Biotechnology and International Trade Regime: Options before Developing Countries

Sachin Chaturvedi[*]
S. R. Rao[**]

In recent past, adoption and diffusion of biotechnology has raised several policy challenges for the governance of this technology especially in the developing countries due to rapid expansion of the biotechnology industry. These countries have been strategically strengthening capacity, infrastructure and expertise in regulation and commercialization of biotechnology particularly in the areas where rich bioresources are utilized. The applications of this technology, both in pharmaceuticals and agriculture, are finding new vistas of economic growth for developing countries. Illegal introduction of GM products, threat of overexploitation of natural resources (their biomolecules and genes), potential risks to environment and global contention on the technology has confounded the prevailing confusion on some of the intricate issues linked to the trade and biosafety of GMOs. However, the position taken by the civil society organizations and some of the national governments especially from Europe and Africa 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

* Fellow, Research and Information System for the Non-Aligned and Other Developing Countries (RIS) and Managing Editor, *ABDR*, New Delhi. Email: sachin@ris.org.in
** Director, Department of Biotechnology, Ministry of Science & Technology, New Delhi. Email: srrao@dbt.nic.in

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. This affects the exports of developing countries adversely.

The related challenge is that the international regulatory arrangements like the Cartagena Protocol on biosafety have yet to become effective international instruments to guide policy frameworks dealing with transboundary movement of GMOs. The development of multilateral, regional and national standards and regulations for the release, safety assessment of food from genetically modified organisms has to be formulated as per the letter and spirit of the Convention on Biological Diversity (CBD). Along with this, the negotiations are taking place in other international organisations such as the WTO, which may have impact on international trade. They include Technical Barriers to Trade (TBT), the Sanitary and Phytosanitary Measures (SPS), Trade-related Aspects of Intellectual Property Rights (TRIPs) and Agreement on Agriculture. They also become relevant in the overarching trade issues such as market access and competitiveness.

This paper makes an effort to critically analyze each of these dimensions of international negotiations and emerging perspectives for developing countries. Section II takes an account of the global status of biotechnology while Section III discusses at length the Cartagena Protocol and different national regulatory regimes. In Section IV, WTO and trade related implications are analyzed.

Adoption and Diffusion of Agricultural Biotechnology

In the last one decade or so, the area under commercial cultivation of GM crops has gone up many times. Between 1996 and 2001, the area under transgenic crops in industrial countries increased (5.6 million hectares) compared with developing countries (2.8 million hectares). The percentage growth was higher in the developing countries of the South (26 per cent) than in the industrial countries of the North (17 per cent).[1] The area under GMOs in the developing countries grew at a rate of 14 per cent in 1997 to

16 per cent, in 1998, to 18 per cent by 1999, 24 per cent in 2000 and 26 per cent in 2001. Thus, in 2001 it showed a rise of more than a quarter. Developing countries have almost 19 million hectares under transgenic crop cultivation. Latin American and CIS countries are the leading developing countries which have embarked on the GM adoption path in the last two years. However, no agricultural biotechnology product has yet been approved in the EU. In addition, several countries including Japan, Korea and temporarily Sri Lanka have already passed or are considering regulations mandating labelling for foods obtained from biotechnology.

In the US, in the year 2001, biotechnology varieties accounted for about 26 per cent of corn, 68 per cent of soybeans and 69 per cent of cotton planted.[2] These crops are the source of various ingredients used extensively in many processed foods, such as corn syrup, soybean oil and cottonseed oil. In Argentina, the main biotechnology crop is soybean while in Canada it is canola. As is clear, the total area under GM crops is 19 per cent of the total cultivated area while 46 per cent of the area under soybean is with GM crops and 7, 20 and 11 per cent under maize, cotton and grape, respectively. Thus, in some areas, concomitant cultivation of GM and non-GM leads to mixed produce. The extant of GM in non-GM produce has become a matter of concern for trade, both for raw and processed produce.

