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Review of Conformity of India's Regulatory System for GE Plants with the Cartagena Protocol on Biosafety

UNEP/GEF supported Phase II
Capacity Building Project on Biosafety

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Ministry of Environment, Forest and Climate Change
Government of India

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Prepared by

Ministry of Environment, Forest and Climate Change (MoEF&CC) in association with Centre for Environmental Risk Assessment-ILSI Research Foundation, Washington, USA under UNEP/GEF supported Phase II Capacity Building Project on Biosafety

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1. Introduction

The Ministry of Environment, Forest & Climate Change (MoEF&CC) is implementing UNEP/GEF supported Phase II Capacity Building Project on Biosafety to strengthen biosafety management systems in India. One of the activities in the risk assessment component is to prepare a base paper to study conformity of India's existing laws, regulations, guidelines and policies governing genetically engineered (GE) plants with Articles 15 and 16 and Annex III of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

This paper provides an overview of relevant obligations under the CPB vis-à-vis existing Risk Assessment/Risk Management (RARM) procedures and guidelines followed by Indian regulatory agencies for GE plants.

2. The Cartagena Protocol on Biosafety

2.1 Overview

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity ("the Protocol" or "CPB") entered into force on September 11, 2003. The CPB is currently the only multinational treaty that addresses potential risks to biological diversity resulting from trade in and use of, living modified organisms (LMOs). The CPB has a single objective, expressed in Article I of the Protocol. That objective is

… to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of the biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements.

The CPB lays out three significant provisions in pursuit of this objective:

i) The Advance Informed Agreement (AIA): The AIA is an administrative process through which countries seeking to import LMOs receive from the exporting country all the information needed to make an informed decision about potential environmental risks resulting from the importation.

ii) The affirmation of a precautionary policy regarding decisions made as to international trade and use of LMOs. This policy was originally put forth in Principle 15 of the Rio Declaration of Environment and Development.[1]

[1] http://www.unep.org/Documents.Multilingual/Default asp?documentid=78&articleid=1163

Essentially the principle states that a government, when trying to forestall serious or irreversible environmental damage, may decide on a course of action without full scientific certainty as to the outcome of the action.

iii) The creation of the Biosafety Clearing House (BCH)[2]: The BCH is an online depository of scientific, technical, environmental and legal information regarding LMOs, which is intended to facilitate access to this information by the global community and to help Parties to the CPB meet their obligations under the Protocol.

The CPB consists of 40 Articles and three Annexes, which lay out the major provisions of the Protocol as follows:

- Articles 1 – 5 describe the Protocol generally, provide definitions of terms and define the scope of the treaty.
- Articles 6 – 14 and Annexes 1 and 2 describe the information to be included in an AIA and how the AIA and other agreements can be used to inform decision making by a country considering the importation of a LMO.
- Articles 15 – 17 and Annex III provide guidance for the assessment and management of risks caused by LMOs, including unintentional and emergency movements.
- Article 18 describes how LMOs should be packaged and labeled.
- Articles 19 – 24 and 27 – 40 lay out procedures countries should follow in the administration of the CPB.
- Article 25 discusses the treatment of illegal transboundary movements.
- Article 26 discusses the consideration of socio-economic factors in the decision making process.

2.2 Obligations under the CPB

In some of its provisions, the CPB suggests actions that Parties "may" take under certain circumstances, but many of the provisions of the Protocol are described as things the Parties "shall" do, that is, Parties are obligated to comply with these provisions. An obligation fundamental to the CPB is articulated in Article 2, paragraphs 1 & 2: Parties to the CPB "shall take necessary and appropriate legal, administrative and other measures" to implement their obligations under the Protocol and achieve the Protocol's Objective. Although the Protocol allows parties to use existing legislation, if it complies with CPB provisions, many Parties to the CPB have elected to enact new legislation and promulgate new regulations and policies to implement Article 2 obligations. If Parties choose this route, the CPB requires that any such domestic regulatory frameworks be consistent with the Protocol.[3]

[2] http://bch.cbd.int/

[3] See, for example, CPB, Article 9(3); Article 10(1); Article 11(4).

However, the Protocol provides Parties with another option, as stated in Article 9, that is, to use the procedures within Protocol itself in decision making regarding LMOs.

