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ESTABLISHING A REGIONAL BIOSAFETY ADVISORY BODY: A HYPOTHETICAL MODEL

Submission by Canada

Note by the Executive Secretary

At the request of the delegation of the Canada, the Executive Secretary is circulating herewith, for the information of participants in the first meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), a paper entitled "Establishing a regional biosafety advisory body: a hypothetical model". The paper is being distributed in the form and language in which it was received by the Secretariat.

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ESTABLISHING A REGIONAL BIOSAFETY ADVISORY BODY

A Hypothetical Model

{Each regional situation is unique and requires regional, sub-regional and national consultation and context setting to determine the most appropriate approach, if any, to regional collaboration in implementing the Protocol.}

Executive Summary:

A Regional Biosafety Advisory Body could provide a biosafety centre of excellence for a number of countries in a region. The Advisory Body could offer five major services for member governments to call upon when needed and when seen as appropriate by the governments in question:

1. Focal Point: Provide a regional focal point to member countries on selected matters pertaining to biosafety.
2. Perform risk assessments and advise member governments as to the consequences of allowing imports of LMOs.
3. Regional clearing house: Provide a reference centre on local biodiversity including crops, potential specific regional risks and possible consequential relationships to human health.
4. Capacity building: Provide hands-on training to enable local people to manage biosafety within the region.
5. Communications: Provide information material for use by member Parties to improve the level of understanding of biotechnology, biodiversity and sustainable development among representatives from industry, government, educational institutions, primary producers and consumers.

A Regional Biosafety Advisory Body is intended as a pragmatic response to evolve quickly an effective biosafety regulatory support system to protect a region's biodiversity. It is expected to be particularly advantageous for countries with similar ecological characteristics. It harnesses limited human and financial resources efficiently. Initially each member government might require only two or three people within their own government to receive the information from their Regional Advisory Body and prepare the appropriate documentation for sovereign decision making by their government. The local officials would be responsible for ensuring that their government departments impacted by biosafety regulatory decisions are kept informed.

As local expertise develops, or additional financial resources become available, governments may decide later to use their own expertise. Or, member governments may decide to retain the regional body approach as the most cost-effective long-term solution to managing LMOs within their country. In the meantime, a regional approach rapidly provides countries the opportunity to enjoy a high standard of protection.

A Regional Biosafety Advisory Body would have two major parts, a Governing Board and the Body itself. Each member country would name a representative to the Board. Attention would be given to attracting a multi discipline capability. Member governments would interface through the Board to ensure the Body is aware of their positions and that they are aware of the Ad visory Body's activities. The Board would be responsible for establishing the broad policy guidelines under which the Advisory Body would operate.

The Advisory Body itself could consist of about 15 people. They would include an Executive Director, Administrative Officer, Communications Advisor, , Management Information Officer (computer specialist), Director of Risk Assessment as well as necessary administrative support personnel and scientific personnel in such areas as plant molecular biology, ecology, entomology, animal molecular biology and toxicology. The actual scientific expertise may vary, depending upon availability and demand. Scientific personnel would be knowledgeable, or be able to be trained in risk management, risk assessment and risk mitigation. The Regional Body would not require staff in all scientific knowledge required in risk assessment. Some expertise may be more cost effective to obtain through specific job contracts or from within existing national facilities.

Capital and operating costs could be covered by outside grants in years one and two. Grants could be phased out over a 10-year period with a 10% reduction each year. An agreed plan to sustain the Body into the future would be prepared at the outset. Beginning in year three, member governments could contribute on a fee for service basis. Governments would have the option of selecting the services they desire. For example, if they develop their own competent authority, they would not select the competent authority option and thus would not be assessed a fee for this service. But they may still wish to receive other services and thus would be charged accordingly. Once a member government withdraws from a service, that government's representative on the Governing Board would not participate in policy discussions about that service.

REGIONAL BIOSAFETY ADVISORY BODY

I. MISSION STATEMENT

To become a biosafety centre of excellence to protect a region's biodiversity and to respond rapidly to requests to advise member governments on risks associated with the importation of living modified organisms.

II. GOALS

- To become the regional centre of excellence for member governments on biosafety regulatory matters.
- To perform appropriate risk assessments and manage effectively the notification process for member countries in support of competent authorities as envisaged in the Biosafety Protocol.
- To protect the region's biodiversity and any consequent implications for human health by advising member governments as to the consequences of allowing the import of LMO's.
- To perform quality research and provide a clearing house on local biodiversity including crops, and potential specific regional risks.
- To facilitate capacity building through the development of local human resources to manage biosafety within the region.
- To provide resource materials to facilitate implementation of communications plans within the region to improve the level of understanding of biotechnology, biodiversity and sustainable development among representatives from industry, government, educational institutions and primary producers and consumers.