The global market of biotechnology has also grown rapidly in the last few years. In 1995 it was at $75 million while in 1998 it was $1.5 billion. This is now being projected to $6 billion by 2005. This period has also seen a very rapid rise in acquisition, alliances and mergers. There are several factors responsible for these initiatives. James (1998) explains that firms having larger status in pharmaceuticals/biotechnology are now entering in agricultural sector. In the period 1995-98 there were 25 major acquisitions and alliances, which alone were worth $17 billion. Out of them three major mergers were worth $13 billion. In this game of mergers Monsanto has emerged as the biggest player. It has acquired some of the largest firms in this US commodity markets and has got acquisition of important patents. For instance, DeKalb has 11 per cent of US commodity market with lots of important patents. Similarly, Delta & Pineland is the largest US company

for cotton seeds. Monsanto has also acquired international seed operations of Cargill for $1.4 billion. Cargill specialised in seeds of corn, sunflower, rapessed, soyabean, alfalfa, sorghum, wheat and hybrid rice in 51 countries. Unilever owned Plant Breeding International Cambridge Ltd. (PBIC), earlier a public research institute has also been brought by Monsanto. PBIC largely focuses on cereal varieties and potato. Among the mergers, one finds creations of Novartis as a major step towards tapping of synergies in the biotechnology business. Ciba and Sandoz have merged their pesticide and seed business of $5 billion to take form of Novartis. Similarly, the impose of the merger of Hoechst and Rhone Poulenc to form Aventis was to achieve better operational efficiency. Aventis now has an R&D budget of $3 billion and annual sales of $20 billion, all over the world.

Advances in Biotechnology

These growth patterns are likely to go up as technology advances. Now biotechnology offers several ways by which average yield can be directly increased. One is through improvements in the "architecture" of the plant to enable it to absorb more photosynthetic energy or convert a larger portion of that energy into grain rather than stem or leaf. This was, in essence, the "Green Revolution" approach of breeding dwarfing genes into plants, so that the plants could make better use of fertiliser and water and produce more grain. This approach is being pursued in the new rice architecture being studied by the International Rice Research Institute (IRRI), Manila as well as by some private sector industry undertaking research in the fundamental mechanisms that controls plant architecture. Another approach for climates, where it is useful, to modify the plant for a shorter growing season by enhancing its efficiency in the use of fertilizer, pesticides and water. Molecular hybridization has also been demonstrated to increase the productivity of several crops, including rice and wheat, by 15 to 20 per cent.[3] It must be noted that the on-farm yield improvements observed so far have been for transgenic varieties developed to reduce on-farm production costs rather than for the purpose of increasing yields.

However, it is not yet clear whether yield-increasing experiences reflect a one-time advancement, or indicate achievement of a continuing increase in

the yield. Considering that there are many new technologies that will, over time, be applicable for plant improvements and/or integrated into plants, the most reasonable conjecture is that the new technologies will continue to provide yield increases. These will be introduced on a regular basis, and that each of the associated yield increase will be somewhat more than historical trends.[4] Similarly, there are possibilities to improve the nutritional value of cereals by enhancing the presence of special nutrients or chemicals. A commercial example is the increase in the levels of biotin (vitamin H) for application in animal and human nutrition and development of golden rice with carotenoid production.

Public sector breeders have also been looking into similar special purpose applications, such as inserting genes so that vitamin A and iron becomes available through the consumption of rice.[5] Among the potentially more important applications for specific markets are those that seek to improve the quality of feed crops. New varieties of transgenic maize that contain higher oil levels to boost energy and improve feeding efficiency or have characteristics to reduce phosphorous in animal waste are examples that are currently under development.[6] In an interesting development that is certainly relevant to feed grains, is a patent covering the insertion of a protein into plants, which when eaten would facilitate control of animal parasites.

Developing crop varieties with many improved traits than single gene based single trait transgenics is also researched. Companies like Garst Seeds, a subsidiary of Advanta, has developed maize hybrids, which can tolerate two different classes of chemical herbicides.[7] In the United States, currently about 20 per cent of the maize production is destined for such markets, with the production of high-fructose corn syrup and of alcohol being the largest with a number of the industrial uses.[8] Maize and sorghum are among the crops that produce a high yield of starch/energy per hectare, and are the leading temperate zone crops for production characteristic of important crop plants within wide bounds, making it possible to use almost any starch producing plant for many industrial purposes.

