TRANSBOUNDARY MOVEMENT IN GENETICALLY MODIFIED ORGANISMS WITH SPECIAL EMPHASIS ON CARTEGENA PROTOCOL

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Introduction

Biodiversity, the term given to fauna and flora on the earth are shaped due to the continuous process of evolution either by intervention of human ingenuity or through gene manipulations. The resources are mostly community utilized resources, that is, resources common to all, is well protected by millions of people passed on to the next generation without damaging the intrinsic value of the source. The sustainable use of the living resources of our planet *vis-a-vis* with the trade development called for an international consensus in the 'Rio Declaration' on Biological Diversity. It is the most comprehensive and integrated legal document for conservation of biodiversity. A fine balance is made to achieve the dual object of protecting and preserving the biodiversity. The Convention of Biodiversity (CBD) also deals with a fair and equitable sharing of benefits, genetic resources and appropriate transfer technologies.

The convention emphasized the need for the parties to the convention to develop national policies and programmes for the conservation and sustainable use of biodiversity. The focus is on the establishment and the regulations to manage; control the risks associated with the use and release of Living Modified Organisms (LMOs) from the biotechnology which are likely to have adverse environment impacts that could affect conservation and sustainable use of bio-resources.[1] Recognizing that trade and environment agreements are mutually supportive for achieving sustainable development and also keeping in view the positive benefits the mankind derived with the biotechnological inventions, with adequate safety measures this tool can be used for the well being of mankind.

The Cartegena protocol laid emphasis on the modalities for appropriate procedures in particular, Advance Information Agreement (AIA) in the field of safe transfer (transboundary) handling and use of LMOs resulting from Biotechnology that may have adverse affect on the conservation and sustainable use of biodiversity.[2] With this backdrop the author tries to present a brief account of the international regime relating to transboundary

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1. Article 8(G) of Convention on Biodiversity (CBD).
2. Article 19(3) (4) of CBD.

movement of Genetically Modified (GM) foods and the impact of the Canadian Supreme Court decision on GM foods on developing countries. The paper is divided into the following sections: Section II-The Cartagena (Biosafety) Protocol; Section III-The Conflicts and Controversies on GMOs; Section IV- Cartegena *vis-à-vis* WTO; Section V- The Schmeiser's Controversy; Section VI-Implications of the Judgment; Section VII-Significance for India; Section VIII-Conclusions.

The Cartegena (Biosafety) Protocol

It is the first international treaty on Biosafety which came into force on 11.09.2003 and India is a party to this multilateral treaty. The introduction of Genetically Modified Organisms (GMOs) has been highly controversial throughout the world.[3] The main provisions of the protocol, deals with the international trade in GMO foods. It gained significance in the global trade due to the scientific uncertainties surrounding the risk and benefits associated with the use of agri-biotechnology. The AIA in the protocol requires that an exporter seek consent from an importing country prior to the first shipment of LMO intended for introduction into the environment. The exception to this rule is it does not apply to LMO commodities that are intended for foods, feed or processing or for scientific research. The importers are to make decision on the import of the LMO intended for introduction in the environment based on scientific risk assessment within 270 days of notification of intention to export. The exports need to label the shipment as GM varieties and the importing country can decide whether to import these commodities based on scientific assessment.

The convention requires the concerned governments to provide Bio safety Clearing House (BCH) with the data relating to the final decisions on the domestic use of LMO commodity. The convention specified the shipment documentation relating to this GMOs transboundary movement. The precautionary clause mentions clearly that lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse affects of a LMO.[4] The protocol reaffirms the Precautionary approach contained in Article 15 of Rio declaration on environment and development; and any doubt exists as to the safety of the substances or processes; Government may take precautions to protect the public until they are proven to be safe. The European Union (EU) laid down clear guidelines basing on precautionary principle to achieve high

3. Many environmental activists, religious organizations and scientists raised concerns about GM foods. The most important concerns are a) environmental hazards b) human health risk and c) economic concerns.
4. The U.S. State Department.

level of protection to environment, human, animal and plant health. The Precautionary principle is a complementary to Sanitary and Phyto Sanitary (SPS) measures included into WTO Agreement.

