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Genetically Modified Organisms: Biosafety and Risk Asssessment

Introduction

The decade of 90's has witnessed tremendous growth in biotechnology industry and trans-boundary movement of genetically modified organisms (GMOs), which are also known as living modified organisms (LMOs). Consumers and environmental organisations are concerned about the serious implications such transfer could have on their health, safety and physical environment. A need for regulation of such transfers were long felt and was also included in the Convention on Biological Diversity (CBD) signed at the Rio Conference in June 1992. The Conference of Parties to the CBD finally agreed to the Biosafety Protocol in 2000, but this too could not completely ally the fears of the international community.

There are a number of policy choices developing countries in general and the countries of South Asia in particular should consider in order to assess the risks associated with the trade in GMOs and minimise them wherever possible. Among the number of policy options identified in this paper, the focus of this paper has been on the elements of biosafety and trade related aspects of GMOs. While the nation states are free to enact legislation and put in place institutional mechanism to contain the element of risks, such measures should be made without violating the fundamental principles of the World Trade Organisation (WTO).

The purpose of this briefing paper is to explain briefly the nature of risk assessment measures that can be adopted by a country importing LMOs and products derived from them, and to provide some recommendations to the governments and civil society organisations with a view to minimising the risks associated with such imports.

Background

Commercial application of genetic modification of crops began around mid-1990s in the United States, Canada and Argentina, with the cultivation of genetically modified ('GM') corn, cotton and soyabean varieties, genetically engineered to be tolerant to herbicides, or to resist pests and viruses. No special regulations were however enacted at the initial stages for the testing of such crops. Further, commercial application was allowed by these countries without any requirement for segregation and labeling requirements.

European countries, on the other hand, were a little more cautious to allow commercial application of genetically modified crops. There was a greater pressure from consumer and environmental organisations, and organic farmers, because of which the European Union began imposing labeling requirements on GM crop and foods in 1997. This was followed in 1998 by a moratorium on registration of any new varieties of GM crops.

GM crops are slowly making their appearance in the South Asian region. However, there is lack of an informed debate on the same. Of specific concern are the recent reports on testing of genetically modified crops such as cotton and mustard in some parts of India. Field testing of genetically modified cotton crops in India has also been reported. Despite public concerns and doubts regarding the health and environmental safety of such crops, there has been no effort at the state level to make available information regarding such implications. There has therefore been a fair bit of mistrust and skepticism regarding such crops. Added to this is the fact that, as of now, there is lack of effective risk assessment procedures in place in the South Asian region.

There are several policy choices to be made by South Asian countries in different areas relating to GM crops. From the experience of the US and Europe, it can be said that the important areas wherein policy choices would be required to be made are: (1) Intellectual Property Rights Policy; (2) Biosafety Policy; (3) Trade Policy; (4) Food Safety and Consumer Choice Policy; and (5) Public Research Policy.

The range of policy options in each of these areas can be classified between 'promotional', at one end of the spectrum (which would encourage use of GM crops), to 'preventive' at the other end (which would adopt a more cautious approach towards such crops). The scientific, technical and regulatory capacities in each country would, to a large extent, be determinative of the policy choice it eventually adopts. The basic features of each of the sets of policy choices are summarised in the table 1.

While each of the above areas of policy making is critical, for the purposes of a focused debate, this paper