3. India's Regulatory Framework for GMOs

India signed the Protocol on January 23, 2001 and ratified it on September 11, 2003. However, India had already established its legal and administrative framework to regulate products of modern biotechnology, including GE crops, many years before the Protocol was adopted. There are series of documents upon which India's policies on GE crops are based and these documents were issued prior to the existence of the CPB:

- In 1986, Ministry of Environment & Forest (now called Ministry of Environment, Forest & Climate Change) introduced "The Environment (Protection) Act" ("the Act"), which provided the Central Government with the power to take appropriate actions serving to protect and improve the quality of the environment and prevent, control and abate environmental pollution.
- Subsequent to the enactment of the Act, the MoEF promulgated the "Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms, Genetically Engineered Organisms or Cells" in 1989. The stated goal of the rules was the protection of "the environment, nature and health."
- In 1990, India's Department of Biotechnology (DBT) issued "Recombinant DNA Safety Guidelines," which were revised once in 1994 and then again in 1998, resulting in the current version entitled "Revised Guidelines for Research in Transgenic Plants & Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts."
- Application form for seeking approval under Rules 8, 9, 10 & 11 of the Notification no. GSR1037(E) dated 05.12.1989 issued by MOEF under the EPA, 1986, for Transgenic Plants
- Decision documents pertaining to release of *Bt* cotton from 2002 onwards
- Lastly, in 2011, the DBT issued its "Guidelines and Handbook for Institutional Biosafety Committees (IBSCs)."

3.1 Environment (Protection) Act of 1986

The Environment (Protection) Act ("the Act") of 1986 was enacted in response to a 1972 United Nations Conference on Environmental Protection and that it was enacted to protect humans and the environment from environmental pollutants[4] and hazardous substances[5] that may be injurious to the

[4] The Environment Act, 1986, Section 2(b)
[5] The Environment Act, 1986, Section 2(e)

environment.[6] There is no reference in the Act to environmental harms caused by living organisms and it is unlikely that the drafters of the Act envisioned that the Act would encompass harms other than those caused by chemical pollutants. Indeed, the insertion of a foreign gene into plants had only just been accomplished in 1983. The first confined field trials would not be held until the mid-1980s and a GE plant would not be considered for commercial release until the early 1990s. It should therefore not be surprising that a law enacted in 1986 would not specifically consider environmental impacts from GE plants, nor is this a unique situation. For example, the United States' regulatory system for GE organisms is based on a policy statement, the "Coordinated Framework," that was also issued in 1986.[7]

The Act does address the same protection goals mentioned in the Protocol, although in different terms. The Act's purpose is to protect and improve the environment: "water, air and land and the inter-relationship that exists among and between water, air and land and human beings, other living creatures, plants, micro-organisms and property." The Protocol's focus is on "the conservation and sustainable use of biological diversity taking into account risks to human health," but these are arguably different ways of expressing the same goals. Similarly, the Act authorizes the promulgation of rules to "regulate handling and intentional and accidental discharges of environmental pollutants," which is comparable to the Protocol's provision to establish "mechanisms to manage identified risks," although the identified risks referred to by the Protocol are potential environmental risks from LMOs, as opposed to environmental pollutants.

3.2 Rules for the Manufacture, Use, Import, Export & Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989

The biotechnological context to the Environment (Protection) Act, 1986 was provided when the 1989 rules were promulgated, because the MoEF recognized the need to regulate hazardous living organisms,including genetically engineered organisms also. Specifically, the MoEF&CC interpreted Section 6 of the Act, concerning "Rules to Regulate Environmental Pollution," to authorize its promulgation of rules governing the "application of gene technology and micro-organisms." In essence, the MoEF&CC appropriated the concept of hazardous substances from the Act and applied it to GE plants and products made from them.

[6] The Hazardous Wastes Rules, 1989 and the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989, were promulgated pursuant to the Environment Act.
[7] Coordinated Framework for the Regulation of Biotechnology, 51 Federal Register 23302 (June 26, 1986).

Although the Rules contain provisions addressing some of the same goals of the Protocol--Sections 10 ("Permission and Approval for Certain Substances") and 11 ("Permission and Approval for Food Stuffs"), for example, forbid the production, sale, importation and use of these materials without government approval--the terminology used in the Rules, 1989 is different from the Protocol. For example, the Protocol deals specifically with "living modified organisms," not with foods or substances made from these organisms, but the Rules focus on "substances," that includes cells, due to their reliance on the Act. The scope of 1989 Rules is broader in this sense.

Of course, just as the drafters of the Act could not have anticipated the development of agricultural biotechnology, the framers of the Rules, 1989 could not have foreseen the creation of the Protocol nor its particular approach to environmental protection. It is therefore not surprising that there are instances where conformity between the Rules. 1989 and the Protocol is lacking. Many of the lapses of conformity are due to the Rules' silence on provisions that are laid out in detail by the Protocol, rather than the Rules' direct conflict with the Protocol.

