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BIOTECHNOLOGY, BIODIVERSITY AND BIOSAFETY: THE NEED FOR NATIONAL GUIDELINES ON BIOSAFETY FOR SRI LANKA

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ABSTRACT

Conservation and sustainable management of biodiversity and development of biotechnology have projected biology as the frontier science in the new millenium. The Agenda 21 adopted at UNCED and the resulting Convention on Biological Diversity (CBD) have underscored the importance of safe and responsible development of biotechnology which culminated in adopting the Cartagena Protocol on Biosafety (CPB) in Modern Biotechnology in January 2000. Sri Lanka, having ratified the CBD and being a signatory to the CPB is required to have its biosafety regulations in place as an international and national obligation. A set of national guidelines for the import and planned release of Genetically Modified Organisms (GMOs) and products thereof have been drafted by a subcommittee of the National Experts' committee on Biodiversity of the Ministry of Forestry and Environment and this is currently being reviewed. Research on GMOs in contained environments, use of genetically modified food and feed items and pharmaceuticals are not covered by these guidelines and the relevant ministries are expected to develop guidelines and/or upgrade existing legislation once their policies on GMOs and their products are revised.

INTRODUCTION

If the 20th century was the 'Age of Industry', the 21st century is emerging as the 'Age of Biology'. Among the multifarious challenges faced and opportunities endowed with in the new millenium, are two major ones of biological nature that are of global significance.

i. Sustainable management of biological diversity, the foundation of human existence, in a rapidly changing environment.

ii. Harnessing and equitable sharing of benefits of modern biotechnology while minimizing its potential risks.

Biological diversity and the associated cultural diversity are part and parcel of our daily lives and livelihoods. Such biological materials that contain hereditary information for life and of actual or potential utility value are defined as 'genetic resources'. The humid tropics of the world, of which Sri Lanka is a part, is known to contain disproportionately higher quantum of the world's genetic resources.

With the advent of modern biotechnology involving recombinant DNA technology and the development of intellectual property rights for living organisms, manipulation of living organisms to create new types of medicines, agricultural commodities and other industrial products has revolutionized the global scientific and business climate alike. A recent study has estimated that the combined annual global markets for the products derived from genetic resources in these sectors lies between US$ 500 billion and US$ 800 billion. By comparison, annual global sales of petrochemicals are some US$500 billion and the world computer market in 1997 was US$ 800 billion (Kate and Laird, 1999).

The Global initiative of sustainable development popularly known as Agenda 21 adopted at the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro during June 1992 makes specific reference to 'Environmentally Sound Management of Biotechnology' in its Chapter 16. It recognizes that biotechnology could contribute significantly to sustainable development by improvements in food production and feed supply, health care, and environmental protection. It also has recognized that the global community at large can only benefit maximally from biotechnology if it is developed and applied judiciously and with social responsibility. Thus, the Agenda 21 promotes safety in biotechnology development, application, exchange, and transfer through an international agreement based on scientific principles for risk assessment and risk management.

Convention on Biological Diversity (CBD)

One of the significant developments pursuant to the Agenda 21 is the formulation of the Convention on Biological Diversity (CBD) ratified by over 170 states including Sri Lanka which highlights the importance of the conservation and sustainable development of biological diversity and the equitable distribution of its benefits. The CBD addresses the issue of safety in biotechnology in Article 8(g) of the Convention, which stipulates, each Contracting Party shall, as far as possible and appropriate at the national level:

> *'Establish or maintain means to regulate, manage, or control the risks associated with the use and release of Living Modified Organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.'*

The Convention also emphasizes the need for safety in biotechnology at international level among contracting parties in the Article19 (3) and (4) which stipulates:

> 19 (3). *'The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advanced informed agreement in the field of the safe transfer, handling and use of LMOs resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity'*

> 19 (4). *'Each Contracting Party shall directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph (3) above, provide any available information about the use and safety regulations required by that Contracting Party in handling of such organisms, as well as any available information on the potential adverse impact of the specific organism concerned*

to the Contracting Party into which those organisms are to be introduced.'

The above Articles on safety in biotechnology were elaborated for action at the Second Conference of the Parties of the CBD (COP II Decision II/5) which recommended the development of an International Protocol on Biosafety especially for transboundary movement of Living Modified Organismss (LMO) for which an Open Ended Ad-Hoc Working Group on Biosafety was established in 1995. After four years of negotiations, a legally binding International protocol -the Cartagena Protocol on Biosafety - was adopted in January 2000.

According to international analysts, the Cartagena Protocol overall is a mixed package. Some of the tougher issues on trade and environment have been postponed until a later date, and others remain unsettled through ambiguity. But the progressive elements of this agreement is the strong elaboration of the precautionary principle prime among them to make it a strong addition to the body of international environmental law. It is also welcome as a signpost on the road to more enlightened trade policy-making. The failure of WTO negotiations in Seattle, the denial of fast-track negotiating authority in the U.S., the death of the OECD efforts to conclude an investment agreement, and now the Cartagena Protocol, these are all about making trade and investment policy reflect a balance between commercial interests and other public policy objectives. According to these analysts, although more to achieve, the Cartagena Protocol may be the closest to reconciling trade and environmental objectives.