Table 1

	Promotional	Permissive	Precautionary	Preventive
Intellectual Property Rights	Full patent protection, plus Plant Breeders Rights (PBRs) under UPOV '91	PBRs under UPOV '91	PBRs under UPOV '78 which preserves farmer's rights	No IPRs for plants or animals
Biosafety	No careful screening, only token screening, or approval based on approvals in other countries	Case-by-case screening primarily for demonstrated risk, depending on intended use of product	Case-by-case screening also for scientific uncertainties owing to novelty of GM process	No careful case-by-case screening; risk assumed because of GM process
Trade	GM crops promoted to lower commodity production costs and boost exports; no restrictions on imports of GM seeds or plant materials	GM crops neither promoted nor prevented; imports of GM commodities limited in same way as no-GM in accordance with science-based WTO standards	Imports of GM seeds and materials screened or restrained separately and more tightly than non-GM; labeling requirements imposed on import of GM foods or commodities	GM seeds and plant imports blocked
Food Safety and Consumer Choice	No regulatory distinction between GM and non-GM foods when either testing or labeling for food safety	Distinction made between GM and non-GM foods on some existing food labels but not so as to require segregation of market channels	Comprehensive positive labeling of all GM foods required and enforced with segregated market channels	GM food sales banned or warning labels that stigmatise GM foods as unsafe to consumers required
Public Research Investment	Treasury resources spent on both development and local adaptations of GM crop technologies	Treasury resources spent on local adaptation of GM crop technologies but not on development of new transgenes	No significant treasury resources spent on either GM crop research or adaptation; donors allowed to finance local adaptations of GM crops	Neither treasury nor donor funds spent on any adaptation or development of GM crops technology

shall focus on the elements of Biosafety and Trade Related Aspects of GMOs.

As mentioned above, the purpose of this paper is to explain briefly and in simple terms the nature of risk assessment measures that can be adopted by a country importing genetically modified organisms - GMOs and products derived from them. The challenge while putting a legal and regulatory system in place is that such a system would have to ensure compliance with each country's international obligations, especially under the GATT/WTO Agreement.

The challenge therefore seems to be of reconciling seemingly competing objectives including:

(i) the need to have greater scientific research for assessing the benefits or otherwise of biotechnology;

(ii) establishing legal and regulatory systems which ensure that biotechnology is not exploited before a full and careful assessment of its implications, as well as an informed public debate on its uses;

(iii) ensuring that such systems protect the national interest, and yet do not fall foul of the provisions of the GATT/WTO Agreement.

Convention on Biological Diversity

The debate regarding risk assessment and risk management techniques for LMOs and products containing LMOs has been a contentious issue at the negotiations of the parties to the Convention on Biological Diversity (CBD). The concern of the CBD springs from Article 19 that specifies certain broad set of measures that countries may undertake in the context of handling biotechnology.

Article 19 of the CBD deals with certain broad principles for the handling of biotechnology and the distribution of its benefits, *inter alia,* the adoption of legislative, administrative or policy measure, as appropriate, to provide for effective participation in biotechnological research activities. It further mandates the putting in place of a legal mechanism in the field of the safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

At the fourth Conference of Parties to the CBD in 1998, a decision was adopted to the effect that the Biosafety Protocol should be finalised and adopted by

early 1999. When the CBD Parties met at Cartegena in February 1999, it was with the agenda to arrive at the biosafety protocol, and name it the Cartegena Protocol. However, the legal framework took another year to evolve since the Parties were divided over a number of controversial issues. To put it simplistically, some countries are of the opinion that biotechnology is the technology for the future and its over-regulation would endanger competitiveness in the world market. A group of six grain exporting countries (called the Miami Group which includes Argentina, Australia, Canada, Chile, Uruguay, the United States of America), supported by the Biotechnology Industry Organisation emerged quite strongly at the Cartegena meeting and maintained highly inflexible positions on most of the contentious issues of the Protocol. The countries opposing the Miami Group was a diffused group of countries called the Like-Minded Group. This group basically consisted of the G-77 countries and China, excluding Chile, Uruguay and Argentina. The Like-Minded Group insisted on a precautionary approach and emphasised that the concerns of many developing countries including the need to provide adequate safety measures and a system of accountability be addressed. They also emphasised the need to put in place proper redressal mechanism to minimise the harm resulting from transboundary movement of LMOs, as well as enhance their capacity to deal with biosafety issues. The Cartegena meeting also witnessed strong resistance to the applicability of the *precautionary principle* from the Miami Group *(See Box1 for 'Precautionary Principle').*

Precautionary Principle

The essence of the precautionary approach embodied in Principle 15 of the Rio Declaration provides that: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environment degradation". The Preamble to the CBD also recognizes this when it states that "where there is a threat of significant reduction or loss of biodiversity, lack of full scientific certainty shall not be used as a reason for postponing measures to avoid or minimize such threats."

