulations
- Guidelines for the registration of microbial pesticides
- Feeds Act and Regulations
- Seeds Act and Regulations
- Canadian Environmental and Protection Act and Regulations
- Environmental Contaminants Act and Regulations
- Food and Drugs Act and Regulations
- Hazardous Products Act and Regulations

China

The Institute of Genetics and the Chinese Academy of Agricultural Sciences have advised that no guidelines have been established for surveillance of GMO, as this field has as yet undergone little development in China. However, a quarantine

system is operated by the Animal Drug Administrative Division of the Bureau of Animal Husbandry, Ministry of Agriculture in Beijing, which also handles the registration of veterinary products. Pharmaceuticals are registered by the State Pharmaceuticals Administration of China, also in Beijing. The Ministry of Labour administers laws relating to health and safety at work which would apply to the fabrication of biotechnology products.Patent protection is afforded to micro-organisms and provides for plant variety rights.

CSFR

Applied and existing regulations in connection with Genetic Engineering

- Decree on Protection Against Pests, Plant Diseases and Weeds within Import (No.63/1964 of Col. in working of No.51/1977 of Col.)
- Act on Protection of Agricultural Soil Fund (No.53/1966 of Col. in working of the Act No.75/1976 of Col.)
- Act on Water Management State Administration (No.130/1974 of Col. and No.135/1974 of Col.)
- Water Act (No.138/1973 of Col.)
- Act on Provision Against Air Pollution (No.35/1967 of Col.)
- Decree on Creation and Protection of Healthy Living Conditions (No.45/1966 of Col.)
- Act on Health Care (No.20/1966 of Col.)
- Labour Act (No.65/1965 of Col.)
- Act on Technical Standardization (No.96/1964 of Col.)
- Decree (No.62/1964 of Col.)
- Act on Plant Production (No.61/1964 of Col.)
- Act on State Technical Supervision Regarding Safety on Work
- Decree on Ground and Underground Waters
- Directives on Hygienic Services

Denmark

Genetic Engineering

- Environment and Genetic Engineering Law, June 1986 (Act No. 288 of 4 June 1986)

The National Agency for Environmental Protection
The Biotechnology Office
Strandgade 29
DK-1401 Copenhagen K
Att: Kaj Juhl Madsen

Finland

Applied and existing regulations in connection with Genetic Engineering

- The Law on Pesticides
- The Law on Infectious Diseases
- The Law on Water
- The Law on Air Protection
- The Law on Waste Management

France

Genetic Engineering

- Note No.86-32 of 19 September 1986 concerning installations classified under the protection of the environment (Ordonnance of 30 July 1985, chapter 58-11: installations necessitating micro-organisms)
- Manual of good research practices and "field testing"(Development under natural conditions, reproduced in a laboratory) of transgenic plants (class 1)

Germany

Genetic Engineering

- Law for the regulation of Genetic Engineering matters, 1990
- Gene Technology Record Keeping Ordinance, 1990
- Gene Technology Safety Ordinance, 1990
- Gene Technology Consultation Ordinance, 1990
- Procedural Ordinance relating to Gene Technology, 1990
- Environment and Genetic Engineering Law, June 1986
(Act No. 288 of June 1986)
- Rule for the in vitro recombination of genetic material, 1986
- Rules and regulations for safety in biotechnological research and production
- Genetic Engineering Safety Directive
- Directive concerning the Central Commission for Biological Safety
- Genetic Engineering Hearings Directive
- Genetic Engineering Procedures Directive
- Directive concerning written documentation about genetic works for research or for commercial purposes

Bundesministerium fuer Gesundheit (BMG)
Referat 353 Gentechnologie
Postfach 20 02 20
5300 Bonn 2
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Hong Kong

The Government of Hong Kong has neither guidelines nor laws for surveillance of GMO. Vaccines and pharmaceuticals for human and veterinary use are controlled via the Pharmacy and Poisons Ordinance (Cap 138), and each consignment from overseas requires an import licence. All importations of biological materials, including live bacterial cultures and disease-causing organisms, require a permit which is issued by the Port Health Office of the Department of Health.