There are also other non-traditional uses of cereal crops such as production cellulose, clearly available from other sources, but perhaps usefully produced

in grain cultivation under certain circumstance. These developments may have significance for rice and other cereals, which are more widely grown in the developing countries. To the extent that imported cereals are priced higher than those domestically grown, using starch and other traits from domestically produced bio-engineered cereals in developing countries industries could lead to costs savings and boost farm incomes. Another important possibility is genetically altering crop plants for the production of proteins of pharmacological significance. Some of the patents in this area have wide applicability to different products, including for example, to the production of maize. One patent has very broad claims, but its example, emphasize production in rice. Several of the patents mention production of specific products not all of which are therapeutic. However, commercial applications of these technologies are not yet widely available. Cartagena Protocol and National Regulatory Regimes in Agricultural Biotechnology are two broad sets of regulatory regimes, which have become part of the system. One set emanates from national regulatory mechanisms evolved during last one decade and the other from the recently enforced Cartagena Protocol. The former, apart from having individual countries, also have groupings like the EU which has proposed to establish regulations requiring documentation to trace the presence of biotechnology products through each step of grain handling and food production processes. In fact, the EU now has also proposed to apply similar regulations for animal feeds.

It would be interesting to take stock of this important protocol. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted by the Conference of the Parties to the Convention on 29 January 2000. In accordance with its Article 36, the Protocol was opened for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15th to 26th May 2000, and remained open for signature at United Nations Headquarters in New York from June 5, 2000 to June 4, 2001. The Protocol has been signed on behalf of 107 States and regional economic integration organizations while very few have ratified. Ukraine is the 39th country to have ratified the Protocol in December 2002. The Protocol has become effective after the 50th ratification. India has also ratified this and the concerned Cabinet Committee has also cleared the proposal.

After five years of intense negotiations, governments have finalised this legally binding agreement for protecting the environment from risks posed by the transboundary transport of Living Modified Organisms (LMOs) using modern biotechnology.

This international protocol uses the term LMO rather than GMO. It is assumed that this is a more precise term. LMO is defined as, "Any living organism that possess a novel combination of genetic material obtained through the use of modern biotechnology" (Article 3 g). Under the Cartagena Protocol on Biosafety, governments will signal whether or not they are willing to accept imports of agricultural commodities that include LMOs by communicating their decision to the world community via an Internet-based Biosafety Clearing House. In addition, shipments of these commodities that may contain LMOs are to be clearly labelled. LMOs include various food crops that have been genetically modified for greater productivity or nutritional value, or for resistance to pests or diseases. Common examples include tomatoes, grains, cassava, corn, and soybeans. Seeds for growing crops are particularly important because they are used intentionally to propagate or reproduce LMOs in the environment. Together, these agricultural LMOs form the basis of a multibillion dollar global industry. Pharmaceuticals derived by using LMOs form the basis of an even larger industry (although pharmaceuticals are not covered by this agreement).

Stricter 'Advanced Informed Agreement' (AIA) procedures will apply to seeds, live fish, and other LMOs that are to be intentionally introduced into the environment (Article 7.2). In these cases, the exporter must provide detailed information to each importing country in advance of the first shipment, and the importer must then authorise the shipment. The aim is to ensure that recipient countries have both the opportunity and the capacity to assess risks involving the products of modern biotechnology. Moreover, the information should also include the modifications introduced; the technique used; the resulting characteristics of the LMO; the regulatory status of the LMO in the country of export and the contact details of the importer and the exporter. The notification has to be accompanied by a risk

assessment report. Another important feature of the Protocol emanates from the Preamble as well as from the Articles 1, 10 and 11. This is "precautionary approach". This means that if there is a scientific uncertainty about the impact of genetic manipulation on biodiversity and human health, then the importer country may enforce restrictions on imports and this flexibility would remain till importer on its own arrives on scientific certainty about implications.

One of the most contentious issues that negotiators had to resolve involved the relationship between the Protocol and other international agreements, notably those under the WTO. It is important to ensure that the Protocol and the WTO are mutually supportive. The Protocol is not to affect the rights and obligations of governments under any existing international agreements. While at the same time one also has to ensure that the potentially dangerous activities can be restricted or prohibited even before they can be scientifically proven to cause serious damage.

Regulatory Regime at National and Regional Level

Over the years, the regulatory regime in different countries has emerged at different pace and has taken all different directions. The national responses have largely been driven by specific national situations. For instance "mad cow disease" in European situation led to extreme consumer rigidity for genetically modified food. Annex 1 briefly depicts the evolution and current shape of biosafety policy across various countries.