III. OBJECTIVES

A. Within six months:

1. Administrative

- Identify the need for a Biosafety Regional Advisory Body among potential member countries;
- Create a Biosafety Regional Advisory Body Governing Board;
- Identify a host government;
- Hire key personnel including Executive Director, Administrative Officer, Communications Officer, , Information Officer, Director of Risk Assessment and required scientists;
- Obtain office space from the host government (nominally 350 square meters) with appropriate furnishings, supplies and equipment including computers with Internet connections;
- Develop and implement appropriate administrative policies including financial, travel and personnel.

2. Competent Authorities

- Liaison with competent authorities of member governments to develop the procedure to manage the notification process for LMOs on behalf of countries within the region.

3. Risk Assessment

- Collect generic background information at international level on such topics as crop biology, plant ecology and risk assessment reviews.
- Develop methodologies to identify and assess risks/benefits at regional level.
- Begin to develop data base to provide a clearing house on local biodiversity including crops, wild relatives, ecosystem characteristics, sensitive areas.
- Begin to identify potential specific regional risks.
- Develop a list of LMOs possessing minimal risk to the region for rapid assessments.

4. Capacity Building

- Identify necessary experience for risk management, risk assessment, risk mitigation and public information administration.
- Identify existing resources within the region and gaps in local knowledge.
- Identify people within the region requiring training, giving priority to people who have potential to train others.
- Identify regional and international sources available to assist in capacity building including possible internships.
- Develop training program modules to train local people to fill knowledge gaps.

5. Communications

- Identify potential publics for specialized or targeted educational materials including specialized stakeholders such as representatives from industry, government, universities and Non Government Organizations (NGOs); primary sector producers who may use LMOs; local populations living near possible experimental or commercial sites involving LMOs; consumers.
- Identify information sources, electronic and print on biotechnology, environment and health.
- Prepare balanced information materials, both electronic and printed in the language(s) of the region, appropriate for national distribution to each stakeholder group.
- Develop networking activities within the region to consolidate information distribution.

B. By end of year one:

1. Administration

- Administration policies/procedures fully operational.
- Review mission statement and goals and make alterations as required.
- Update objectives for year two to include specific targets, such as number and type of training programs, number and type of risk assessments, specific educational materials to be prepared etc.

2. Process:

- Manage notification process for LMOs among member countries in support of their own competent authorities.
- If required, the Regional Advisory Body would be responsible for performing the risk assessment and advising governments within the region of its results. Each government within the region would make the decision as to whether or not to allow the LMO to enter its sovereign territory.
- The Regional Advisory Body may request further information in accordance with the Protocol prior to advising member governments on the implications to the region of allowing the LMO to be imported.
- The Regional Advisory Body may change its advice to member governments at any time should new scientific information become available.

3. Risk Assessment

- Search international data bases to obtain advance information on new LMOs being developed of particular interest to countries within the region, noting especially those that could be for food, feed or processing, requiring advance assessment.
- Provide a regional clearing-house service to member governments.
- Identify regional and international experts who may be available from governments or on a contract basis to perform risk assessments.
- Perform risk assessment as required in support of competent authorities in the notification process.

4. Capacity Building

- Facilitate delivery of appropriate hands-on training programs.
- Organize regional workshops.
- Carry out on-the-job training,

5. Communications

- Develop educational materials for schools focusing on biosafety in the context of biotechnology, biodiversity and sustainable development.
- Prepare and make available background materials on specific LMOs and their uses that are made available within the region.

C. By end of year two: the Regional Biosafety Advisory Body would be fully operative with a plan, agreed among the member countries, for long term self-sufficiency in its operations.

IV. BUSINESS ENVIRONMENT:

Biotechnology is expanding rapidly and living modified organisms produced through modern biotechnology are increasingly been offered to the international food chain and modern medicine. At the same time, concerns continue to grow that the release of living modified organisms created through modern biotechnology may have an adverse impact upon the world's biodiversity. Most developed countries have created regulatory frameworks but many countries possess neither the expertise nor financial resources to manage the new technology judiciously. Thus the concept of countries with similar geographic and climatic conditions working together to create the necessary expertise to manage the new technology has evolved.