For example, two fundamental under pinnings of the Protocol are not reflected from the Rules, 1989: that an environmental risk assessment must be scientifically sound [8] and that any potential risks associated with the release of the GE organism be evaluated in the context of the risks posed by the non-GE organism.[9] In addition, the Rules are silent regarding the key steps of a risk assessment, which are fully described in the Protocol:

- The identification of any novel genotypic and phenotypic characteristics that may have adverse effects
- An evaluation of the likelihood of these adverse effects being realized
- An evaluation of the consequences should these adverse effects be realized
- An estimation of the overall risk posed by the living modified organism
- A recommendation as to whether the risks are acceptable or manageable [10]

Any limitation in the Rules, 1989 due to scientific advancements are addressed by regulatory agencies through data requirements and updation of guidelines from time to time. Rules, 1989 also require statutory regulatory committees to review scientific advancements and issue manuals/guidelines for risk assessment and risk management.

3.3 Revised Guidelines for Research in Transgenic Plants, 1998

In 1998, pursuant to authority derived from the Rules, 1989 the DBT issued

[8] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Annex III(3).
[9] Ibid., Annex III(5).
[10] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Annex III(8).

revised guidelines on the use of transgenic plants in research. The Protocol does not cover the development of GE plants, only their transboundary movement and subsequent release into the environment, however the 1998 Guidelines do provide additional insights into the state of the art of environmental risk assessment in India, prior to the adoption of the Protocol. For example, the Guidelines support the use of existing data and recognized international methods and standards, as does the Protocol. In addition, the Guidelines provide an extensive list of risk management methods, meeting the recommendations in Annex III of the protocol.

The 1998 Guidelines also provide specific details regarding data relevant to environmental risk assessment, all of which are recommended in Annex III of the Protocol:

- The characteristics of the donor organisms
- The characteristics of the vectors used
- The characteristics of the transgenic inserts used
- Methods of detection for the transgenic plant

Together these features demonstrate both a refinement of the thought process underlying the environmental risk assessment of transgenic plants and a movement in the direction of greater transparency regarding the process itself.

3.4 Application form for seeking Approval of Transgenic Plants

The data requirements prescribed by the apex regulatory committee i.e. Genetic Engineering Appraisal Committee (GEAC) for the release of transgenic plants include information on various parameters. The relevant parameters for Environmental Risk Assessment (ERA) of GE plants are as follows:

a. Germination and vigour results of the transgenic line in field & in the lab
b. Description of the Phenotype of the transformed plant
c. Composition and quality of the transformed plant and the seeds/ fruits of the plants and comparison with non-transgenic phenotypes.
d. Competitive Toxicant analysis of the transformed plant and potential for weediness in cases of uncontrolled release of transgenic plants
e. Risks during the processing / handling of the transformed plant/ fruits
f. Susceptibility of the plant products / fruits to diseases and pests
g. Long term influence of the plant pests to the transformed plants, fruits and seeds.
h. Gene transfer to non-transgenic lines including near relatives and percentage of transfer under specific field conditions.

i. Out-crossing potential including pollen transfer to cultivated genotypes and wild species and its implications.

j. Implication of transfer of genetic information to species to which it can inter breed.

k. Possible impact on environment on overall assessment.

It is evident that ERA is an integral part of the risk assessment process, though not explicitly defined in the regulatory guidelines

3.5 *Bt* Cotton Decision Documents

Publicly available[11] sources of information that provide some insights as to the actualimplementation of the Act and the 1989 Rules is the set of five risk assessments performed prior to the commercial release of various GE *Bt* cotton varieties, all of which were performed after India signed the Protocol. The five decision documents pertain to insect-resistant cotton varieties producing the following *Bt* toxins: *Cry*1Ac (March 26, 2002); *Cry*1Ab + *Cry*1Ac (April 4, 2006); *Cry*1Ac (April 4, 2006); *Cry*2Ab2 (May 22, 2006) and *Cry*1C (May 13, 2009). Together these documents serve as a snapshot of the type of risk assessments performed by the MoEF&CC Change in a post-Protocol environment, although, the steps taken in the risk assessment process and the goals of the process have not been elaborated. These documents focus on the data considered by the regulators and the conclusions drawn from that data. The documents provide insight into the government's view of how specific requirements in Article 15 and Annex III of the Protocol would be met.

For example, Article 15 of the Protocol requires Parties to identify and evaluate possible adverse effects to conservation and sustainable use of biological diversity. In all five decision documents, the following factors were identified as potential adverse effects to be considered before *Bt* cotton could be released commercially:

- Changes in outcrossing due to the *Bt* trait
- Changes in weediness due to the *Bt* trait
- Effects of the *Bt* trait on non-target organisms
- Persistence of the *Bt* toxin in the soil
- Adverse effects of the *Bt* trait on soil microflora
- Changes in nutritional composition due to the *Bt* trait
- Changes in potential allergenicity due to the *Bt* trait

[11] Executive summaries of the decisions have been posted on the Biosafety Clearing house.

Each of these potential adverse effects has been identified and assessed in numerous regulatory decision documents issued by other jurisdictions when evaluating impacts from GE crops (e.g., Australia, Brazil, Canada, EU, United States) and it is likely that these adverse effects would meet the requirements of Article 15.