The Cartegena meeting was followed in February 2000 by a week of intense negotiations in Canada, and the Biosafety Protocol was finally concluded. A brief analysis of the provisions of the Protocol would be important here to understand the biosafety measures that have been internationally recognised.

Cartegena Protocol

Objective

The Cartegena Protocol, states as its objective the ensuring of an adequate level of protection in the field of 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 biological diversity. For this purpose, it highlights the centrality of the precautionary approach as defined in Principle 15 of the Rio Declaration on Environment and Development, which was concluded at the Earth Summit in 1992, along with the CBD. It specifically focuses on the transboundary movement of LMOs.

LMO

The Protocol defines "living modified organism" as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology; and "living organism" as any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

Balancing of Interests

Article 2(4) embodies the confusion emerging from the balancing of various interests in the negotiation of the Protocol. On the one hand it states that there shall be no restriction on the right of a Party to the Protocol to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol. It however adds the caveat that such action should be consistent with the objective and the provisions of the Protocol as well as in accordance with that Party's other obligations under international law, which by implication include the GATT/WTO Agreement.

Risk Assessment & Advanced Informed Agreement

The legal instrument by which the Protocol intends to regulate the transboundary movement of LMOs is by mandating the Advanced Informed Agreement (AIA). Article 7 of the Protocol shall be applicable to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import.

The Party of export shall notify, or require the exporter to notify, the competent authority in the country of import regarding the proposed import of LMOs. The

conditions of such notification, specified in Annex I, shall comprise, *inter alia,* of the following aspects:

(a) Name and identity of the LMO, as well as the domestic classification, if any, of the biosafety level of the LMO in the State of export.

(b) Details of the parental and recipient organism.

(c) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the LMO.

(d) Intended use of the living modified organism or prod ucts thereof, namely, processed materials that are of LMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(e) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(f) Regulatory status of the LMO within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the LMO is banned in the State of export, the reason or reasons for the ban.

The exporter is also required to prepare a risk assessment report regarding the LMO and file the same with the competent authority of the importer, so as to enable such authority to take informed decisions regarding such LMOs. The basic criteria to be fulfilled in such risk assessment reports are detailed out in Annex III to the Protocol, which include the following aspects:

(a) Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organisations.

(b) Risks associated with LMOs or products thereof, namely, processed materials that are of LMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

(c) Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

The manner and procedure for decision-making of the importing state are to be decided by the Conference of Parties. Article 10 of the Protocol broadly provides that the importing state, upon receipt of notification from the exporting state/exporter shall have the option to approve the import with or without conditions, or ask for additional information, or prohibit the import. All decisions except an unconditional acceptance, are required to be justified by reasons. Such decision is required to be communicated to the Biosafety Clearing House constituted under the Protocol.

AIA and LMOs for Food, Feed, Processing

AIA does not apply to LMOs intended for direct use as food or feed, or for processing. This was a closely contested issue at the Cartegena negotiations, with the Like-minded Group emphasising that there was no real difference between the risks of a GM crop or a GM food. In any case, the issue ended as a small victory for the US and the Miami Group. The Protocol states that "intentional introduction into the environment" does not refer to LMOs intended for direct use as food or feed, or for processing. With regard to LMOs "intended for direct use as food or feed, or for processing", any state Party that makes a final decision regarding domestic use, including placing on the market, of an LMO that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within 15 days of making that decision, inform the other state Parties through the Biosafety Clearing House.

While the AIA procedure is not mandated under the Protocol for LMOs intended for direct use as food or feed, or for processing, the Protocol states that an importing state may have its own regulatory framework to take decisions on the import of LMOs intended for direct use as food or feed, or for processing, and that such domestic regulations should be consistent with the objective of the Protocol.