In January 1999 more than 150 participants and observers from 62 countries attended an International Workshop on Biosafety Regulatory Capacity Building in Mexico City. The Workshop, hosted by Mexico and sponsored by Canada, examined the basic elements of a biosafety regulatory framework, explored the experience gained by countries in implementing a framework and reviewed current regulatory capacity building initiatives. Special emphasis was placed on identifying the emerging needs of developing countries and countries with economies in transition to implement the basic elements of a biosafety regulatory system as envisaged by the Biosafety Protocol.

The most frequently suggested needs included:

- Hands-on training of local people to manage LMOs within the context of their own region.
- Regional data-bases related to biosafety within the region.
- Strengthening of local management and administration capacity.
- International access to information.
- A framework of alliances among governments and the private sector to address biosafety issues.

The Mexican Workshop indicated that the cost of creating biosafety regulatory frameworks in all countries will be expensive and time consuming. This paper outlining a potential model Biosafety Regional Advisory Body builds on the regional concept discussed at the Mexican Workshops to facilitate capacity building among developing countries and countries with economies in transition. It has expanded the concept to include advising countries within the region on whether or not to allow LMOs into the region. A Regional Advisory Body could be a pragmatic interim means to evolve quickly an effective biosafety assessment system to protect a region's biodversity. As local expertise develops over time, countries within the region can decide at a later time the desirability of establishing their own authorities.

V. DESCRIPTION

A. Organization

The Regional Advisory Body should consist of two major parts, a Governing Board and the Authority itself.

1. Governing Board

The Board would bring together national representatives from within the region. Each member country would name a representative. Attention would be given to attracting a multi discipline capability within the Committee. The Committee's membership could be supplemented by the addition of observers from appropriate government departments within the region. During its initial period local representation on the committee may be supported by additional outside experts to provide the necessary expertise.

The Board would perform a multi-faceted function. It would be the vehicle through which member governments interface with, establish operating and communicating policies for and guide the Advisory Body. It would ensure the Body was aware of member governments' positions as well as that member governments were fully informed of its activities. The Advisory Body would present policy items to the Board for discussion and approval.

2. Advisory Body

A. Administration

The Advisory Body would consist of about 15 people including an Executive Director, Administrative Officer, Communications Officer, Information Officer (computer specialist), Director of Risk Assessment as well as the necessary administrative support personnel and scientific personnel in such areas as plant molecular biology, ecology, entomology and animal molecular biology. The actual scientific expertise would vary, depending upon availability and demand. Scientific personnel should be knowledgeable, or be able to be trained in risk management, risk assessment and risk mitigation.

It is difficult to predict accurately the demand for risk assessments and therefore the number of scientists required. In Canada, after five years experience, four biologists are used to process five to eight applications each year from companies and universities for unconfined release of LMOs. The biologists answer the key question: Does the LMO provide a significant risk to the environment? Each application takes about five months to process. In addition, the biologists review an additional 50 to 100 submissions for confined trials. These applications are normally processed in about four weeks. In addition, two scientists are involved in processing applications for LMOs to be used in livestock feeds to bring the total number of scientists to six.

The Body would not require staff in all scientific knowledge required in risk assessment. Some expertise may be more cost effective to obtain through specific job contracts or loan from governments. The Body would begin with a basic scientific complement, use specific job contracts when necessary and then add scientific staff as required.

As the Body would always be a relatively small organization, its design would be kept simple and functional. All personnel would report to the Executive Director except scientific personnel who would report to the Director of Risk Assessment and administrative support personnel who would report to the Administrative Officer.

B. Financial Arrangements

The first two years of capital and operating costs could be financed through grants from outside sources. Beginning in year three, or later, depending on the needs of the region, member countries would begin to contribute to costs by paying a fee to cover 10 % of the costs for each service being used by the country. Member country fees would continue to increase each year by 10 % such that by year 12, all costs would be paid by member countries.

Some opportunity exists to obtain revenues from outside sources through charging a risk assessment fee for service. Canada charges about $500 for each confined release submission plus $100 per trial and about $3,000 for an unconfined release application.

VI. CONCLUSION

With such a mandate a Biosafety Regional Advisory Body could become the centre of biosafety excellence within the region and soon would possess or have access to the necessary expertise to protect a region's biodiversity and any consequent implications for human health. Obviously for it to be effective, it must possess:

- A good information system harnessing Internet technology.
- A scientific knowledge capable of reviewing and understanding risk assessment technology.
- A knowledge of the local ecology and how it might be influenced by LMOs.
- A capacity building capability to develop local people in risk assessment technology.
- Confidence by governments within the region in its mandate and capability.