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Biosafety Protocol, Precautionary Approach and Trade:

Identifying Plausible Policy Options

Background

The Rio Earth Summit (1992) signified the international commitment for sustainable global development. The Summit adopted various instruments for translating the principles of Agenda 21 into reality including the Convention on Biological Diversity (CBD). As part of its mandate the CBD established an Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety. The work at this group eventually led to the adoption of the Cartagena Protocol on Biosafety in the year 2000. The protocol entered into force on 11 September 2003. There are 124 national governments which have signed the Protocol.

The Protocol is a legally binding international agreement with direct bearing on global trade in genetically modified organisms (GMOs). It seeks to guard biological diversity from the potential risks posed by MOs resulting from modern biotechnology. The Protocol has adequate mechanisms to ensure safe transfer, handling and use of living modified organisms that may have adverse effect on the biological diversity on account of transboundary movements and human health. India signed the Protocol in 2001 and has now initiated several measures to ensure an effective implementation of the Protocol. This assumes importance since the investment in the agricultural biotechnology has gone up and biotechnology is being seen as an emerging technology with various possibilities to intervene in the genetic composition of plants for ensuring desired results. Several Indian agricultural and seed companies are entering the agricultural biotechnology sector with ever growing export share.

In this scenario a strategy is needed to regulate GMO introduction - as in India, no precautionary measure on GMO imports have been implemented so far. In fact, most developing countries have limited experience and capacity in their domestic regulations and some are currently in the process of elaborating their legal framework. Many countries including EU, Japan and South Korea have adopted a restrictive approach advocating the precautionary principle. The precautionary approach, in general, aims to deal with the hypothetical risks, when the link between the cause and the harm is yet to be determined. The approach is particularly relevant to GMOs since it is an evolving technology where environmental and health implications are to be assessed. India, being a party to both the WTO and the Biosafety Protocol, has to meet the challenges thrown up by the two agreements whose provisions are sometimes seems to be contradictory.

Cartagena Protocol and Precautionary Approach

There are two different set of groups of countries with different approaches towards GM products. Some countries have adopted the principle of 'sound science' as a basis for facilitating trade in GM products, while some others promote the use of 'precaution' in decision-making when there is no absolute scientific certainty and thereby restricting the trade in GM products. The US, Canada, and Argentina represent the former group while EU, Japan and South Korea are from the later group. This debate has triggered a sort of fear among several developing countries which are exporting agricultural commodities to EU and other countries as the export prospects of their agricultural products become very bleak. This raises a sever policy dilemma, for example in China. Though Bt Rice is being grown in a sizably large area, the government is not officially acknowledging the fact due to fear of loosing European rice markets. The US has lost market

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of more than $7 billion in EU and Japan for corn and other GM products.

The precautionary principle, in the form of legislation, was first widely adopted in the environmental policies of European countries in the 1970s and 1980s. The EU's *Communication on the Precautionary Principle* (2000) advocated the principle's implementation in environmental laws within the EU. In fact, the EU's regulation on GMOs is based largely on the precautionary principle. It has become a familiar component of multilateral environment agreements (MEAs) and domestic policies relating to the environment. In the international trade arena too, there are significant implications, particularly within the realm of trade and environment. There are more than 200 MEAs and reference to precaution has been outlined in more than ten. Precaution has also been cited in about 14 treaties and other declarations. The most common reference to precaution is enshrined into the Principle 15 of the Rio Declaration on Environment and Development, 1992. The precautionary principle continues to provide the basis for several other global environmental agreements.

Conflict with WTO

The precautionary approach in the Protocol differs from that of the WTO agreements and is a potential source of conflict. The two agreements, within the realm of environment and trade, are governed by often-divergent set of principles and objectives. The SPS Article 5.7 states that where scientific evidence is insufficient, a member can adopt a measure *provisionally* based on pertinent information, but they should obtain scientific evidence '*within a reasonable period of time*'. Meanwhile, the Protocol Articles 10 and 11, recognize a country's right to take precaution in the face of uncertainty. The European Commission and Consumer groups oppose the use of the word 'provisionally' in the SPS since it suggests the imposition of time limits. On the other hand, business groups argue that it is a lacuna that allows trade restriction without a scientific basis.

The WTO dispute between EU and US on beef with hormone was one of the first disputes where precautionary principle was applied. The European Union had banned the beef, because its scientists were worried that hormone-treated meat carries health risks, possibly causing cancer and triggering reproductive disorders in men. US scientists challenged this at the WTO dispute panel and retaliated by imposing 100 per cent punitive tariffs on EU products. The affected products included chocolate, pork, onions and truffles among the goods on the $116.8m blacklist. All the 14 EU exporters were hit, with France, Germany, Denmark and Italy being singled out for particularly harsh import duties. The trade sanctions were approved by the WTO, which ruled that the EU ban had cost US farmers about $117m. Canada was also given the right to retaliate, with damage to farmers estimated to be about $7m.US officials and farmers representatives had originally demanded penalties worth more than $900m.

