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Review

LMOs/GMOs, the environment and the people: A critical exposition

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A continuous viable research used to develop living modified organisms/genetically modified organisms (LMOs/GMOs) by biotechnologists around the world is a *sine qua non* for providing subsistence to the ever growing populations in developing and least developed countries because they will continually experience rise in population till 2050. Moreover, it is necessary that all LMOs/GMOs are safe for human consumption and compatible with the environment; thus, they should save lives instead of taking lives by being spurious. This requires restraint on self-interests, economic and personal interests on the part of the developers of LMOs/GMOs, especially biotechnologists, companies engaged with biotechnology researches and governments. As a matter of fact, all LMOs/GMOs must pass through an intensive risk assessment provided in certain international legal instruments before they are allowed to be marketed for human consumption or introduced into the environment. So far international trade in LMOs/GMOs is concerned, it is the duty of the exporting as well as importing countries to perform universally acclaimed lab and field testing in order to ensure their safety to human health and to be environmentally friendly so that sustainability imperatives are adhered to. This study discusses ways and means to achieve these imperatives in the light of relevant international laws, and it offers certain amicable suggestions for ensuring pubic interests.

Key words: LMOs, GMOs, traditional knowledge, geographical indication, environment, international trade.

INTRODUCTION

As we know, in order to provide food to the ever-growing population of the world, especially to the developing and least developed countries, genetically modified organisms (living and non-living), food containing genetically modified stuff and GMOs, which may be living and non living and which are commonly known as LMOs and GM food and feed, are *sine qua non*. Without their large scale production and worldwide consumption, the population in developing and least developed countries, where the population is supposed to grow until 2050, will suffer from food scarcity and malnutrition (Population Bulletin, 2008; Ida et al., 2011). Although, most of the GMOs are produced by developed countries, developing and least developed countries are also trying hard to augment agricultural biotechnology by all means, such as: Allocating funds, transfer of technology and South-South cooperation. Thus, they largely depend on LMOs produced and marketed by developed countries, especially the United States, Australia and West European countries. Among developing counties, Argentina and Mexico, South Africa and Brazil, China and India are notable, but they also fall short of developed countries. This is testified in Table 1.

It is notable that initially when GM food were sought to be exported from producing countries to countries where they were squarely required, there were no welcome responses, but this skepticism did not stay long. Gradually, states have now started accepting them subject to fulfillment of safety requirements. Some countries, includ-

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Table 1. Living modified organisms (LMOs) already being marketed (Ida Madieha et al., 2011; Biotechnology Law and Policy, 2011).

Country	LMOs marketed
Canada	3
USA	4
Australia	2
West Europe	3
Argentina	3
Mexico	1
China	1
South Africa	3
Brazil	1
India	1
Paraguay	1
Colombia	1