Hungary

Two EC Directives have been translated and adapted to Hungarian law. These will be presented to Parliament for adoption by the end of 1991 (90/219/EEC and 90/229/EEC)

India

Genetic Engineering

- Recombinant DNA Advisory Committee, Dept. of Biotechnology: Safety Guidelines for the Genetic Engineering Research
- Recombinant DNA Safety Guidelines and Regulations
- Release Approval Committee: Environmental Protection Act Notification

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Lodi Road
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Indonesia

At present there are no guidelines for GMO, but the existing regulations, administered by the Ministry of Health for the safety

of production and efficacy of products, could be used to control GMO.The Ministry of Justice controls the patents on GMOs as well as plant variety rights.Quarantine is controlled by the Ministry of Agriculture and pollution is controlled the State Ministry for Population and Environment.

Ireland

Genetic Engineering

- Guide to recombinant DNA regulation on Ireland, June 1987: Application of NIH Guidelines (May 1986, Definition of Recombinant DNA Molecules) and other existing regulations in connection with the release of genetically modified organisms, as:
- Water Pollution Act, 1977
- The Dangerous Substances Act, 1972
- Destructive Insects and Pests (Consolidation) Act, 1958
- Council Directive 77/95/EEC on protective measures against the introduction into the Member States of harmful organisms of plants or plant products

Japan

Genetic Engineering

- Guidelines for the application of recombinant DNA organisms in agriculture, forestry, fisheries, food industry and other related industries, Dec. 1986
- Guidelines for recombinant DNA experiments, 1983
- Guidelines for manufacture of drug products by application of recombinant DNA technology
- Guidelines for industrial application of recombinant DNA technology
- Guidelines for field-testing of genetically engineered plants

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Dr. T. Takahashi, M.D.
Director, Life Science Division
Science and Technology Agency
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Dr. S. Tsuru, Secretariat
Council of Agriculture, Forestry and Fisheries
Tokyo

Prof. H. Uchida
Advisor, University of Tokyo
Tokyo

Korea

Although no guidelines for GMO exist at present in Korea, the Director General for Livestock in the Ministry of Agriculture, Forestry and Fisheries will administer them once they are implemented.The same Ministry is responsible for all quarantine matters and for registering veterinary products.Pharmaceuticals are registered under the Pharmaceutical Laws administered by the Ministry of Health and Social Welfare.The Industrial Office of the Ministry of Trade and Industry oversees all patents, and it is considered that this power would enable plant varieties and GMO to be protected.

Malaysia

There are no guidelines at present for GMO, but the import of all biological materials to Malaysia is controlled by the Plant Quarantine Regulations (1981), administered by the Department of Agriculture.The Ministry of Health is responsible for the control and registration of all pharmaceuticals, drugs and vaccines. At present there are no regulations for health and safety at work, nor patent protection for GMO or plant variety rights.

Netherlands

Genetic Engineering

• Resolution of 25 January 1990 for the preparation of a general directive concerning the existing Article 24 of the Law on

Environmentally Hazardous Materials
- Guidelines for environmental applications with genetically modified organisms

New Zealand

Genetic Engineering
- Recommendations for the control of field testing and release of genetically modified organisms in New Zealand, February 1987
- Until a relevant rule will be passed, the Interim Assessment Group for the Field Testing and Release of Genetically Modified Organisms (Section 33 of the Environment Act) will exercise this control function, 1990

Dr. Lin Roberts
Ministry for the Environment
84 Boulcott Street
PO Box 10362
Wellington

Norway

- Environment and Genetic Engineering Law (in preparation for 1992)

Philippines

- Executive Order No. 430, series of 1990, establishedthe National Biosafety Committee

The Chairman
National Biosafety Committee
Department of Science and Technology
Bicutan, Taguig
Metro Manila
Tel: 632 822 0961 to 67

Singapore

In Singapore, permits to import live organisms are issued by the Commissioner of Public Health through the Infectious Disease Act.The Ministry of Health administers the Medicines Act, which provides for the registration, safety and efficacy of

pharmaceuticals, while the Veterinary Division of Primary Production deals with veterinary products.Safety at work is enforced by the Ministry of Health.Patent protection is based on the model of UK patent laws, but Singapore is currently preparing its own patent law for this area and for a Plant Variety Act.