This decision is perhaps a reflection of the hesitation of the WTO in implementing the precautionary principle. The dispute settlement in most MEAs is considered to be institutionally weak. The Protocol lacks a dispute settlement mechanism, unlike the WTO which is well equipped with one.

Liability and Redress

One of the main operative principles of the Biosafety Protocol is the precautionary principle which influences the whole legal regime to put in place something which needs to be reflected in the liability and redress regime. There is no established international liability regime for genetically modified crops so the challenge lies in linking GMOs to liability and redress issues. The Biosafety Protocol is the start of a process leading to the development of international rules on liability and redress. The introduction of GMOs into the environment raises novel issues that have not been examined in the previous negotiations over environmental liability regimes, including the question of socio-economic damage and patent liability.

The Organization of African Unity's Model Law on Safety in Biotechnology and the Switzerland's Gene Technology Act provide the most comprehensive precedence for an international and a domestic liability and redress regime. One of the important contributions of the Model Law is with regard to socio-economic aspects. It specifically provides that liability extends to harm or damage caused directly or indirectly to the economy or social or cultural practices or the livelihood or indigenous knowledge systems or technologies of a community. Such harm includes disruption or damage to agricultural systems, reduction in yields and damage to the economy of an area or community. The Gene Technology Law is a general biosafety law based on the precautionary and the polluter-pay principle. The central characteristic is the adoption of a strict liability framework where the injured party is a consumer or farmer. The legislation also specifically provides a duty to compensate environmental harm. The law states that the right to claim damages would expire thirty years after the event causing the damage or thirty years after the date on which the GMO was marketed.

Though these rules may provide some pointers in the development of a liability regime in India, there are certain areas of concern that are specific to each country. However, it is clear that are three main elements which need to be taken into account in the context of the development of a liability and redress regime for GMOs. These elements include environmental damage, socio-economic aspects and patent liability. Relying on existing mechanisms such as torts in common law countries or existing principles

of international law is an inadequate legal strategy because it creates significant uncertainty of outcomes in view of biotechnology's specificities.

The central role of the precautionary principle in the regulation of biotechnology necessitates the adoption of a strict liability approach. There is an increasing link between the biosafety and patent liability and this needs to be taken into account at different points in the regulatory framework apart from specific socio-economic issues, which may be of key importance in various parts of India.

Socio-economic Considerations

The prevailing socio-economic conditions of a country determine and influence, to a large extent, its policy decisions. There are huge variations in the socio-economic settings of different countries due to which the concerns and interests also vary, thus leading to different technological trajectories for each economy. The differences are explicit and clear in case of agricultural biotechnology which are linked with production chain as well as food chain. This brings in issues related to food safety, environmental protection, judicious distribution, ethical aspects and most importantly the equity issues related with technology development and the impact of biotechnology products on indigenous communities, their culture and socio-economic setting. The position taken by the civil society organizations have highlighted the growing polarization on this issue. These discussions have important implications not only for developed countries, which are major exporters of GM goods, but also for some of the developing countries which have infused GM goods in the production chain. Developing countries, that are major exporters of non-GM agricultural goods, are also affected due to requirement of GM free certification by some importers.

At present, there is no internationally agreed definition of socio-economic considerations. These limitations are largely due to the difference in priorities as countries are at various stages of economic development. The recently concluded COP/MOP-2 reiterated the need for research on socio-economic impacts and the allocation of resources to such research. It also suggested information sharing through the implementation of the Akwe:Kon Voluntary Guidelines on impact assessment under the CBD.

It is important to prioritize and incorporate socio-economic aspects into the national biosafety policy since a sizeable population is dependent on agriculture. Prior to release of LMOs, some important inputs are needed to understand both their adverse and beneficial impacts such as: a) knowledge about the gene flow; b) the kind of preparedness required; c) traits vis-à-vis agro-climatic factors; d) exposure to LMOs and risks; e) Nature of risk and implications for health; f) Steps for minimizing risk; and g) Institutional mechanisms in the country, state, district and village *panchayat*.

Key Policy Options

In India, the private sector growth in biotechnology is expanding at a high pace. The number of biotechnology firms in 2005 is about 400 out of which 32 per cent are focussing on agricultural sector. There are more than 20 firms in the agricultural sector that are involved in the development of transgenic crops. There is a growing indigenous strength in the area of agricultural biotechnology and burgeoning agricultural imports, and on the other hand are the challenges that emanate from the ambiguities in the national biosafety guidelines. Some policy measures have to be taken to make biosafety guidelines a comprehensive and dynamic policy mechanism rather than just a tool for regulation. The regulatory agencies are yet to gear up to respond to these dynamic developments in biotechnology.

