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TRANSGENIC TECHNOLOGY AND THE ENVIRONMENT: A PERSPECTIVE FROM INTERNATIONAL REGULATORY FRAMEWORK

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Abstract
The impact of the introduction of transgenic crops into the environment is a highly contentious issue. The acceptance of such technology has led to a polarized debate between many countries especially United States and the European Union. The United States considers transgenic products as substantially equivalent to their conventional counterparts and favours free trade; on the other hand, European Union adopts a precautionary approach to trade such products on the rationale that they may have adverse impact on the human health and the environment. In the terms of International trade, transgenic products are forecast to command a significant share of world trade in both developed and developing countries whereas in the terms of environment, transgenic technology has aroused tremendous environmental concerns such as loss of biodiversity, invasive species, genetic pollution, climate change etc. Such impact makes the technology controversial in the trade arena and the subject of widespread international concern. Public acceptance is also another hurdle for its adoption as the public wants to avail the maximum benefits of advancements with the condition that they are completely risk free. To utilize the potential benefits while safeguarding against the risks, most of the Countries have participated ratifying and signing the UN Convention on Biological Diversity, 1992; Cartagena Protocol on Bio diversity, 2000 and many other regulatory legislations. However, there are many ambiguities, complications and inconsistencies in the provisions. Therefore, there is an opportunity as well as a challenge to the regulatory authorities to develop effective laws.

Keywords: Transgenic Crops, Precautionary Approach, Biodiversity, Genetic Pollution, Climate Change, Invasive Species, Trade, Regulatory Provisions.

INTRODUCTION

World agriculture is passing through a distinct phase of transformation, called the 'Second Green Revolution', in which modern biotechnology enables the production of genetically modified(GM) crops/ foods that are claimed to help resolve the pressing problems of food security, malnutrition and abject poverty in different parts of the world[3]. However, there are apprehensions the world over that the GM technology as it unveils may have harmful consequences on sustainable livelihoods in view of the potential threats to food security and subsequent environmental and health challenges.[1]

These transgenic crops are being planted at increasing rates in agricultural areas the world over. Proponents of agricultural biotechnology like transnational corporations such as Monsanto, DuPont, and Novartis, argue that planned and careful introduction of GM crops would help in feeding the world's growing population, eliminate the enormous crop losses due to weeds, insect pests, and pathogens, combat diseases, be more nutritious and enable use of more environmentally sound agricultural practices like significantly reducing the use of agrochemicals etc.[2]

Antagonists on the other hand argue that the side effects in terms of potentially adverse impacts on the environment and human health are unknown. So far there is no conformity that it would actually be a remarkable human innovation for the betterment of the society, in fact as per many scientists, council studies and environmentalists long term testing is required to determine whether this technology is safe for our environment or not.[3] Thus the conflict in accepting GM technology has led to the polarisation of the countries in the area of the regulatory procedures.

TRANSGENIC CONCEPT AND ITS SPREAD

The use of GMOs or transgenic concept in agriculture has been controversial since the late 1990s. GM crops were commercialised in the early 1990s by a handful of multinational corporations headquartered in the USA. Since then, the global use of agricultural biotechnology has increased steadily and dramatically. The developing countries and other poor

[1] *UNCTAD, "Key Issues in Biotechnology", United Nations Conference on Trade and Development 6 (2002).*
[2] *S. Krimsky and R.P Wrubel, Agricultural Biotechnology and the Environment: Science, Policy and Social Issues (University of Illinois Press, Urbana, 1996).*
[3] *Chantal Pohl Nielsen and Kym Anderson, "GMOs, Trade Policy and Welfare in Rich and Poor Countries", SJFI – Working Paper No. 3 8 (2000).*

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countries in various part of the world have accepted this technology to an extent to tide over their food shortages for the growing population; notwithstanding the risks to the public health and the environment.