The European Community (EC) introduced an approval system for the deliberate release of GMOs in the environment. In the following years, the labelling of GMOs was made mandatory. This included foodstuffs and food containing additives or flavourings that have been genetically modified. Gradually, now even animal feed has to be mandatorily labelled. These initiatives of the EU have created a large public debate world over. However, the European Commission has reserved the right to support biotechnology research. The Commission has also acknowledged that Europe's biotechnology industry is lagging behind. In fact, a four-prong strategy has been worked out to catch up in this technology race.[9]

Apart from EU, Japan has also come out with stringent regulations. A committee in charge of developing rules for biotechnology labelling was appointed in 1997 under the Ministry of Agriculture, Forestry and Fishery (MAFF). This ministry has announced to introduce mandatory safety checks to guard against imports of unapproved genetically modified crops for human consumption as well as animal feed.[10] This almost has set in a zero tolerance for food imports containing unapproved gene spliced products.

As the global debate over the benefits and safety of genetically modified food rages on, China has passed regulations that require clearer labelling of these types of products. Now it is being proposed that China would introduce mandatory labelling of food. China's State Council considered and passed the Regulations Concerning the Biotech Safety Management of Agricultural Gene Alteration. In the past, when crops with genetic alterations graduate from the laboratory to the field, they had to be approved by the Ministry of Agriculture. However, when they were transformed into merchandise, there were no such regulations. The new legislation will regulate the biological products with gene alterations requiring the above-mentioned food labelling, for example, so that the issues related to gene alteration can meet international standards.[11]

In India, though biosafety policy evolved in last decade, it has yet to address trade-related issues. The policy was announced in 1990 and then subsequently revised. However, the issues like imports of genetically modified goods are now being further strengthened. One of the recent controversies which highlighted this lacuna was related to import of genetically modified soybean from the US by a donor agency serving food programme for children.[12] India's Biosafety and Recombinant DNA Guidelines (1990) fall under the Environment (Protection) Act of 1986. In 1994, after India signed the Convention on Biodiversity, the DBT revised its earlier guidelines to accommodate the safe handling of GMOs in research, application and technology transfer. This includes the large scale production and deliberate release of GMOs plants, animals and products into the environment. Guidelines are also provided for the shipment and importation of GMOs for laboratory research.

In India the most important committees are: the Institutional Biosafety Committees (IBSC), responsible for the local implementation of guidelines, the Review Committee on Genetic Manipulations (RCGM) responsible for issuing permits; and the Genetic Engineering Approval Committee (GEAC), responsible for monitoring the large scale and commercial use of transgenic materials. These committees have statutory authority. Most of the committee members are from the scientific community and the staff of Department of Biotechnology (DBT) and the Ministry of Environment and Forestry (MoEF). DBT appoints the members to the committees. The GEAC is supposed to be assisted by the State Biotechnology Coordination Committees (SBCC) and District Level Committees (DLC). However, several states are still in the process of establishing SBCC and DLC committees. Efforts are being made to technically equip the members of these committees with information and literature.

WTO and Trade Implications

The issue of GMO possibly span several WTO agreements, including SPS, Agriculture, Trade-related Aspects of Intellectual Property Rights (TRIPs) and Technical Barriers to Trade (TBT). They GMOs related issues have also been discussed in the Committee on Trade and Environment (CTE). Although member governments have notified a large number of regulations related to GMOs to the SPS Committee, most of the discussion on the subject has been in the TBT Committee with the focus on labelling regulations. In the current agriculture negotiations, some members have called for clarity in the WTO rules as applied to products of new technologies.

The SPS Committee, meeting on October 31 and November 1, 2001, for the first time discussed Genetically Modified Organisms. In considering notifications for the first time in the SPS Committee, the US and Canada enquired about the EU's restrictions on Genetically Modified Organisms (GMOs). They complained that the EU had failed to notify its latest directives on traceability and labelling under SPS, even though these indicate that health protection is one of the objectives. The EU delegate mentioned that any comments on this notification should be sent to its authority handling technical barriers to trade issues. Under "other business", the US also

complained about the lack of scientific justification for the EU's continued de facto moratorium on approval of GMO products, and Canada said that the latest EC measures discriminate against products produced by GM technology, even where no trace remains in the final products.

In the TRIPs Committee, it is the Article 27 which has remained at the centre of focus. Article 27 of the TRIPs Agreement defines the types of inventions, which have to be eligible for patent protection and those which can be exempt.These include both products and processes, and they cover all fields of technology.

The Article 27.3(b) covers biotechnological inventions. It is currently under review in the TRIPs Council, as required by the TRIPs Agreement. Some countries have broadened the discussion to cover biodiversity and traditional knowledge. India and many other developing countries have been demanding an explicit position on benefit sharing on traditional knowledge system. The Doha Ministerial statement said:

> "We instruct the Council for TRIPs, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPs Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPs Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPs Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPs Agreement and shall take fully into account the development dimension."