Article 11 specifies that a Party that makes a final decision regarding domestic use, including placing on the market, of an LMO that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within 15 days of making that decision, inform the Parties through the Biosafety Clearing House. This information shall contain, at a minimum, the information specified in Annex II to the Protocol, which includes information as discussed in the context of other LMOs above, i.e., identity and characteristics of the LMO, identity of the exporter and risk assessment report under Annex III. Further it should also contain information on approved uses of the LMO as well

as suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate.

Article 11 (4) states that a State may take a decision on the import of LMOs intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

Labeling

Article 18 of the Protocol prescribes that the general norm of 'safety' shall be adhered to in the handling, transport, packaging and identification of LMOs. However it prescribes differential standards in that while LMOs intended for contained use or for release into the environment are to be identified as such, LMOs intended for direct use as food or feed, or for processing, need to be identified only with the label that they "may contain" LMOs and are not intended for intentional introduction into the environment. This is an obvious concession to trade and industrial interests, and has generated a fair bit of concern and controversy. It may be argued that any import is subject to domestic legislation and it would be open to states to frame strict regulations in this regard demanding disclosure of the contents of the import if it deems necessary in the national interest. However the actual implication and effectiveness of such a demand have to be tested. Can stricter import regulations be challenged as violative of the GATT, for instance, in the absence of any other international regulation rendering credence to it is a question that would have to be answered. It cannot be denied that the burden really is on the recipient importing state.

From a plain reading of the language used in the Protocol, the obligation to seek an AIA is only with respect to LMOs not intended for direct use as food or feed, or for processing. The provision of Article 11(4) however suggests that it is open for States to frame their domestic regulations to address this issue. The onus is also on States to keep themselves adequately equipped by evaluating the information in the Biosafety Clearing House regarding such LMOs, and seek additional information where required. Parties also have the freedom to determine that their domestic regulations shall apply with respect to specific imports into their territories and shall notify the Biosafety Clearing House of the decision.

Article 12 provides for review of decisions by the importing party and states that a Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. The responsibility to formulate suitable laws, rules and regulations ultimately lies with the State.

Application of the Precautionary Principle

An analysis of the Cartegena Protocol makes it clear that states can frame their own regulations on biosafety pursuant to the basic principles for the same as provided under the Cartegena Protocol. The Protocol is fairly detailed on the nature of procedural and substantive steps to be followed in the context of transboundary movement of LMOs. The Protocol further states that an importing state may have its own regulatory framework to take decisions on the import of LMOs intended for direct use as food or feed, or for processing, so long as such measures are consistent with the objectives of the Protocol.

Box 2

EU's Regulation on Labeling

The European Union's Novel Foods and Novel Food Ingredients Regulation 258/97 requires food to be labeled if, *inter alia*, it consists of or contains a GMO. The regulation provides that food must be approved and labeled before it is released into the market, and all food that consists of , or contains, GMOs must satisfy a detailed environmental risk and food safety assessment as a precondition to commercial release. The EU law applies equally to all GMO food, and does not discriminate on basis of origin.

Laws dealing with biotechnology normally adopt a risk assessment approach; however the difference of opinion invariably surrounds the thresholds of risk and degree of uncertainty allowed in such approaches. The exact interpretation and application of the precautionary principle would, therefore, be critical.

Article 10 of the Protocol provides that "lack of scientific certainty shall not prevent a Party from taking a decision *as appropriate*... in order to avoid or minimise such potential adverse effects." However there could be a potential conflict with the applicability of this provision and the language used in Annex III of the Protocol. An intriguing aspect of Annex III to the Cartegena Protocol is that it states: "lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence

of risk, or an acceptable risk." The language used herein conflicts with the very definition of the 'precautionary principle' which has been said to be the basic objective of the Protocol. *(See Box on Precautionary Principle for definition of the 'Precautionary Principle').* It is yet to be seen how such a provision would be interpreted in the event of a dispute.