The principle needs to be applied only in case of actual risk or perceived risk, and not to be in an arbitrary manner to form as trade block. The essential imperatives for the existence of a potential risk are:

- The actual adverse effects
- Evaluation of scientific data
- Extent of uncertainty

The guidelines for applying the precautionary principle indicate a cautious approach while assessing the scientific uncertainty.[5] The U.N. in the Earth Summit 1992 discussed the liability based on precautionary principle in Article 3.[6] The protocol contains references to precautionary approach and also the establishment of BCH to facilitate the exchange of information on GMOs. Thus before the existence of the protocol there is no binding international agreement that helps to regulate the transboundary movement and biosafety of GMOs. The scope of Cartegena Protocol is wider in its application and a detailed procedure is laid down in the field of liability and redress for damages resulting from transboundary movement of LMOs. The protocol is also applicable in transit, handling and use of LMOs that have adverse effect or risk on human health.[7]

The Conflicts and Controversies on GMOS

Introducing genes from one species to other in order to get the desirable traits produce the GMOs. The divergent opinions are that the GMOs may damage the ecosystem and possible health risk on humans, animals and plants. The two major concerns are (a) the vectors used for introducing genes from one organism to another to make GMO highly infectious and virulent biological agents. It is this infectious nature that makes them useful as vectors to introduce alien genes into biological

5. The three specific principles are (a) implementation of the principle should be based on the fullest possible scientific examination (b) the risk evaluation should precede potential consequence of inaction (c) the interested parties needs to be given full opportunity to ensure transparency.
6. Article 3 of the Earth Summit 1992 - "The parties should take precautionary measures to anticipate, prevent or minimize the causes of climatic change and mitigate its adverse effects where there is threats of "
7. The African Model Law on bio safety is wider in its application and covers not only the damage to person, property but included damage to economic and cultural practices if indigenous knowledge systems. The disruption is damage to the biological mass, economy of an area or community-Draft Model Law on Bio-safety.

organism (b) the GMOs are novel organisms which are not existed in nature, their impact on environment and human, animal and plant health is not fully assessed lack of scientific certainty is taken as safety in some cases.[8]

The agreement on Sanitary and Pyto-Sanitary measures (SPS) which requires the government to regulate GMOs must justify the regulation with risk assessment based on scientific assessment /evidence that have a direct threat. Lack of scientific data is no defense. The proof that use of that particular GMO is dangerous or a perceived danger is very essential before the ban.

The positive concerns are with the advances in biotechnology and gene transfer thereby required traits can be induced in the original variety, which is pest resistant, drought resistant and high yield varieties can be obtained; that solves the world's food scarcity problems. Thus gene technology with reference to GMOs is having a bright future with enormous potential benefits; however, a cautious approach is required.

Cartegena Protocol *vis-à-vis* WTO

An analysis of the conventions raises two important issues that is, do we need two separate agreements on trade and environment and if so how the interests of the developing countries be protected. Secondly, in case the subjects overlap and conflict arises the reconciliation to be viewed both from countries trade and environmental policies.--7 The WTO focuses the attention between free trade *vis-a-vis* with governmental desire to maintain domestic health, safety and environmental standards. These health provisions, safety provisions designed by the governments, should not be a bottleneck to free trade, especially as a disguised means of protectionism. The multi trade agreements with the object of facilitating free trade should deal these conflicts with harmonious interpretation of these two conventions with WTO on Trade and Environment. U.S. raised an interesting issue against E.U that their ban of GMO is inconsistent with the provisions of WTO.

8. 1.The agreement on Sanitary and Pyto-Sanitary measures (SPS) which requires the government to regulate GMOs must justify the regulation with risk assessment based on scientific assessment /evidence that have a direct threat. Lack of scientific data is no defense. The proof that use of that particular GMO is dangerous or a perceived danger is very essential before the ban. 2.The agreement on Technical Barriers to Trade (TBT) which requires that trade restrictive measures to accomplish the goods should conform to the international standards. The most related are international products, process methods, symbols, packing, labeling and marketing. A link between international standards and redesigning of domestic legislations is of greater importance and these provisions should not act as trade restraints. Both TBT and SPS are based on scientific information and should not cause an obstacle to international trade.3.TRIPs agreement is conflicting

The U.S. government incorporated the Cartegena Protocol as a part of U.N. Environment Programme (UNEP) on biological diversity. The two conventions, i.e., the bio-safety and biological diversity, appear to be contradictory, but a closer look reveals they are mutually supportive of trade and sustainable development.[9] The successful implementation of these conventions would have a positive impact on international trade. For Example, the AIA would remove the doubts in the minds of importer while importing a GMO from other countries. Similarly the exporters label the exportable goods with caution by following the international standards of packaging and labeling. This would also infuse the transparency in trade, which leads to Foreign Direct Investments. The protocol also encouraged the national governments to develop their legislative framework regarding the export and import of the GMOs. The precautionary principle based on scientific assessment would lead to scientific uncertainty at each stage. The protocol is having beneficial implementation, by protecting the biodiversity in a broader sense and bio-safety in specific.