Broadly speaking, Article 27.3(b) allows governments to exclude plants, animals and "essentially" biological processes (but micro-organisms, and non-biological and microbiological processes have to be eligible for patents). However, plant varieties have to be eligible either for patent protection or

through a system created specifically for the purpose ("*sui generis*"), or a combination of the two. For example, countries could enact a plant varieties protection law based on a model of the International Union for the Protection of New Varieties of Plants (UPOV). The review of Article 27.3(b) began in 1999 as required by the TRIPS Agreement.

The topics raised in the TRIPs Council's discussions include: the pros and cons of various types of protection for new plant varieties (patents, UPOV, etc); how to handle moral and ethical issues (e.g. whether invented life forms should be eligible for protection); how to deal with traditional knowledge and the rights of the communities where genetic material originates (including benefit sharing when inventors in one country have rights to creations based on material obtained from another country); and whether there is a conflict between the TRIPs Agreement and the UN Convention on Biological Diversity (CBD). At WTO some developing countries including India have also suggested that patent applicants disclose the origin of genetic material used, which would make benefit sharing easier to implement. These countries have also emphasized on benefit sharing through prior agreement between the researchers and the host country where the genetic material originates.

However, some countries are seeking clarification on issues such as the meaning of the term "micro-organism" and the difference between "biological" and "microbiological" processes. Some countries say that life forms and living creatures should not be patented and that ethical questions should also be discussed. Some developing countries want to make sure that the TRIPs Agreement takes account of more specific concerns such as allowing their farmers to continue to save and exchange seeds that they have harvested, and preventing anti-competitive practices which threaten developing countries' "food sovereignty".

The pertinent question is what agenda developing countries should pursue and to what extent it is technologically tenable.[13] An answer to this should only guide the future course of action for the developing countries, not only with respect to the TRIPs negotiations but also their IPR policy in general. In this context, it needs to be mentioned at the outset that the increasing

importance of genetic engineering in agricultural research across the world, a continued increase of Genetically Modified Organisms (GMOs) and the ability to patent plants has actually reduced the importance of plant variety protection and consequently of the *sui generis* system within the IPR regime.

Here it would be interesting to take note of the broad trends in the intellectual property regime at the level of individual developed countries. Till recently, life forms used to be exempted from patenting. However, developments in biotechnology are compelling for revising the approach towards the intellectual property regime. These policy changes have largely been taking place in the USA, but now European Union and Japan are also all set to closely follow in this race despite the fact that EU and Japan are opposed to biotechnology. Accordingly, various national governments are bringing in changes in the national laws in order to protect and encourage investments in biotechnology. These policy changes have further widened the scope of the ongoing debate. Now it covers a wide range of issues such as the range of product patents and the patentability of genes, gene-sequences and parts of gene-sequences derived from humans, animals, plants or microorganisms. The added aspect is of the relationship between the patent system and the plant variety system. Moreover, patenting, especially of human body parts, has posed an ethical limit for biotechnology itself. In the following sections we attempt to analyse some of these prominent trends in the patenting regime.

The Plant Variety Protection (PVP) and the patents are the two important forms of intellectual property rights. In context of developing countries, PVP has been there for some time but patents for plants is a recent phenomenon. Both patents and PVP provide exclusive monopoly rights on the creation for commercial purposes over a period of time. A patent is a right granted to an inventor to prevent all others from making, using, and/or selling the patented invention for some years. The criteria for a patent are novelty, inventiveness (non-obviousness), utility, and reproducibility. Although patents were designed for industrial application, with biotechnology patent offices now grant patents on micro-organisms and, in some countries, on all life forms.

The intellectual property regime for plant variety protection emerged with a strong commitment for public interest in mind. The whole provision for compulsory licensing was introduced with this intention only. Under this provision of compulsory licensing, a holder of plant breeders' rights can neither refuse any applicant nor can offer unreasonable terms for this. Plant variety protection has worked well as a mechanism to promote the interests of the plant breeders for developing new varieties through giving them proprietary rights on the one hand and as a custodian of public rights of access and use of genetic material on the other. PVP gives patent-like rights to plant breeders. What gets protected in this case is the genetic make-up of a specific plant variety. The criteria for protection are different: novelty, distinctness, uniformity, and stability. PVP laws can provide exemptions for breeders, allowing them to use protected varieties for further breeding, and for farmers, allowing them to save seeds from their harvest.