ing the European Union (EU), have their intensive testing and approval mechanism based on the following EU regulations, which are worth mentioning for this purpose: Directive 2001/18 EC on environmental release of GMOs; Regulation (EC) No 1829/2003 on GM Food and feed about pre-marketing authorization; and Regulation (EC) No 1830/2003 on labeling of GMOs and traceability of food and feed products from GMOs. It is notable here that EU ratified the Cartagena Protocol in June 2003, in that they allowed imports and consumption of LMOs, GMOs and GM Food only after approval by their testing institutions (Ngobese, 2003). The Cartagena Protocol, made under the Convention on Biological Diversity (CBD), makes it incumbent on all Member States to perform an appropriate scientific procedure for measuring the risk, to take measures that prevent or mitigate the risk and to inform other countries about the results through the Biosafety Clearing House mechanism. In order to ensure safety, it requires the Member States to conduct an appropriate lab and field testing before LMOs are commercialized. Their shipments must have labeling to the effect that they are not to be introduced into the environment. The Protocol prescribes that movement of LMOs from one country to another can take place only on informed consent basis known as advance inform agreement (AIA), contained in sections 7 to 10 and 12 of the Protocol, which requires the party to export and to inform the party to import about the intended export. Then, the party to import will acknowledge the receipt of this information and may allow or prohibit the intended export to the country. LMOs, which are exported for direct use in food or fodder, are exempted. Further exemption can be prescribed by the Conference of Parties (COP), in so far there are no exemptions. However, this requirement has been eased by providing five exceptions to it, for example: Pharmaceuticals for humans, LMOs in transit to a third party, LMOs destined for contained use, LMO-FFPs (it covers a number of agricultural produce) to be used for food or feed, or for processing, and LMOs that have been declared safe by a meeting of the parties. These exceptions have narrowed the scope of application of the Protocol. It is for this reason that this part of the Protocol has been highly debatable (Bhagwati, 2001; Peel, 2007). However, in effect, the Protocol has made an attempt to ensure human health and prevent the environment being contaminated by LMOs (Jusoh, 2006). It is hoped that when the safety provisions of the Cartagena Protocol is widely accepted, international trade in LMOs will experience a notable boost (Ansari, 2007; Peel, 2005). The Protocol seeks, in effect, to protect human life and conserve the environment; and for ensuring them, it requires certain procedures to be followed. When we look at the Protocol from the point of view of the protection of the 'human, animal and plant life and health' in light of the risk assessment provisions of the SPS Agreement and decisions given by the DSB of the World Trade Organization (WTO), a number of socio-economic and environmental questions for protecting the interests of the public around the world are required to be addressed for getting viable answers for them (Henckels, 2006; Firbank, 2003; Philbrick, 2008).

Based on the literature review, we can say that there is an urgent need to develop such a mechanism that ensures the biosafety and protection of the rights of poor people, including poor farmers of the third world countries. This study, therefore, discusses some pertinent questions related to safe GMOs, LMOs and GM Food, and resolves the dispute between international trade law and protection of the environment, after which it came out with amicable suggestions in order to protect the right to life of people around the world and conservation of the environment for ensuring sustainable development imperatives. In addition, the paper discuss-es about certain pertinent issues related to Traditional Knowledge (TK), Geographical Indications (GI), ethical and religious values and public participation pertaining to biotechnology research.

CO-EXISTENCE OF TRADE LAW AND ENVIRONMENTAL LAW

Ever since it was realized that in achieving long-term plans, conservation of the environment along with human health must be ensured, Jurists and scientists around the world agitated their minds to bringing about an amicable co-existence of environmental law, especially those contained in multilateral environmental agreements (MEAs), and international trade law, especially the WTO rules, in the interest of the general public around the world for all times to come. It is because both had developed in different circumstances to serve different purposes. International trade, free from all kinds of barriers (qualitative and quantitative), got support in order to speedily redress the economic loss suffered due to the two World Wars, and to further develop at a faster rate. Initially, nobody questioned this *laissez-faire* policy as

development was warranted evidently, but this appreciative attitude did not last long because in the 1970s and after, it was realised that unfettered development might cause adverse impacts on the environment, and some of them might be irreparable. Among all, loss of biodiversity was rightly considered as quite significant. It started since the United Nations Conference on Human Environment, 1972 (UNCHE). Since then, consciousness among the people and many governments about protection of the environment got impetus. We saw the biggest milestone towards this direction at the United Nations Conference on Environment and Development (UNCED) held in 1992 at the Rio Dajenero. At this conference, along with the GATT-94, several other international legal instruments were discussed and signed. In all these legal instruments, Agenda 21 for sustainable development and the conservation of the biodiversity under the CBD, especially conservation of the biodiversity for broader interest of the people living in all states (developed, developing and least developed), which received noteworthy importance and SPS Agreement, provided for risk assessment as a *sine qua non*, were significant. The Cartagena Protocol, a later addition to the CBD, made certain provisions on measuring risk via scientific assessment with due consideration of the conservation of the biodiversity (Ansari et al., 2008). It raised a potent question: Should we interpret the risk assessment provisions of the SPS Agreement in light with the similar provisions in the CBD, Cartagena Protocol and Agenda 21 on sustainable development?