As observed by one author, "the key to application of the precautionary principle lies in its approach to scientific uncertainty. Confronting uncertainty, both policy making and liability determinations, increasingly rely on assessing environmental risks associated with a given activity (probability of consequences and magnitude of harm). Once the assessment is reached, the political issue always remains of deciding whether the perceived level of risk is acceptable." *[See, Shelton, D. (1996)].*

The 'precautionary principle' has been applied in the context of several recent Supreme Court judgements in India, especially in 'pollution' cases. However, the exact parameters of this principle are yet to be enacted into law in any of the South Asian countries. An important challenge for our countries would therefore be to reflect this principle in risk assessment procedures. At the minimum, the law should mandate disclosure of all risk assessment studies pertaining to LMO/product derived from the LMO; and particularly, if the same has been rejected in any jurisdiction, law should mandate disclosure of complete information on the same.

As discussed before, the EU has been advocating a precautionary approach with regard to GM crops and foods. The basis for this approach is summarised at in the EU Paper on the Precautionary Principle. The principle features of this principle as applied in the EU are discussed in the Box 3.

Box 3

EU's Position on the Precautionary Principle

Recourse to the precautionary principle presupposes:

- Identification of potentially negative effects resulting from a phenomenon, product or process; and
- A scientific evaluation of the risk which because of the insufficiency of the data, their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the risk in question.

The appropriate response in a given situation is thus the result of a political decision, a function of the risk level that is "acceptable" to the society on which the risk is imposed.

The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty. An assessment of the potential consequences of inaction and of the uncertainties of the scientific evaluation should be considered by decision-makers when determining whether to trigger action based on the precautionary principle. All interested parties should be involved to the fullest extent possible in the study of various risk management options that may be envisaged once the results of the scientific evaluation and/or risk assessment are available and the procedure be as transparent as possible.

Measures based on the precautionary principle shall be reexamined and if necessary modified depending on the results of the scientific research and the follow up of their impact. Measures based on the precautionary principle may assign responsibility for producing the scientific evidence necessary for a comprehensive risk evaluation.

Source: www.wto.org.

SPS Agreement

One risk that national regulatory measures on biosafety *may* face, is that of being challenged under the WTO regime as being trade-restrictive. While compliance with the Biosafety Protocol would be a valuable defense, it may be that much more difficult to justify standards that are more stringent than that imposed by the Protocol. For example, LMOs intended for direct use as food or feed, or for processing, as explained earlier, are not covered within the purview of the Biosafety Protocol. What would also be a matter of dispute is the justification of decisions to restrict trade on the basis of the precautionary principle.

As explained before, the Cartegena Protocol provides the basis for the approach towards risk assessment to be taken by Parties to it. However, in the event that a measure is actually taken to restrict trade on the basis of scientific uncertainty (applying the precautionary principle), it is not clear how the regime under the WTO would react to such a situation. The matter could get further complicated because of the language used in the Preamble to the Protocol, Article 10, and Annex III are not entirely in sync with each other. *(See the section on Application of Precautionary Principle, for further discussion).*

Whatever may be said about the Cartegena Protocol and the WTO regime, would only be a hypothetical debate as of now. However, it may be useful to have a

quick overview of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which is a part of the WTO agreements, and the manner in which the rulings of the WTO Panel and the Appellate Authority have addressed the issues of labeling, health concerns and the precautionary approach.

The SPS Agreement in broad terms pertain to laws that protect against exposure to pests, disease carrying organisms, disease causing organisms, disease carrying animals or plants, and to laws restricting additives, contaminants and toxins in food and foodstuffs. Risks from bio-engineered processed products are not mentioned as being covered under the SPS Agreement. It is however the belief of this author that these decisions would also have implications on the nature of measures that states can undertake to safeguard health and achieve biosafety under the Cartegena Protocol.