It must be understood that in this era of modern technology, scientific evaluation cannot guarantee cent percent safety. Invariably there would be some gray areas which would hamper to find precise answers to the risks involved in the spread of biotechnological inventions because of inadequate precision assessment and management tools. For example, the effects of cross-pollination by transgenic pollen to its near relatives cannot be accurately predicted. The question of transfer of marker genes including antibiotic resistant genes from living modified organism (LMO) plants to micro-organisms and further to higher life forms along with the effects of such transfers cannot be quantitatively resolved. Most developing countries including India do not have adequate expertise in assessing the environmental risks from GM plants both on a short-term as well as on a long-term basis.[4]

ENVIRONMENTAL CONCERNS

The environment is a vulnerable stakeholder, to whom we owe a special duty because it does not have the voice to defend itself from the meddling of mankind. Tampering with the genetic blueprints of life carries the possibility for enormous actual as well as potential impact on the environment, particularly non target organisms, ecosystems, and lack of biodiversity including heightened development of resistant insects; out crossing of trans-genes; and cross-contamination that may lead to GM crops as the dominant species. The development of insect-resistant to the microbial insecticide Bacillus thuringiensis (Bt), the dissemination of herbicide-resistant super weeds, injury to the natural predators of target pests, harm to beneficial soil organisms, and potential extinction of wild species are other concerns.

The process of creating GM plants differs from ordinary hybrids because it forces recombination that does not occur in nature. The ecological effects are not limited to pest resistance and creation of new weeds or virus strains but it can produce environmental toxins that move through the food chain and also may end up in the soil and water affecting invertebrates and probably ecological processes such as nutrient cycling. The transgenic plants have damaging effect on beneficial insects like monarch butterflies, lady bugs and lacewings, and other wild life as well.

The major environmental and ecological drawbacks associated with the rapid development and widespread commercialisati ----on 's of GMOs are interrelated and are a threat to our bio diversity. These are:

(a) Loss of biodiversity
(b) Genetic Pollution
(c) Threat to the Natural Ecosystem
(d) Spread of Non-indigenous Transgenic Species into Natural Habitats
(e) Impact on Non Target Organisms and Ecosystem Processes- Unstable Gene Expression
(f) Next Generation Concerns
(g) Genetic Erosion
(h) Disrupting Nature's Process of Speciation
(i) Highly Unpredictable consequences
(j) Climate Change
(k) Miscellaneous Environmental Effects

Supporters of this technology point to the potential of GM crops to improve human health and increase environmental protection. However, some concerned groups and individuals have argued that the risks of GM crops may outweigh their benefits. These groups urge avoiding GM crops or, at the very least, subjecting them to more rigorous scrutiny by government regulators.

Environmentalists often hold that modern biotechnology has "apocalyptic potential" because it tampers with the basic processes of life. If GMOs are released into the environment, the ultimate consequences for the natural flora and fauna are extremely hard to predict but may well be irreversible. However, many environmentalists believe that the Precautionary Principle can be brought in as a trump card to override all other considerations and arguments. Proponents of the

[4] *Dr PK Ghosh, Dr TV Ramanaiah and Dr KK Tripathi, "Capacity Building and its Relevance to Implementation of Cartagena Protocol on Bio-safety" Financial Express, Nov. 25, 2002.*

Precautionary Principle assert that the principle is already "enshrined" in such International agreements as the Convention on Biological Diversity (CBD), 1992 and the Cartagena Protocol on Bio-safety, 2000, but existing definitions of it are at best partial and incomplete.

CONFLICT BETWEEN INTERNATIONAL REGIME OF TRADE AND ENVIRONMENT

The uncertainty raised by GM technology claiming benefits on one hand and fear/concerns on the other requires to be settled with the help of appropriate measures to regulate the technology. Currently there is no binding international protocol, instrument or institution created for the exclusive purpose of regulating biotechnology and its products[5] particularly GMOs. This is simply because there are numerous international issues emerging from GMOs such as commerce, trade, health, safety, environment and biodiversity, politics and international relations, science and technology for framing comprehensive regulations[6]. The debate over regulating the GMOs had been intense between United States (US) and the European Union (EU). A lot of pressure was created by public, media and NGOs such as Green peace, Friends of the Earth, Union of concerned scientists etc. They questioned the impact of food and environmental safety of bio-engineered crops such as Bt corn and Roundup Ready Soybean.[7]

US APPROACH OF SUBSTANTIAL EQUIVALENCE TOWARDS REGULATING GMOS

The US has most developed and well documented GMO regulatory system. Biotechnological regulations are conducted via three agencies namely: Animal and Plant Health Inspection Service that notifies introduction of GMOs in the US and regulates small scale testing before commercialisation; Environmental Protection Agency is responsible for regulating plants that are genetically engineered to express pesticides such as Bt corn; and Food and Drug Administration (FDA) that is responsible for regulation of pre-market approval of GMOs and foods containing GM ingredients and also provides guidelines on the labelling of GM foods. The pesticide expressed by the GM plant has to be approved and registered for its intended use by the FDA.