Sweden

- AFS 1988:12.Occupational guidelines for the use of micro-organisms
- SFS 1988:534.Animal Protection Law.Gives the government the right to ban or set criteria for developing or using genetically modified animals
- SFS 1989:492.Amendment to Plant Protection Law (1972:318).Gives the government the right to ban or set criteria for developing or using genetically modified plants and genetically modified micro-organisms used in conjunction with plants
- SFS 1990:34.Governmental decree requiring a permit for growing genetically modified plants in greenhouse experiments or field tests.Administrative responsibility for issuing permits rests with the National Board of Agriculture after obligatory consultation with the Environmental Protection Agency and the Recombinant DNA Advisory Committee
- SFS 1991:114.Law on selected use of genetic screening in healthcare
- SFS 1991:115.Human embryo research law
- SFS 1991:116.Amendment to law on healthcare worker supervision (1980:11).Refers to specific rules regarding legal action if law SFS 1991:115 is not followed
- Proposed law on pre-market risk assessment of biological pesticides (non-modified as well as genetically modified)

Switzerland

Genetic Engineering

- Ordinance on the prevention of major accidents, April 1991
- Federal law relating to the protection of the environment (revision in preparation)
- Guidelines for the safe use of genetically modified organisms, SKBS/SGGB 1991

Taiwan

• Guidelines for research involving recombinant DNA molecules (1978)
• Law of animal drugs

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Taipei 10636

Thailand

Applied and existing regulations in connection with Genetic Engineering and Biotechnology
• Plant Quarantine Act B.E. 2507 (1964)
• Poisonous Article Act B.E. 2510 (1967) amended B.E. 2516 (1973)
• Animal Disease Control Act B.E. 2505 (1962)
• Animal Pathogen and Toxin Act B.E. 2525 (1985)
• National Environmental Quality and Protection Act B.E. 2518 (1975)
• Patent Law B.E. 2522 (1979)
• Copyright Law B.E. 2521 (1978)

United Kingdom

Genetic Engineering
• Code: Genetic Manipulation Regulations (1989); EC Directives 90/219 and 90/220 also apply. mInformation obtainable from Health and Safety Executive, Branch MDA3, Baynards House, 1 Chepstow Place, Westbourne Grove, London W2 4TF (Tel: 071-243-6000).Advisory/Regulatory Bodies: Health and Safety Executive (HSE); Advisory Committee on Genetic Modification (ACGM); Advisory Committee on Releases to the Environment (ACRE).Coverage of Code: Construction of GMOs; use of a cell or organism constructed by genetic manipulation, including use at large-scale; intentional introduction of GMOs into the environment.The regulations are supplemented by several Notes of Guidance:

1. Construction of recombinants containing potentially oncogenic nucleic acid sequences
2. Disabled host/vector systems
3. Intentional introduction of GMOs into the environment
4. Health surveillance
5. Eukaryotic viral vectors
6. Large-scale use of GMOs
7. Categorisation of genetic manipulation experiments
8. Laboratory containment facilities
9. Transgenic animals
10. Plants and plant pests
11. Genetic manipulation safety committees

Codes for related areas:

- Control of Substances Hazardous to Health (1988) Regulations
- Health and Safety (Dangerous Pathogens) Regulations (in preparation, 1991)
- Environment Act (in preparation, 1991)
- Guidelines on work involving the genetic manipulation of plants and plant pests (ACGM/HSE/Note 10, 1990)
- Guidelines on work with transgenic animals (ACGM/HSE/Note 9, 1988)
- Laboratory containment facilities for genetic manipulation (ACGM/HSE/Note 8, 1988)
- Guidelines for the categorisation of genetic manipulation experiments (ACGM/HSE/Note 7, 1988)
- Guidelines for the large-scale use of genetically manipulated organisms (ACGM/HSE/Note 6, 1988)
- Guidance on the use of eukaryotic viral vectors in genetic manipulation (ACGM/HSE/Note 5)
- Guidelines for the health surveillance for those involved in genetic manipulation at laboratory and large-scale (ACGM/HSE/Note 4)
- The planned release of genetically manipulated organisms for agricultural and environmental purposes/Guidelines for risk assessment and for the notification of proposals for such work (ACGM/HSE/Note 3)
- Disabled host vector system (revised and incorporated in ACGM/HSE/Note 7) (ACGM/HSE/Note 2)
- Guidance on construction of recombinants containing potentially oncogenic nucleic acid sequences (ACGM/HSE/Note 1)

Applied and existing regulations in connection with Genetic Engineering

- Control of substances hazardous to health regulations 1988 (COSHH)