From an environmental perspective, one of the highlights of the Cartegena Protocol on Biosafety is its treatment of the precautionary principle. Even though the strong provisions in the Protocol are limited by the strictures of the WTO SPS Agreement, it is an important precedent to have the principle so fully elaborated in an international agreement. The text makes it clear that there are times when restricting trade is appropriate for the public good, even when there is a 'lack of scientific certainty.' The precautionary

principle's treatment in the Protocol will make it much harder to argue that it is not a principle of customary international law. It is noteworthy that the burden of proof is put on the Party of export and notifier, who can be required to conduct and/or finance a risk assessment. Perhaps most interesting is the way in which the Protocol's precautionary provisions actually inform and supplement those of a trade agreement.

In accordance with the Biosafety Protocol, each ratifying party shall designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this protocol and which shall be authorized to act on its behalf with respect to those functions by developing and implementing national legislation for biosafety in biotechnology.

Most countries especially the developed countries already have very stringent National Biosafety Guidelines and Regulations for the development and release of Genetically Modified (Manipulated) Organisms (GMOs) into the environment. In recent times, there has been a strong concern on GMOs and their products, particularly in the developed countries' public health. This has resulted in a significant reduction in imports of genetically modified foods in to some countries particularly in the Western Europe from other major producers.

As a consequence of these events, nations of the developing countries are faced with the prospect of increased levels of introduction of GMOs and products thereof, some of which may have adverse effects to the environment and health, in those countries with trade liberalization. However, most developing countries including Sri Lanka do neither have safety guidelines for activities related to GMOs nor do have a mechanism to evaluate the potential risks associated with the range of genetically modified organisms/products and plans for their management.

As a country which has ratified the Convention on Biological Diversity and signed the Cartagena Biosafety Protocol, Sri

Lanka is obliged to develop national regulatory framework for the safe transfer, handling, use and release of any genetically modified organism resulting from modern biotechnology to safeguard her environment including the richly endowed biological diversity and the human health of its inhabitants. The National Experts Committee on Biodiversity of the Ministry of Forestry and Environment appointed a subcommittee to draft guidelines on biosafety in modern biotechnology.

The development of techniques in genetic modifications which include recombinant DNA technology and cellular techniques of introducing DNA into an organism has resulted in vast advances in agriculture, human health, environmental science and the processing industry. The modern genetic manipulative techniques can transfer genetic material between species, which may not normally exchange genetic material under natural circumstances. An organism altered by any of these techniques is referred to as a Genetically Modified Organism (GMO).

However, the development of genetically modified plants, animals and microorganisms with novel genetic traits and their subsequent release into the environment can have potential risks that may affect different aspects of modern society some of which may be irreversible. The risk factors associated with the altered genetic capabilities of a GMO may give rise to safety concerns in public health, agricultural production, animal husbandry and environmental quality including biological diversity.

Taking these into consideration, there is an urgent need for developing biosafety procedures at the national level, monitoring and regulation of activities related to all aspects of GMOs and providing advice to the Government on biosafety policies. Introduction of a GMO into the environment should be carried out according to the 'step by step' principle to limit its possible negative consequences for human health and the environment with due attention being given to the prevention of accidents and the regulation of their waste disposal.

The focal point ministry for the implementation of the Convention on Biological Diversity through its experts' committee on biodiversity drafted a set of 'National Guidelines for Import and Planned Release of Genetically Modified Organisms and Products Thereof which is being reviewed. Annex 1 gives the content page of this draft document. It proposes the establishment of a National Biosafety Committee (NBC) and appropriate subcommittees who shall be responsible for carrying out the requirements of these guidelines and its annexes (Annex 2).

A National Biosafety Committee (NBC) established by the Ministry of Forestry and Environment of the Government of the Democratic Socialist Republic of Sri Lanka, should have the following roles and responsibilities:

1. To oversee and regulate specified activities related to Genetically Modified Organisms (GMOs) and products derived from or containing GMOs (products thereof) so that any biosafety risks associated with them are identified and can be managed, and

2. To advise the Ministry about matters concerned with the regulation of such activities related to import and planned release of GMOs and products thereof to the Sri Lankan environment. The activities include importation, planned or deliberate release to the environment and placing on the market of GMOs and products thereof.

For the purpose of its overseeing and regulating the above activities, the proposed Guidelines apply to import and planned release of GMOs for field trials and commercial releases including placing on the market of GMOs and specified products thereof. As a standard practice, all field trials must be preceded by contained laboratory work and planned releases of GMOs to the environment must be preceded by field trials. Research on GMOs in contained environments, genetically modified food items, and pharmaceuticals

are not covered by these proposed guidelines and the relevant ministries are expected to develop guidelines and/or upgrade the existing regulations once their policies on Genetically Modified Organisms and their products are formulated.

The proposed guidelines suggest compliance of the safeguards through a voluntary approach initially over a period of two years from the date of their entry into force. During this interim period, institutional framework and training of personnel needed for the implementation of these guidelines are to be established. At the end of this two-year period, these guidelines could be considered to be transformed into mandatory regulations through a consultative process.

LITERATURE CITED

Tate, K.T. and S.A. Laird. 1999. The Commercial Use of Biodiversity-Access to Genetic Resources and Benefit-Sharing, Earth Scan Publications Ltd. London, 398 p.

Annex 1

(DRAFT) NATIONAL GUIDELINES FOR IMPORT AND PLANNED RELEASE OF GENETICALLY MODIFIED ORGANISMS AND PRODUCTS THEREOF

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Annex 2

PROPOSED NATIONAL BIOSAFELY COMMITTEE AND SUB COMMITTES