US regulatory approach is based on the concept of substantial equivalence. It is consistent with the recommendations made by the WHO/FAO and the Codex Alimentarius Commission (CODEX) for assessing the safety of GMOs and the principles for evaluation of GM foods put forward by the Organization for Economic Cooperation and Development (OECD), 1993. The objective of substantial equivalence approach is not to establish absolute safety but to consider whether a GM food is as safe as its conventional counterpart. The key to this approach is the principle of minimal oversight of food products that are generally regarded as safe.

EU APPROACH OF PRECAUTIONARY PRINCIPLE TOWARDS REGULATING GMOS

The EU approach is based on the policy of Precautionary Principle. It is based on the notion that regulation should prevent damage occurring from a particular action rather than letting it arise and then dealing with the consequences. This Principle is enshrined in the Articles 130(2) and 174 of the EC Treaty. Hence the European community acted on precautionary basis when introducing measures designed to protect human health, even where science does not provide conclusive evidence that there is any potential risk.

Two directives were introduced by the European Community in the early 1990's to harmonise those provisions already operating in the individual Member States regulating the contained use of GM micro-organisms and the deliberate release of GMOs.[8]

Directive 90/219/EEC on the Contained use of Genetically Modified Micro-organisms- It concerns the management of GMO research and development, covering containment and control, record keeping, emergency planning and notification with a view to protect human health and the environment.[9]

[5] *Donald E. Buckingham and Peter W. B. Phillips, "Issues and Options for the Multilateral Regulation of GM Foods", Vol. 2 no. 1, ECJILTP 178-189 (2001).*
[6] *Donald E. Bukingham and Peter W.B. Philips, "Hot Potato, Hot Potato: Regulating Products of Biotechnology by International Community", Vol. 35 no.1, J.W.T 21(2001).*
[7] *Ian M. Sheldon, "Regulation of biotechnology: Will we ever "freely" trade GMOs?", 77th EAAE Seminar / NJF Seminar No. 325 The Ohio State University, Department of Agricultural, Environmental, and Development Economics (August 17-18, 2001).*
[8] *Caoimhin MacMaolain, "The New Genetically Modified Food Labelling Requirements: Finally a Lasting Solution?", ELR (2003).*
[9] *Article 1-18.*

Directive 90/220/EEC on the Deliberate Release of GMOs into the Environment- It covers the main elements of the directive requiring notification of the release to the relevant authority in the Member State where the GMO would first be marketed.

Novel Food Regulation No. 258/97- After becoming apparent that there are some major shortcomings in the GM food labelling legislation, additional labelling requirement was adopted in January 1997. This regulation established an approval procedure for novel foods and novel food ingredients, which are defined either as foods or food ingredients containing or consisting of GMOs or foods and food ingredients produced from but not containing GMOs. Novel Foods Regulation further required both unprocessed GMOs and food that may contain GMOs to be labelled, and that labels must indicate whether it is no longer equivalent to the conventional version of that food.

Directive 2001/18 on the Deliberate Release into the Environment of GMOs- This Directive is the cornerstone of the regulatory framework on GMOs and GM products in Europe. The EU has adopted this legislative framework on the deliberate release of GMOs into the environment and the placing of GMOs on the market in accordance with the precautionary principle. Major regulating features relating to the general obligations of Member States stated were as follows[10]:

a. Precautionary Principle should be applied to ensure appropriate measures are taken to avoid any adverse effects on human health and the environment from the release and marketing of GMOs.
b. An environment risk assessment has to be carried out before any notification is made to the relevant EU authority of intent to release a GMO.
c. Use of antibiotic resistance marker genes to be phased out in the case of commercial release of GMOs and for research purposes.
d. Assessment of risk should be concluded on a case-by-case basis.
e. To take measures to ensure traceability at all stages of the placing on market of GMOs.[11]
f. Deliberate release of GMOs for experimental purposes.[12]
g. Notification to the relevant Member State of the release.[13]
h. Member States to consult the public over deliberate release.[14]
i. Notifying Party to provide results of the release as they affect human health and the environment.[15]
j. Establishes a system for the exchange of information relating to notifications and the deliberate release of GMOs in each Member State.[16]
k. Commercial marketing of either GMOs or products containing GMOs.[17]
l. Notification procedure requires an environmental risk assessment, plan for monitoring, a proposal for labelling and proposal for packing. The consent to market GMO is for 10 years which is subject to same procedure at the time of renewal.[18]
m. No Member State can restrict marketing of any GMO that has met the requirements for approval under the revised directive. There is however, a safeguard clause contained in Article 23, which allows a Member State to provisionally restrict or prohibit marketing of a GMO if they have either new or additional information about the risk to human health and the environment, made available since the date of consent.[19]
n. Where either an objection is raised as regards the risk of a GMO to human health and the environment, or where consent is not given to place the GMO on the market, the European Commission will consult the relevant scientific committee.[20]
o. The European Commission may also consult the relevant committees concerning any ethical implications of biotechnology[21].

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[10] *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.*
[11] *First Part A, .Article 4.*
[12] *Part B, Article 4.*
[13] *Article 6.*
[14] *Article 9.*
[15] *Article 10.*
[16] *Article 11.*
[17] *Part C, Article 4.*
[18] *Article 13, 14 and 15.*
[19] *Article 22 and 23.*
[20] *Article 28.*
[21] *Article 29.*

p. It is expected to implement Cartagena Protocol on Bio-safety.[22]

Regulation 1829/2003 on GM Food and Feed- It lays down procedures for the authorization and supervision of GM food and feed, including rules for its labelling. It provides for a scientific evaluation of risks that GM food or feed may present for human and animal health and for the environment. It also provides that a GM food or feed must not mislead the consumer or the user and must not differ from the food or feed which it is intended to replace to such an extent that the normal consumption become nutritionally disadvantageous for human or animals.

Regulation 1830/2003 on labelling and traceability of GMOs- It aims to facilitate accurate labelling, monitoring the effects on the environment and where appropriate on health and the implementation of the appropriate risk management measures. It deals with authorized GM products, food and feed produced from authorized GMOs.[23] It requires the transmission of information in writing to the operator receiving the product that it contains or consists of GMOs and the unique identification has to be assigned to those GMOs[24] and labelling.

From the aforesaid it is clear that there are distinct approaches to regulation of GMOs between US and EU, the US following the principle of substantial equivalence and the EU following the Precautionary Principle. The US and EU are also influencing other countries development of their regulatory regimes; hence the possibility is that the global pattern of regulation of GMO may fall into one of these two approaches.

WORLD TRADE ORGANIZATION AND INTERNATIONAL REGIMES

The World Trade Organization (WTO) has played a very crucial role in deepening the international regime of trade and environment. Each of these regimes which is known to be governed by guiding principle, namely scientific risk assessment in trade and the Precautionary Principle in environment are found incompatible and are likely to be in conflict with each other. Such conflict can hamper the effective implementation of international trade and environmental law.[25] The Protocol adopted under the CBD especially shares concerns of trans-boundary movement of LMOs and its impact on the environment and health of people of the importing country. Countries like US and Canada, that are promoting LMOs, argue that the provisions of the Protocol may prevent free movement of goods raising a conflict with WTO agreements and the Protocol.[26]Thus the debate over GMOs has sharply increased the conflict between the trade and environment regimes.[27]

The WTO explicitly recognizes the right of countries to develop policies that protect human, plant and animal health.[28] Therefore the WTO would not get involved in regulation for the testing and adoption of GMOs in specific countries. In this sense, the Bio-safety Protocol is not in conflict with obligation countries have under the WTO.

CONFLICT BETWEEN CARTAGENA PROTOCOL AND THE SANITARY AND PHYTOSANITARY (SPS) AGREEMENT.