The Schmeiser's Controversy

The recent decision of Canadian Supreme Court in *Monsanto* v. *Schmeiser*[10] raised an interesting issue regarding the patents in GMOs. Earlier the Monsanto raised the objections only with reference to environment protection vs. sustainable development. The issue of patents was not of much focused area. The Canadian Supreme Court discussed at length the Intellectual Property Rights (IPRs) issue in the above case. The discussions and the judgment are of great relevance to the farmers' **community specifically in developing countries.**

The crucial issue regarding the seed patenting and other related IPRs were dealt in depth by the Canadian Supreme Court and settled the legal uncertainty about the genetically modified food crops. The primary issue for discussions is whether a living organism could be patented at all, genetically modified or otherwise. This recalls the previous decision by U.S. Supreme Court in *Anand Mohan Chakravarthi's* case. The U.S. Apex Court gave the judgment that life forms are also included for patent protection. This judgment was based on the fact that in U.S. Constitution

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with biodiversity and foods security concerns. The divergent opinion is the TRIPs agreement failed to provide a specific mechanism to achieve the WTO objective of sustainable development vis-à-vis environment protection. The positive side is TRIPs enhance protection and encourage the transfer of environmentally sound technology.

9. Articles 7, 8, 27.2, 27.3, 31 and 33 of TRIPs agreement; Articles 15, 16.1, 16.5, 22 of CBD and Chapter 34 of Agenda 21 of Rio Declaration.

10. SC (Canada) SCC 2004.

there is no provision expressly excludes such inventions.[11] The issue was opened again in a recent case when the U.S. government refused to grant patent on Harvard University's 'oncomouse' the mouse genetically engineering for cancer research. The Court rejected the issue of patenting life forms, as it would raise moral and ethical issues.[12].

The Courts' decision in Dr. Chakravarti's case was spilt 4 out of 9 judges ruling as per the earlier ruling of Canadian Supreme Court, organisms including plants cannot be patented – as was the case with Harvard University's oncomouse.

Schmeiser argued the case basing on the traditional concept of property. The jurisprudential debate on possession and ownership was not appreciated by the judges and they made it clear that the focused issue is on patents and not on the ownership.

Thus there is no international consensus on this vital issue.

These decisions have a great impact on the contentious issue whether the genetically modified organism/ living modified organism can be patented, if yes, the product that contained a patented compound was itself covered by the provisions of the patents, if the owner intended to sell. The defense raised by the defendant in the present case, when the Court ordered him to pay a compensation of $100,000 to Monsanto is- he used only the seeds that he has harvested himself and GM seed must have come from plants that propagated themselves from the seeds blown from the neighboring farms. He never wanted an herbicide resistant crop though many of his neighboring farm owners were using such seeds. He countered it that it is through the GM contamination for which he should be compensated from Monsanto.

The judges decided the case exclusively on infringement of patents held by *Monsanto*-, and the immediate concern was to determine the validity of patent held by Monsanto. The issue is whether the patentability of a component contains GM cells includes patenting the single GM cell or extension is granted to the whole of the product. The analogy is that if the dominant characters of the structure are based mainly on the GM cell and

11. Dr. Ananda Chakravathy developed a bacterium which splits the oil ingredients into its basic elements. The bacterium is very useful to clear the oil spillings on the high seas, which are very potential for high risk dangers. The legal battle in this case is to have clarity of thought on the conceptual analysis of patentable inventions.
12. The Courts' decision in Dr. Chakravarti's case was spilt 4 out of 9 judges ruling as per the earlier ruling of Canadian Supreme Court, organisms including plants cannot be patented – as was the case with Harvard University's oncomouse.

the significant results can be mainly related to the patent gene, the patent owner can demand royalty from the user. The Court also made it clear that mere presence of a cell would not amount to infringement for commercial gains. In the present case the successful defense that Schmeiser could raise is that even if the GM cell contaminated his own original crop (where he never wanted any GM crop) was not commercially exploited. The judges went much beyond the arguments and concluded that even though Schmeiser commercially exploited GM seed, the borrower/buyer of the seed would be depriving the royalties that Monsanto would have received from them. The presumption was so strong that the ignorance of GM seeds on his farm was not a defense.[13]