In plant breeding, thus, PVP is the weaker sister of patenting mainly because of these exemptions. PVP also encourages cross licensing between a holder of PVP and a holder of a patent. Under the breeders' exemption of plant variety rights, anyone may use protected material for breeding purposes. However, the patent regime does not reciprocate this.

Impact on Trade

As is clear, though international trade regime at WTO has yet to address challenges emanating from advancements in biotechnology, the prohibitive measures have already started affecting the trade. Table 1 shows how US export of corn and soybean has declined in several of those countries which have resorted to these prohibitive tactics. In 1997 import of Corn from European Union was 1000 metric tonnes, which declined to 0.07 metric tonnes by 2000. Similarly, import of Soybean from EU has declined from 8000 metric tonnes in 1997 to 6000 metric tonnes by 2000. Apart from this, delays in authorization to import some Bt corn from the US by France cost US exporters about $300 million in exports to the European Union (Cunningham *et. al.* 2000). Only about 2 million tonnes of the 42 million tonnes of US corn exports went to the EU in 1997. In 1998, only 0.3 million

Table 1: US Exports of Corn and Soybeans to Selected Regions/ Countries, 1997-2000

	Corn (10^6 metric tones)*			Soyabeans (10^6 metric tones)		
Region/ Country	**1997 Jan-Dec**	**1999 Jan-Dec**	**2000 Jan-Dec**	**1997 Jan-Dec**	**1999 Jan-Dec**	**2000 Jan-Dec**
Africa	3.95	6.69	6.46	0.11	0.28	0.23
Asia	27.68	31.45	26.73	11.68	12.14	14.94
European Union	1.56	0.09	0.07	8.96	6.46	6.10
Japan	15.45	15.33	14.87	3.70	3.68	3.58
South Korea	3.44	6.16	2.29	1.25	1.17	1.34
Canada	1.03	0.97	1.49	0.26	0.33	0.33
China (Taiwan)	5.44	4.73	4.72	2.27	1.95	1.93

* 1 metric tonne = 2,204 pounds.
Source: ERS/ USDA. FATUS Report. Available online at http://www.ers.usda.gov/db/fatus/

tonnes of the 41 million tonnes went to the EU. Factors that have been used to explain the declines include bans of GM corn by France, Austria and Luxemburg (Cunningham *et al.* 2000). Similar declines have been documented for soybeans. Only 9 million tonnes (out of 26 million tonnes) of US soybean exports went to the EU in 1997 and only 6 million tonnes (out of 20 million tonnes) were exported to the EU.

Some developing countries like India have recently gone through very tough time in terms of governance of biotechnology.[14] Genetically modified cotton was initially illegally introduced in the production system, which is all set to create problems in those countries where imports of GM variety are banned, a problem similar to what we mentioned in case of US. However, as Table 2 shows, total impact on exports of only those crops in which biotechnological applications have been planned, for instance, cotton, corn, soybean and vegetables to only three countries would be $6201 million in case of India. It would nearly be $1700 million to the EU alone. The situation becomes much more challenging when one realises that there are very few equipped laboratories in which GMO testing can be done. Therefore, a clear market strategy and options with technological choices would have to be made with a lot of precaution.

Table 2: India's Exports of (Potential GM) Crops

(US $ Million)

	Cotton	Corn	Soyabean	Vegetables	Tot Crops imported by countries	% Share In Total Exports of Crops
EU	1725.64 (28.99)	0.05 (2.27)	0.08 (32.00)	41.44 (16.77)	1767.21	28.50
Japan	161.79 (2.72)	—	0.11 (44.00)	1.36 (0.55)	163.26	2.63
South Korea	189.03 (3.18)	—	—	0.52 (0.21)	189.55	3.06
Total	**5951.7**	**2.2**	**0.25**	**247.07**	**6201.22**	**100.00**

Source: India Trade 2001.
Note: Figures in Parenthesis are percentage share in total exports.

At the Committee on Agriculture this issue came up again in the same context. In a special session of the Committee on Agriculture, the European Union tabled a controversial paper on food safety, proposing criteria for the application of precaution under the Agreement on Sanitary and Phytosanitary Measures (SPS) that would serve as a guideline for panelists in future disputes. According to the EU, the issue needs to be addressed to avoid the public perception that the WTO requires members to force consumers to accept unsafe food. The EU, other European countries, Japan and Korea argued that Article 5.7 of the SPS Agreement should be clarified through an understanding that would send the right signals to consumers.