Bio-safety measures require safe and sustainable use of biological resources and their products, including GMOs. The sustainability is tested on the criteria of safety to human, animal, plant life and health, and which is environmentally friendly. FAO (2000) defines it as: "… safe and environmentally sustainable use of all biological products and applications for human health, biodiversity and environmental sustainability, in support of improved food security." For ensuring safe use of GMOs along with its public acceptability, there has to be a competent risk assessment and risk management within an appropriate bio-safety legal and institutional framework. However, in most cases, risk assessment is done by the producing private sector, which as a matter of principle, cannot be fully relied upon even though they follow international standards, and producing countries plead for their safety and allow commercialization without giving guarantee for the safety of GMOs being produced by them.

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[22] *Article 32.*
[23] *Article 1 and 2.*
[24] *Article 4.*
[25] *A. Bluthner, and R. Quick, "Has the Appellate Body Erred? An Appraisal and Criticism of the Ruling in the WTO Hormones Case", Vol. 2,* JIEL *603-639 (1999).*
[26] *K.D Raju, "Biotechnolohy Applications in the Agriculture Sector: Cartagena Protocol and Possible Conflict with Different International Agreements" in K.D Raju (ed.), Genetically Modified Organisms-Emerging Law and Policy in India 25 (TERI Press, New Delhi, 2007).*
[27] *W.D. Coleman, and M. Gabler, "Agricultural Biotechnology and Regime Formation: A Constructivist Assessment of the Prospects", Vol. 46(4), Int. Stud. Q. 481-506 (2002).*
[28] *GATT, 1994, Article XX.*

If safety of GMOs cannot be sufficiently determined on the basis of risk assessment done on acceptable scientific procedures, the Precautionary Principle is applicable, which would require that those GMOs should not be introduced[29]. In view of this it is suggested that all importing countries, including ASEAN countries, should develop their own capability to determine safety of GMOs based on an internationally acceptable scientific procedure.

CARTAGENA PROTOCOL ON BIO-SAFETY

The Cartagena Protocol supports safe international trade in biotechnologically developed LMOs while at the same time seeks to ensure that the human health and the environment are not adversely affected. Under the Cartagena Protocol, it is incumbent upon each Party (exporting and importing) to perform an appropriate scientific procedure for measuring the risk, if any; and to take measures that prevent or mitigate the risk. They are also required to have appropriate legal, administrative and other measures to implement the Advance Informed Agreement (AIA) obligation (Articles 7-12). A large number of States have already enacted laws and approval mechanism for commercial use of LMOs.[30] The exporter must provide detailed information in advance of first shipment. It is the duty of the exporting country to provide documentation accompanying LMOs in addition to handling, transport, packaging and identification. (Article18). Any measure adopted by the importing country should be only to the extent necessary to meet the identified risk (Article 16). This is of trade law origin, and includes a requirement well defined under trade law for the measure to be at least trade restrictive as possible to meet the identified risk.

Approval for commercial use has been one of the most controversial aspects of the LMOs trade. In some countries, including India, experts are of the opinion that approval body should not rely on the scientific data released by GM Crop producing companies. They suggest that it is the duty of the producing State and importing State to perform certain appropriate scientific tests. It is necessary because a small quantity of LMO might have the potential to cause a big harm, sometimes irreparable damage.

The Cartagena Protocol has excluded five types of LMOs from the AIA procedure. They are: pharmaceuticals for humans; LMOs in transit to a third Party; LMOs destined for contained use; LMO-FFPs (subject to simplified, less restrictive procedure in Article 11); and LMOs that have been declared safe by a meeting of the Parties. These exclusions (in particular, the exclusion of LMO-FFPs) means that the AIA covers only a small percentage of trade in LMOs, only those destined for direct introduction to the environment for the importer, such as seeds and micro-organisms.

AGREEMENT ON THE APPLICATION OF SPS MEASURES

The primary objective of the SPS Agreement is to protect unnecessary obstruction of international trade of GMOs and their products if they are safe to human, plant and animal life and health. Members are under obligation to develop their own rules based on scientific standards to be applied for the protection of human, animal and plant life or health.