Implications of the Judgments

The Cartegena Protocol on bio-safety examined the environmental and health impacts of genetically modified organisms. Certain countries incorporated some provisions as a part of their domestic regulations. For example, E.U. has formulated a Common Agricultural Policy (CAP) based on the Cartegena Protocol.[14] The decision may have long term implications on developing countries whose food safety and security are the basic concerns, but it may have its impact on pharmaceuticals companies, and seed MNCs who would become powerful in the international markets. The farmer would be liable to pay compensation even though he intentionally/ unintentionally used the patented GMO. The judgment is silent regarding the responsibility of the parties, but lay a strong presumption against the farmer, that he ought to have used GMOP without paying royalties to patent owner or corporation. The traditional practice of exchanging the seeds (especially in developing countries) as a custom is no more a privilege to the farmer and it is for the farmer to watch that his crop is not contaminated by GMO.

The Cartegena Protocol is designed basically to protect the bio safety and assumes significance due to scientific uncertainties. Contrary the focus in Schmeiser's judgment is mainly the patenting of GMO and less importance has been given to bio-safety and precautionary approach. The dispute regarding bio-safety against Monsanto, responsible for introducing GM was

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14 E.Us Common Agricultural Policy (CAP) aims at stable supply of food and reasonable standard of living to the E.U farmer. The focused points are to improve quality of European food, food safety. The national legislation on food security is designed with this basic philosophy.

not addressed directly. Unless the country in its agricultural policy excluded the organic agriculture it is presumed it is supported by the government. The issue is not much of legal angle, but of policy matter of the country's government whether to opt for GMO at all.[15]

Significance for India

The bio-safety protocol in Schmeiser's judgment is of immense value to India. The liberalized trade policy where trade is transboundary it is essential that all the exporters need to be provided sufficient prior information on GMO shipments and risk assessments of GMO. The precautionary principle recognizes the scientific certainty of GMO in order to prevent the environmental hazards, public health and consumer safety.

The protocol would give clear visibility /guidelines for the strict implementation of these principles to protect and preserve the biodiversity and provide credibility to the national systems. A clear thinking whether country like India opts for GM to alleviate food scarcity needs to be discussed at the national level on economic/political fronts. India has not yet announced a policy on GM foods, however it is pertinent to note that India is supportive of Tran genetic plant research. The Cartegena Protocol is well designed to deal with the issues relating to GMOs, but no mention made to protect the environmental from intentional/unintentional contamination of GMOs released through pollination. Schmeiser's case is a glaring example that India can take one or two examples. The Indian legal system needs to design a comprehensive legal framework, exclusively to deal with handling and safe transboundary transfer of GMOs.

However, the Indian government issued a notification on December 5, 1989 in exercise of its power conferred under Sections 6, 8, 25 of the Environment Protection Act of 1986. The object of this notification is to protect the environment, health in connection with the application of gene technology and micro organisms. Rule 2 of the notification is applicable to manufacture, import and storage of micro organisms in gene technological products. It also applies to GMO/Micro organisms and correspondingly any substance, product and food stuffs; of which such cells, organisms which forms part of it and includes exportation and importation, production, manufacturing, storage packing of GMOs. The committee known as Genetic Engineering Approval Committee (GEAC) has been constituted under this

15. Brazil banned GM crops entirely, Japan announced the health testing of GM foods as mandatory as on 2001. Currently testing is voluntary and Japanese super markets are offering GM foods and unmodified foods, but the customers are showing strong preferences to unmodified foods. Canada also banned GM foods.

notification to give permission for the substances and products which contain GMOs for sale or importation.[16]

Conclusion

To conclude, the Schemeiser's case may have a negative impact spreads over the whole globe affecting the farmers' rights and bio-safety provisions in the Cartegena Protocol. Uniform and harmonious bio-safety regulations at the international level would minimize this risk. The basic environment principle of strict liability 'the polluter pays principle is the best option' making it clear that the entity marketing GMO is solely liable for all the consequences of transboundary movement of GMOs. However, the Cartegena Protocol once implemented in its true spirit, subject to adequate and transparent measures would protect bio-safety. It also protects the rights of the Indians to have safe GMOs. To achieve this government should have a well defined bio-safety standards and procedures to protect the mega biodiversity and safe use of biotechnology. Thus bio-safety and biotechnology must go hand in hand for better future of the environment and for the safety of the mankind.

16. India opened the door to GM technologies in 2002 after years of trails and allowed Mahyco in which Monsanto owns 26% share in BT cotton. The GMOs in the list are rice, potato, mustard are being field tested.