The momentous scientific breakthrough in developing GMOs, LMOs and GM Food also prompted those who produced them to engage in international trade in them, but this divided the world into two groups: producers of LMOs/GMOs and their potential importers. However, there is lack of compatibility among them. Due to lack of guarantee of safety of LMOs and food containing GMOs, the incompatibility got widened, and ultimately led to the two schools of thought among scientists, biotechnologists, environmentalists and policy-makers, in which one was in support of international trade in them, and the other to practice it with strict application of a universally acceptable precautionary principle competent enough to protect the biodiversity and ensure human health (Pluridisciplinary Symposium on Environment and Health, 2010; Ansari, 2003). The first school of thought, which is predominantly supportive to free international trade, wishes to apply the precautionary principle contained in the SPS Agreement under the precinct of the WTO rules, which provides for 'sufficient scientific evidence' and 'risk assessment'.

THE WTO PANELS AND THE APPELLATE BODY IN RELEVANT CASES ON 'THE RISK ASSESSMENT' PROVISIONS IN THE SPS AGREEMENT

In *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (Dispute WT/DS 292, 293/R; Panel Report on: 29 September 2006), the action taken by the European Communities against import of certain agricultural products was considered by the WTO Panel. It ruled that the European Community (EC) complied with certain provisions of the SPS Agreement. However, the EC violated it in the following ways:

1) The Panel found that "…by applying the moratorium (on import of GMOs), the European Communities had acted inconsistently with its obligations under Annex C (1) (a), first clause, and Article 8 of the SPS Agreement because the *de facto* moratorium led to undue delays in the completion of the EC approval procedures."
2) The Panel further found that "…the European Communities had acted inconsistently with its obligations under Annex C (1) (a), first clause, and Article 8 of the SPS Agreement in respect of the approval procedures concerning 24 out of 27 biotechnology products identified by the complaining parties because there were undue delays in the completion of the approval procedures for each of these products."
3. The Panel proceeded to state that "…the EC acted inconsistently with its obligations under Articles 5.1 and 2.2 of…the SPS Agreement with regard to all of the safeguard measures, because these measures were not based on risk assessments satisfying the definition of the SPS Agreement and hence could be presumed to be maintained without sufficient scientific evidence."
4. The Panel refused to apply the precautionary provisions contained in the Cartagena Protocol since it is applicable that all the contesting parties must be members of the protocol also [http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm (12 February 2011)].

It is evident from the report that the restrictive approach of the WTO Panel may not be acceptable to environmentalists, as it is strictly SPS Agreement-centered and does not provide any amicable solution for applicability of the precautionary principle acceptable to them. It will certainly facilitate only international trade in them. The WTO Panel had the opportunity to come out with an amicable solution to resolve the conflict between the WTO and MEAs in line with the approach taken by the Appellate Body in *US – Shrimp* case (WT/DS58/R/AB, 6 November 1998). On the contrary, the Panel ruled against the approach taken by the Appellate Body. In this case, the idea of sustainable development was contained in the Agenda 21, the rule of multilateralism, decision on setting up a WTO committee on trade and environment (CTE), and the 1996 CTE Report [*Ministerial Decision on Trade and Environment*, 14 April 1994; *Report of the Committee on Trade and Environment*, WT/CTE/1 (96-4808), 12 November 1996]. The report was criticized by the International Law Commissions for its narrow approach on applicability of

MEAs for interpreting WTO rules [International Law Commissions, *Fragmentation of International Law: Difficulties Arising from the Definition and Expansion of International Law,* U.N. Doc. A/CN.4/L.684, 13 April 2006]. This case has, in effect, narrowed down the possibility of taking a harmonized approach that is, interpreting a WTO rule in light of relevant multilateral environmental agreements (MEAs). It is for this reason that some experts plead for applicability of a harmonized approach of the precautionary principle that complements the provisions contained in both international legal instruments, the Cartagena Protocol and the SPS Agreement. In this regard, the precautionary measure adopted by the United Kingdom is worth quoting (*infra*). The WTO again got the opportunity to deliberate on the issue of applicability of both provisions, but its Appellate Body could not go beyond the traditional SPS Agreement-centric approach.