Article 5.7 allows members to take provisional health measures when relevant scientific evidence is insufficient, and the substance of the discussions revolved around whether the Article was clear enough to maintain the balance between the need for consumer protection on the one hand and the need to avoid disguised protectionism on the other.

To create predictability for members and to prevent Article 5.7 from being abused for protectionist purposes, the EU proposed that precaution be applied according to the following five criteria: (i) the measure should not be discriminatory; (ii) it should be aimed at achieving consistency in the level

of protection that the Member has chosen; (iii) the adopted measure should presuppose an examination of the benefits and costs of action and lack of action; (iv) it should be reviewed if new scientific information is obtained; and (v) the measure must be based on scientific evidence provided by qualified and respected sources, but not necessarily by the majority of the scientific community. The US and many developing countries strongly opposed this effort to bring food safety onto the agriculture negotiating agenda. They argued that the EU's version of the precautionary principle was based on political rather than scientific considerations. Suspecting that the EU was chiefly interested in finding another avenue for addressing the controversial precautionary principle in the WTO, the US, the Cairns Group and India took a position that instead of the agriculture negotiations, food safety should be discussed at the SPS and the TBT Committees.

Concluding Remarks

The entry of biotechnology especially in the post-green revolution scenario when agriculture production seems to pose several challenges, the concerns like food security assumes key importance in the context of developing countries. The opinion about biotechnology among the developing countries is mixed. There are experts who actually enlist several factors why biotechnology per se is not the right technology to ensure food security and reduce poverty in the developing countries. They even go up to the extent of saying that biotechnology is a technology that has been shaped by a narrow range of private interests – interests that are incompatible with the demands of an ecologically sound and socially-just agriculture. Thus, the issues that the advent of this technology raises, cover a much wider canvass. The ethical dimension of the Genetically Modified Organisms have further confounded the ongoing confusion on the relevance of biotechnology for the developing countries.

In the last decade or so, the transnational corporations have emerged as a major source of biotechnology products. This trend has, probably, further contributed to the concerns among the developing countries as reports about bio-piracy become galore. These concerns have got reflected in the sharper debate being initiated to assess the relevance of this technology for developing countries.

In such a scenario it may not be entirely misplaced to observe that, since biotechnology is a frontier technology, upcoming in a dynamic international environment, it probably requires an altogether different approach to ensure the growth of the technology along with the desired socio-economic goals. Thus, it poses a two-fold challenge: on one hand, the growth of technology has to be ensured and on the other, policies would have to be evolved not only to restrict its adverse implications but also for ensuring growth in the agricultural sector. Any imbalance between the two may offset the wider developmental impetus, the agricultural sector needs at this point. It is high time that agricultural R&D plans prioritise investment on new technologies so as to rightly balance or rather supplement the traditional techniques with new technologies to serve socio-economic interests.

The emerging trade regime under WTO has influenced international trade to a great extent. These changes have severe implications for the developing countries. More so when they are already struggling with the implementational hurdles of the TRIPs regime. There are many developing countries, which have yet to put in place national legislations to position themselves vis-à-vis the international negotiations at the WTO. Several of them come out with several drafts of biodiversity and patent laws but they have yet to see light of the day. There have been various reasons for this delay but now it seems to be clear that it would not only adversely affect the access to technology but also the patenting of research tools would also exclude the late comers in the technology race from imitation or even from product development in any other form.

The WTO TRIPs regime article 27.3 (b) refers to have either a patent regime or an effective *sui generis* system for protection of plant varieties. In the last decade or so, the developing countries have strongly debated the various aspects of *sui generis* system and what actually constitutes it. However, as is evident from the earlier sections, the varietial protection is being attempted through much more stronger patent regime, which do not allow any kind of exemption and is much narrower in its scope than the plant patents or plant variety protection. There is a continuous growth in what is called the utility patents in the US and the Biotechnology Directive

of EU has suggested a similar mechanism for the protection of biotechnological inventions in Europe. Along with this there is also a growing trend of patenting the research tools as well. Thus, in light of the developments in biotechnology, the profile of patent regime is fast changing in the developed countries. Needless to mention that a large part of this research is emanating from the private sector.