a. Regulatory Costs

Countries that are able to distinguish and segregate between GMO and non-GMOs have a significant edge over those that arbitrarily adopt GM crops as part of their core strategy in agricultural production. However, creating facilities for segregation incurs huge costs as separate production facilities and labelling would be necessary and this extra cost is likely to be shifted to the consumers. The expenditure for maintenance of a biosafety system in a country mainly falls on the regulatory agencies/governments, (in developing information systems, consultations and meetings, monitoring and other administrative purposes) and the parties interested in the commercialization of GMOs (through tests on allergenicity, toxicity and field trials). If the market size of the GM product is smaller than the cost of regulatory clearances, the operating cost would be exorbitant.

b. Methodology and Socio-Economic Issues

Socio-economic considerations are inextricably linked with risk assessment and decision-making in the context of GMOs, particularly in the developing countries where the social and economic conditions are largely determined by agriculture and where unregulated introduction of GMOs could lead to serious irreversible impacts. The absence of a common international methodology to assess the socio-economic impact can be addressed at the domestic level. Benchmark surveys can be beneficial for the national bodies to make decisions on whether to introduce GMOs into the country.

c. Need for Regional Cooperation and Human Resource Development

Biotechnology has emerged as one of the important links in the regional and sub-regional cooperation programmes. In the Asian context, biotechnology has been identified as a priority area for cooperation and there are several reasons behind this: the region hosts many of the world's biodiversity hotspots; it has a strong research and development base with skilled manpower;

and it is also a large potential market for GM products. In this regard, international support by various agencies should be explored to overcome the scientific uncertainty and methods for traceability.

At the same time, it is important to realize that some of the developing countries especially in South Asia are facing constraints on the front of 'trained manpower' for the second generation biotechnology. In this regard, the GEF supported biosafety programmes should be expanded to cover adequate training programmes for capacity building in the relevant ministries and agencies. Human resource development is also important for facilitating technology transfer and adoption when it comes to international collaborations.

d. Documentation and Trade Facilitation

The impasse at the COP/MOP-2 on the subject of documentation reflects the need to strengthen the Indian biosafety guideline. Studies need to be conducted to tabularize the national experiences in handling, transport and packaging and identification of LMOs at the level of different countries. Then it may be considered what can be done from the trade facilitation perspective. The process of documentation is expected to be rigorous and may also involve high costs which need to be assessed.

On the issue of traceability and threshold value, there is no consensus worldwide due to the inherent difference in sampling and standardization methods. The Indian guidelines should look into the scientific level of harmfulness of the product. But for this, appropriate infrastructure should be in place, such as effective detection and cost involved in segregating and labelling and its ultimate impact on consumers. This may also help in deciding whether documents of LMO shipment should include a commercial invoice, an annex to a commercial invoice, or a stand-alone document and also what should be the content of the invoice which has to be clearly outlined by the national guidelines.

e. Capacity of Quarantine Agency

The quarantine agency is an important focal point for the effective enforcement of biosafety regulations in India. The Plant Quarantine (PQ) Order, 2003, released by the Ministry of Agriculture reflects the vital role played by the quarantine agencies regarding the import of GMOs. Most of the quarantine stations in the country are technically weak in dealing with GMO imports. Since the PQ Order is still a draft, there is space for amendments such as the incorporation of the phytosanitary requirements for GM agricultural commodities that is at par with international standards. It could also include a comprehensive notification regarding the regulation of imports of germplasm/ GMOs/transgenic plant material, including bulk import of GM food grains.

f. Biosafety Clearing House

The biosafety clearing-house is one of the core components of the CPB. It is a storehouse of information on GMOs and other biosafety issues, thereby assisting countries in the implementation of the protocol. Users can readily access or contribute relevant biosafety-related information, as this would assist governments to make informed decisions regarding the importation or release of LMOs. However, India's contribution to the BCH website is certainly minimal and as such information on biosafety issues related to India is limited. A national or regional BCH could be developed by harnessing the talent in the Information Technology industry in India, subsequently providing technical support to other regional partners.

g. Risk Assessment and Management

In India, since risk assessment and risk management (RARM) of GMOs is a relatively new research field, existing facilities are not sufficiently equipped to completely meet the requirements of the Protocol. So the current infrastructure needs to be improved and upgraded. Training courses can be conducted for professionals to identify the potential gene flows and its effect on non-target species. The first step in RARM would be to collect the fundamental information of GMOs followed by the identification of any novel genotypic and phenotypic characteristics associated with it, which may have adverse effects on the biological diversity. Field capacity can be developed which monitors the gene flow between the introduced LMOs and semi domestic and wild relatives.

There is also a need to develop expertise in legal, and socio-economic issues that focus on analysis of the linkages between the protocol and other international agreements, measures related to biosafety and their trade impacts, cost benefit analysis, bioethics, legal drafting and policy analysis. Ultimately, an efficient and credible regulation should be accessible and transparent to incorporate the interest of the public in decision making.

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