The WTO panels and the Appellate Body have handed three SPS judgements, and interestingly, in all the three cases the defendant government employing the heath measure lost. The three cases are: (i) *EC-Measures containing Meat and Meat Products;* (ii) *Australia- Measures affecting the Importation of Salmon*; and (iii) *Japan- Measures affecting Agricultural Products.*

The basic principles adopted in the WTO rulings in the above mentioned cases are summarised as follows:

- Governments should not impose regulations simply on the basis of the 'theoretical' risk that underlies all scientific uncertainty. To be adequate, a risk assessment must find evidence of an 'ascertainable' risk.
- There must be an 'objective' and 'rational' relationship between the risk and the measure adopted to counter the risk.
- The onus is on the complaining party to show that an alternative measure, significantly lesser restrictive to trade, exists to achieve the level of protection intended to be achieved by the SPS measure.
- The status of the precautionary principle awaits more authoritative formulation.
- While considering whether 'sufficient scientific evidence' exists, panels should bear in mind that governments commonly act from the perspectives of prudence and precaution where risks are irreversible.

Box 4

Principles in the SPS Agreement

The basic principles embodied under the SPS Agreement are summarised as follows.

- Article 2.2: Governments shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, and is based on scientific principles and is not maintained without sufficient scientific evidence.
- Article 2.3: Measures that arbitrarily or unjustifiable discriminate between countries where identical or similar conditions prevail, are prohibited. SPS measures shall not be applied in a manner which would constitute a disguised restriction on international trade.
- Article 3.1: Governments shall base their SPS measures on international standards, where they exist, except as otherwise provided.
- Article 4.1: Government of an importing country is required to accept the SPS regulation of an exporting country as equivalent to its own, in the event that the exporting country's government can objectively demonstrate that its health regulation achieves the level of protection chosen by the importing country's government.
- Article 5.1: Governments should ensure that their any sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health.
- Article 5.5: With the objective of achieving consistency in levels of protection against health risks, a government shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.
- Article 5.6: Governments shall ensure that that their sanitary or phytosanitary measures are not more trade-restrictive than required to achieve their appropriate level of protection.
- Article 5.7: In cases where relevant scientific evidence is insufficient, a government may provisionally adopt sanitary and phytosanitary measures on the basis of available pertinent information.

Conclusions

With the rapid emergence of biotechnology, there is also a need for developing the capacity to use the products of biotechnology in a safe and efficient manner. Legislating in the area of GM crops and food is a challenge for countries in the South Asian region. Effective guidance for the nature of legislation is present in the Cartegena Biosafety Protocol. Translating these elements into domestic laws is an urgent necessity. Apart from this, there is also a critical need to have effective enforcement mechanisms and scientific testing procedures, in place in order to ensure that the provisions of law are effectively enforced. Capacity building for this is an urgent necessity.

Recommendations

- Both Government and civil society should work towards strong and effective domestic laws, and put effective institutional mechanisms in place, regulating imports into the country of GMOs and products (including food products) containing GMOs.
- Both Governments and civil society organisations should work towards generating greater awareness and an informed debate among the public regarding GM crop and food.
- The guidelines for risk assessment should clearly spell out the criteria on which to base a decision to use or prohibit use of a GM crop or food. The element of 'cost' should not be used to sacrifice comprehensive risk assessment. Risk assessment should be carried out before any decision is taken whether or not to use a GM crop or food.
- The regulations sought to be enacted should ensure: transparency, provision for public hearing, publication of all risk assessment reports, and clearances, pertaining to a GM crop or food.
- Mechanisms in tune with the AIA agreement under the Cartegena Biosafety Protocol should be put in place.
- Both the Government and civil society organisations should ensure constant vigilance and watch over developments in other countries, and particularly, constantly audit the information in the Biosafety Clearing House established under the Cartgena Protocol.
- Clear and transparent guidelines for labeling of GM crops and foods are required to be put in place, in order to ensure that the consumer has the opportunity to make an informed choice at the time of purchase.

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