Briefly, the legal obligations covered under SPS Agreement are: (a) to achieve Appropriate level of Protection, (b) food safety, human, animal, plant health and life protection, (c) risk assessment, (d) scientific justification and Evidence, (e) non-discrimination and without arbitrariness, (f) transparency, (g) right to restrict trade if necessary to protect health and life, (h) must not constitute a disguised restriction on international trade. The main provisions of the WTO-SPS Agreement are as under:

Application [Article1]- It includes (i) SPS measures are applied on the basis of bilateral agreements or protocols, (ii) It is applicable to all SPS measures which may directly or indirectly affect international trade and (iii) every SPS measure must be based on scientific principles and evidence.

Non-discrimination [Article2] - Article 2 of the SPS Agreement sets out two relevant "basic rights and obligations". Members shall ensure that any SPS measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5. Members has to ensure (i) SPS measure must not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, (ii) SPS measure must not constitute disguised restriction on international trade and (iii) treats imports no differently than domestic produce.

[29] *A.H Ansari, "WTO and MEAs: Resolving the Competing Paradigm", Vol. 6 No. 2, J.I.T.L.&P 2-13(2007).*

[30] Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes, *Secretariat of the Convention on Biological Diversity, Montreal (2000).*

Harmonization [Article3] - It sets out a further obligation on WTO Members to engage in a process to *harmonize* their phytosanitary measures "on as wide a basis as possible", in conformance with or based upon international standards, guidelines or recommendations.[31] WTO Member countries are encouraged to use international standards, guidelines and recommendations where they exist and to recognize and participate actively in the three international standard setting agencies also known as three sisters:

- Codex Alimentarius Commission - Food safety
- International Office of Epizootics –Animal Health
- International Plant Protection Convention - Plant Health

SPS AGREEMENT AND GMO[32]

FROM THE ABOVE PROVISIONS IT seems that the agreement has an obvious relevance to GMOs, as the GMOs fall within the purview of the SPS Agreement, which covers end products as well as processes and production methods.[33] Further, measures related to risk assessment, packaging and labelling in so far as they are directly related to GMO food safety, are also governed by the SPS Agreement.[34] Other packaging and labelling requirements connected with GMOs may fall under the Technical Barriers to Trade (TBT) Agreement.

However, the SPS Agreement raises, from the perspective of GMOs, questions of potential conflicts, gaps, duplication and general incoherence. For instance, does the SPS Agreement cover all the risks arising from GMOs? Does it afford protection to all concerns from the risks arising from GMOs? The SPS Agreement defines SPS measures in a manner that does not encompass all the risks or potential concerns consequential upon the introduction of GMOs in a particular environment. Thus, the risks covered by the national SPS measures that are under the scope of the SPS Agreement, the coverage appears incomplete given the potential risks from biotechnology.

SPS MEASURES AND GATT

Food safety is an important concern in the trade regime. 'General Exception' to the GATT, in Article XX (b), provides that 'nothing in this Agreement shall … prevent the adoption … of measures … necessary to protect human, animal or plant life or health'. The only limitation to this provision was that such measures were not to be applied so as to create arbitrary or unjustifiable discrimination, or a disguised restriction on trade. This provision reflected the attempt of GATT Contracting Parties to balance issues like food safety and trade liberalization.

The SPS Agreement did not provide for the criteria other than scientific procedures that the EU wished to introduce into risk assessment. With regard to the precautionary principle, Article 5.7 did permit Members to apply SPS measures 'where relevant scientific evidence is insufficient', but this exception was qualified by the requirement that the measures be provisional, and that the implementing member should seek to obtain the additional information necessary 'within a reasonable period of time'.[35] Finally, with regard to burden of proof, the clear expectation that Members would rely on international standards arguably placed the burden of proof on non-compliant Members to justify any standards that were higher than international standards.[36] As a result, the exporter would escape the obligation to prove a product was safe in the face of an SPS measure maintained by the importing country. Hence, US negotiators disagreed with the EU on these three concerns, and the US prevailed on these matters in the resulting SPS Agreement.[37]

SPS AGREEMENT AND CARTAGENA PROTOCOL ON BIODIVERSITY

The predominant purpose of the Protocol is to regulate trans-boundary movement of LMOs from one country to another country and to protect the environment; whereas, the emphasis of the SPS Agreement is to protect human, animal and plant