The above analysis shows that it is desirable that developing countries would make choices in the biotechnology at selective levels. Even within agricultural biotechnology there are several options which take the horizon far ahead of adoption and diffusion of GMOs alone. This decision should be subject to a critical evaluation of the need assessment of developing countries. In order to obtain benefits and be competitive in biotechnology, developing countries need to access not only the products but, more importantly, to the technology and certainly the tool for it.

In addition, access to genetic resources and the associated traditional knowledge plays a role, highlighting the need for benefit sharing and prior informed consent. At another level, there has to be a multilateral effort to help build capacity related to institutions, infrastructure, policy development and implementation, human resources, local-level ecological data, and research and development in the developing countries in general and in underdeveloped countries in particular. These countries also require support to adopt GM product along with provisions for its safe use and capability to handle its importers and exporters. As far as international negotiations are concerned, a strategy founded on well-informed opinion on technical aspects should be evolved. This includes participation in international negotiations at the WTO and international standard-setting organisations.

As is clear, biotechnology has great potential to be used as commercial technology and thus would be capable of generating a profit exclusively for its owner and others who may be able to access its conditionally at a very high cost. The access is also determined by the terms and conditions set by the IPR Regime. In case of biotechnology, TNCs have a far stronger monopoly than any time before in the history of agriculture science. As

biotechnology is an emerging technology, the owners guard the source of their competitive advantage to the core. In some cases they may internalize transfer of technology, within their network of affiliates rather than externalising such a transfer to unaffiliated licensees.

This scenario completely rules out any possibility of deploying conventional instruments for transfer of technology. The developing countries would have to reconsider their technology policy to encourage and support innovation in the field of frontier technologies. For this they may have to improve upon the existing technological base. In fact, the need is to set their own R&D agenda in the realm of biotechnology. As at present R&D plans are not based on the economic requirements of respective developing countries. Since this is highly capital-intensive technology, the developing countries may consider to pool their resources for creating common facilities like Gene Banks, instruments for marker assisted technology, etc.

Endnotes

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2 GAO (2002).
3 James and A. Anatole (1999).
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Annex 1: The Regulatory Framework Regarding GMOs : Selected countries

EU	**1990**	-	EC introduced an approval system for the release of GMOs into the environment for experimental and commercial purposes.
	1997	-	EC made labelling mandatory for a product containing GMOs.
	1999	-	EC provided consent to place GMOs in the market for a limited period on the condition of compulsory monitoring.
		-	labelling requirements extended to include foodstuffs and food containing additives or flavouring that have been genetically modified.
	2000	-	a directive was introduced that will include a requirement for animal feeds to be labelled.
		-	need for prior consent of third countries that are importing GMOs.
	2005		was set as a definitive date for phasing out the use of GMOs that are resistant to antibiotics.
Japan	**1999**	-	Japanese government recognized 22 GMOs as "safe products. All imports containing GMOs other than the approved ones to be rejected.
	2000	-	Japan introduced mandatory labelling requirements for final products containing GMOs.
		-	Japanese government circulated the official definition of organic farm products. GM products are among the products that cannot be labelled as organic.
United States	**1996**	-	US government approved some 50 varieties of genetically modified crops.
	1999	-	A bill requiring labelling of all genetically modified entity was introduced, but the issue remains unresolved up till now.
	2000	-	A proposal was introduced by the FDA under which biotech would notify them four months in advance before marketing a new GM product and provide evidence of the safety of that product. This, however, is not mandatory it is followed on voluntary basis.
		-	the FDA released its proposed final rule for definitions of organic foods. Any food labelled 'organic' could not have been developed using GMOS.
New Zealand	**1999**	-	a pre-market safety assessment to be carried out by the food authority before genetically modified food are sold.
		-	Introduced labelling of such products.

Annex 1 continued

Annex 1 continued

Australia	**1999**	-	a pre-market safety assessment to be carried out by the food authority before genetically modified food are sold.
		-	Introduced labelling of such products.
Canada	**1999**	-	the Canadian Council of Grocery Distributors agreed to develop a voluntary GM food labelling regime.
Thailand	**1994**	-	Thailand's legislation on plant quarantine was expanded to cover GMOs. Under this, the release into the environment and the import of GM seeds and crops was subject to strict approval system.
	2001	-	The Thai food authority intends to impose labelling requirements.
Sri Lanka			The National Food Advisory Committee is considering the possibility of imposing a ban on the import of GMOs and GM foods.
Republic of Korea	**2000**	-	passes a legislation regarding mandatory labelling of genetically modified soyabeans, corn, and soyabean sprouts.