Additionally, Annex III(9) (h) of the Protocol suggests considering relevant information on biodiversity and centers of origin. Each of the decision documents considers the likelihood that *Bt* cotton varieties may hybridize with sexually compatible relatives present in India—a key consideration when evaluating impacts on biodiversity.

3.6 IBSC Guidelines

The 2011 Guidelines for Institutional Biosafety Committees (IBSCs) is the most recently published document, which is probably why it most closely tracks the requirements and suggestions in the Protocol. For example, the IBSC Guidelines stress the need to consider the "best up-to-date knowledge and experience," including the use of standardized or internationally recognized methods when performing risk assessments and the Guidelines also state that the details of individual safety assessments will vary on a case-by-case basis. Both of these factors are fundamental to the principles laid out in the Protocol. In addition, the Guidelines take human health into account, as recommended by the Protocol, by requesting risk analyses of any toxicity, allergenicity, pathogenicity and teratogenicity that may be posed by the research using GE plants. Although, the Guidelines do not outline the actual steps in the risk assessment process, these are notable for their significant step forward in increasing the transparency of the risk assessment process. Even though the Guidelines themselves pertain only to ensuring the safety of institutional research with transgenic plants, they clearly indicate the types of relevant data necessary for the risk assessment along with a discussion as to why the data is needed. Each category of information is also referenced in Annex III of the Protocol:

- Characteristics of the donor organisms
- Characteristics of the host/recipient organisms
- Characteristics of the gene construct
- Characteristics of the vector and method of transformation

Arguably, the most significant feature of the IBSC Guidelines is the recognition that the risk assessment is a comparative process:

The first presumption for safety assessment of GMO is that the modified organism is as hazardous as compared to the host. [12]

[12] Guidelines and Handbook for Institutional Biosafety Committees, II.1.1.v.

The comparative approach is one of the fundamental principles of risk assessment recommended in Annex III of the Protocol and it is clearly articulated in the Guidelines.

4. Conclusions and Way Forward

India introduced Rules, 1989 under the EPA, 1986 much before the adoption of the Protocol and thus for reasons largely attributable to historical precedence, the foundational documents, on which the Indian system of regulation for GE plants is based do not conform to the key provisions of the Cartagena Protocol on Biosafety. The use of these documents to support a Protocol compliant risk assessment for a GE plant therefore requires a great deal of interpretation, reading between the lines. In spite of the above, the implementation of the Indian approach, as it exists today, did result in a legitimate risk assessment process, as is evidenced by the five decision documents regarding *Bt* cotton. However, better conformity with the Protocol could result in a regulatory system that is officially grounded in sound science, implemented consistently and perceived as transparent by stakeholders.

To increase conformity with the Protocol, a few different options could be considered by Government of India. First, MoEF&CC could undertake a revision of the Act and Rules, 1989 to bring these documents in line with the provisions of the Protocol. Second, the Government of India could draft completely new legislation and regulations for GE plants, delinking the association between transgenic crops and hazardous substances (as in Rules, 1989). Third, MoEF&CC could publish new ERA guidelines for GE plants, under the authority of the Rules,1989 that promote the approach taken under the Protocol. Any of these approaches will both increase conformity with the Protocol and increase the transparency of the regulatory process.

MoEF&CC, pending the enactment of Biotechnology Regulatory Authority of India Bill, initiated a process through which dedicated guidelines for ERA of GE crops, reflecting the approach prescribed by the CPB, have been prepared under the UNEP/GEF supported Phase-II Capacity Building Project on Biosafety. An Expert Committee worked for over a year to develop a series of guidance documents including ERA guidelines, User's Guide and Risk Analysis Framework. The ERA guidelines provide a practical elaboration of risk assessment framework included in the Indian regulations in conjunction with Annex-III of the CPB, to which India is a Party. The User's guide to accompany the ERA Guidelines provides additional material, illustrative examples and references to scientific literature. Risk analysis Framework includes concepts related to risk management, and risk communication in addition to risk assessment.

These three documents ensure clarity in conformity between the CPB and the Indian regulatory system for GE plants. Most important, they provide a clear statement of what ERA means within the Indian regulatory system and how the Indian government envisions the ERA process working, thereby greatly enhancing the transparency of the process for both domestic and international stakeholders. It also provides positive guidance to assist Indian researchers in their development of new GE plant varieties, particularly in their understanding of the data that must be compiled for the risk assessment process.

Better conformity between the Indian guidelines and the Protocol, achieved through efforts under the Phase II Biosafety Capacity Building Project on Biosafety will simplify and clarify government interactions with the many stakeholders who need to work with this process: researchers, seed producers, food processors and commodity traders, as well as government regulators in other countries.These initiatives will further enhance harmonization of guidance at regional and global level.