[31] *SPS Agreement, Arts.3.1 and 3.2.*
[32] *Asif H. Qureshi, "The Cartagena Protocol on Biosafety and the WTO- Co-existence or Incoherence?", Vol. 49, ICLQ 849-50 (2000).*
[33] *SPS Agreement, Annex A.*
[34] *SPS Agreement, Annex A; S.P. Quintillan, "Free Trade, Public Health Protection and Consumer Information in the European and WTO Context", Vol. 33 No. 6, J.W.T. 171 (1999).*
[35] *W.D Coleman, and M. Gabler, "Agricultural Biotechnology and Regime Formation: A Constructivist Assessment of the Prospects", Vol. 46(4) Int. Stud. Q. 481-506(2002).*
[36] *G. Curzon, "The Management of Trade Relations in the GATT', in Andrew Shonfield (ed.),* International Economic Relations of the Western World 1959-1971. Vol. 1: Politics and Trade *141-283 (Oxford University Press, 1976).*
[37] *Codex Alimentarius (2000), "Communication of the European Commission on the Precautionary Principle", Commission Document CX/GP 00/3-Added as of 2 March.*

life and health. The risk assessment in the SPS Agreement has to be based on more objective scientific procedure and not only to be done in the lab, but also outside in the society, so that only in genuine cases SPS measure are taken and they are neither trade restrictive nor arbitrary.

Cartagena Protocol supports safe international trade in biotechnologically developed LMOs, while at the same time seeks to ensure that the human health and the environment are not adversely affected. Hence, to ensure human health and protection of the environment, the Protocol has heavy dependence on the Precautionary Principle. The inconsistencies between the two legal regimes, however, can be harmonized amicably by making suitable amendments in the SPS Agreement.

RESOLVING THE CONFLICT BETWEEN SPS AGREEMENT AND CARTAGENA PROTOCOL

The two legal instruments are not co-extensive. This is because the primary objects of both of them are different. One has been made to protect unnecessary obstruction of international trade of GMOs and their products if they are safe to human, plant and animal life and health; whereas, the Cartagena Protocol has the object to protect the environment and human health from LMOs. It is notable that since the Cartagena Protocol has been made under the Biodiversity conservation it is leaning more towards conservation of the environment. It is for this reason that it has a better mechanism for risk assessment and Precautionary Principle. It cannot be considered as trade restrictive. However, it is not in total conformity with the SPS Agreement. The SPS Agreement prevents the Members from taking precautionary measures without scientific evidence. On the other hand, the Protocol allows Members to take precautionary measures even in the absence of strict scientific evidence. Hence the measures under the Protocol may clash with the stipulations under the SPS Agreement. As protection of the environment is no less important than ensuring international free trade, an amicable co-existence of both the regimes is needed. Paragraph 31 of the Doha Declaration strives for making both the regimes supportive to each other. Paragraph 32 of the Declaration provides for constituting a Special Session of the Committee on Trade and Environment (CTE). However, the committee's success is loomed by the clouds of uncertainty. The popular solution is that for providing a greater degree of freedom of risk assessment to States should suitably amend Articles 5.5 and 5.7 to bring them in line with CODEX assessment guidelines and the Cartagena Protocol. Even where the State has taken precautionary measure under Article 5.7, it will have to review its measure from time to time.

CONCLUSION

The introduction of GM technology and its acceptance is still at an infant stage. The technology along with tall claims is bound to affect the environment negatively. A need for a proper scientific risk assessment along with the application of precautionary principle is emphasized. The jurisprudence in the international law is also at a very primitive stage. The implications of the Protocol and the conflict and inconsistencies with the SPS agreement are yet to be amicably resolved. It can be done by making suitable amendments in the SPS Agreement. This is warranted because conservation of the biodiversity in effect contributes to the protection of human, animal and plant lives and health in manifest ways. It is suggested that Article 5.5 and 5.7 of the SPS Agreement should be amended in order to bring them in line with the Cartagena Protocol and the CODEX procedure. It is suggested that before an amendment is opted, a proper study should be done by the Special Session of the CTE, so that an amicable balance between international trade in and conservation of the biodiversity may be created and the two will then protect the human, animal and plant health and the environment in the best possible way.