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

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ANNEX I

VOLUNTARY CODE OF CONDUCT FOR THE RELEASE OF ORGANISMS INTO THE RECOMMENDATION TO ESTABLISH AN INTERNATIONAL BIOSAFETY INFORMATION NETWORK AND ADVISORY SERVICE 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 the bibliography (**NOT INCLUDED DUE TO REDUNDANCY OF INFORMATION**).

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 UNIDO/UNEP/WHO/FAO Working Group on Biotechnology Safety.

SECTION II-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, industries 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.

SECTION I-B. Scope

1. The scope of the 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, 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. The document covers safety issues regarding public health and the environment.

SECTION II-C-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, industries, 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.

SECTION II-C-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.

SECTION II-C-3. Responsibilities of the Researcher/Proposer

a. Researchers should take into account for environmental introduction of GMOs: othe characteristics of the organism(s) used including the introduced gene, genetic materials and gene products; othe characteristics of the site and the surrounding environment; oappropriate 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, contact the service for appropriate advice.

SECTION II-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 Bibliography.

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 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 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.

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.