- Food Act, 1984 (In Scotland, the Food and Drugs (Scotland) Act, 1956)
- The Animal Health Act, 1981
- The National Biological Standards Board (Functions) Order, 1976
- The Biological Standards Act, 1975
- Health and Safety at Work etc. Act, 1974
- Agriculture Act, 1970
- Medicines Act, 1968
- The Plant Health Act, 1967

USA

Genetic Engineering

- USDA Guidelines for research with genetically modified organisms outside contained facilities, February 1, 1990
- Final Rule, 52 FR 22882-22914, June 16, 1987
- Principles for Federal oversight of biotechnology:

Planned introduction into the environment of organisms with modified hereditary traits, 31.07.1990, Office for Science and Technology Policy in the White House (OSTP)

- NIH Guidelines for research involving recombinant DNA molecules, 1987
- Co-ordinated framework for regulation of biotechnology; announcement of policy and notice for public comment (Federal Register - June 26, 1986, Part II)
- Animal and Plant Health Inspection Service: Plant Pests: Introduction of genetically engineered organisms or products

Applied and existing regulations in connection with Genetic Engineering

- Toxic Substances Control Act (TSCA)
- Plant Pest Act
- Virus-Serum-Toxin Act
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- Food, Drug, and Cosmetic Act

USSR

Genetic Engineering

- Many guidelines covering the release of genetically modified organisms into the environment

ASEAN [Association of Southeast Asian Nations (Brunei Darussalam, Indonesia, Malaysia, Philippines, Singapore, Thailand)]

• ASEAN Guidelines for the Introduction of Biological Control Agents, 1989
• ASEAN Ministerial Understanding on Plant Quarantine Ring, 1982

EC

Genetic Engineering

• Council Directive of 23 April 1990 on the contained use of genetically modified micro-organisms (90/219/EEC)
• Council Directive of 23 April 1990 on the deliberate release of genetically modified organisms into the environment (90/229/EEC)
• Council Directive on the protection of workers from the risks related to exposure to biological agents at the work place (90/.../EEC)

Latin America

• Guías para el Uso y la Regularidad de las Técnicas de Ingeniería Genética o Tecnología del ADN Recombinante (Guides for the Use and Safety of Genetic Engineering Techniques or Recombinant DNA Technologies).IICA, 1988, 151 pp.

OECD

Genetic Engineering

• Recombinant DNA Safety Considerations: Safety Considerations for industrial, agricultural and environmental applications of organisms derived by Recombinant DNA Techniques, 1986
• Safety Considerations for the Use of Genetically Modified Organisms: Elaboration of Criteria and Principles for Good Industrial Large-scale Practice (GILSP) and Good Development Principles (GDP): Guidance for the Design of Small-scale Field Research with Genetically Modified Plants and Micro-organisms, 1991
• BIOTRACK: The Computerized OECD Pointer System on the Use of Genetically Modified Organisms, 1991
• International Survey on Biotechnology Use and Regulations, OECD Environment Monograph No. 39, 1990

Recombinant DNA Safety Considerations
OECD Publications
2 rue André-Pascal
F-75775 Paris

UNEP

- Ecological Impacts of Introducing Novel Organisms into the Environment (1986)

WHO

- Strategies for assessing the safety of foods produced by biotechnology, 1991
- Guidelines for assuring the quality of medicinal products prepared by recombinant DNA technology. Technical Report Series, 1991
- Laboratory Biosafety Manual, 1983 (Second edition in press)

ANNEX II

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 to the environment.

A. *Role of the Service*

1. The service shall on request provide advice to assist in working toward the setting up of a designated national authority(ies) in each country to provide a point of contact nationally. All contact shall be through, or at least with the knowledge of, such authority(ies). The service may also on request help countries to ensure that they have the means to conduct assessments. The national authority(ies) will make requests for whatever assistance is desired. In some cases, the national authority(ies) 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 co-ordinating 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.

2. The service shall have access to sufficient multi-disciplinary 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(ies) 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 level.

3. The service shall provide assistance to national authority(ies), on request, to facilitate the implementation of the principles set out out in this document.

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

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

6. 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.

B. *Organization of the Service*

1. A scientific steering committee. 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 guidance to the service. It should be made up of a panel of recognized scientists selected to represent appropriate disciplines and regional perspectives.

2. 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.

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

4. 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.

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5. 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.