In *EC – Measures Concerning Meat and Meat Products (Hormones)* case (WT/DS26/AB/R; WT/DS 48 AB/R, 31st March 2008), it was ruled by the Appellate Body that in generalized terms, the object and purpose of Article 3 is to promote the harmonization of the SPS measures of members on a wide basis as possible, while recognizing and safeguarding, at the same time, the right and duty of members to protect the life and health of their people. The ultimate goal of the harmonization of SPS measures is to prevent the use of such measures for arbitrary or unjustifiable discrimination between members, or as a disguised restriction on international trade, without preventing members from adopting or enforcing measures which are both "necessary to protect" human life or health "based on scientific principles", and without requiring them to change their appropriate level of protection. The requirements of a risk assessment under Article 5.1, as well as a "sufficient scientific evidence" under Article 2.2, are essential for the maintenance of the delicate and carefully negotiated balance in the “SPS Agreement” between the shared, but sometimes competing interests of promoting international trade and of protecting the life and health of human beings. We conclude that the Panel's finding which states that the European Communities are required by Article 3.3 to comply with the requirements of Article 5.1 is correct”, and “…Articles 2.2 and 5.1 should constantly be read together. Article 2.2 informs Article 5.1 of the elements that define the basic obligation set out in Article 2.2 to impart meaning to Article 5.1” [the Report at: http://www.pravo.hr/images/50005731/AB%20%20EC%20-%20Hormones.pdf) (10 February 2011)]. It is evident from these passages of the report that the Appellate Body remained engaged with the technicalities of various provisions of the SPS Agreement; thus, various pertinent aspects suggested by the Appellate Body in the *US - Shrimp* case were ignored.

In both cases, the Panel in the first case and the Panel and Appellate Body in the second case could have made attempts to come out with a harmonized view on applicability of the precautionary principle which could be acceptable to all. They relied on JECFA’s risk assessment, which provided them with independent scientific advice on *Codex Alimetarius* (food code), which is a collection of internationally adopted food standards. Thus, they opined that the precautionary principle cannot override the provisions of the SPS Agreement. The authors are of the opinion that in order to protect the environment and human health, WTO will have to give a wider application of both of them. If this is practiced, an attempt to harmonize international trade and protection of environment can be possible. On the contrary, those who supported the other school of thought plead only for the application of the principle contained in the Cartagena Protocol made under the CBD because the Protocol emphatically emphasizes the conservation of the biodiversity of the world on the basis of applicability of a viable approach of the precautionary principle, which according to them should have priority over economic short-term interest (Ansari et al., 2008; Charnovitz, 2002; Balakrishna, 2005). As stated in the foregoing, different authors reiterate that a harmonized approach will be an amicable approach.

The Cartagena Protocol provides measures for safety determination of LMOs, but it has relatively strict rules to be applied. The scope of the SPS Agreement is wider, but it gives liberty to States to apply measures within the limits prescribed by clause (b), (g) and the Preamble of Article XX of the GATT. Moreover, they are not compatible, in that they have been incorporated therein to serve different objectives. In order to protect the environment and human health, it has been suggested by a large number of environmentalists that the biosafety provisions contained in the Biosafety Protocol should be given effect. It means that exporting and importing countries should comply with those provisions, especially those of AIA procedure, but experts in the international trade law, especially those who decide over disputes involving environmental law and international trade law at the World Trade Organization (WTO), do not subscribe to this idea; they prefer to resort to only the provisions of the SPS Agreement. The authors are of the opinion that transboudary movement of LMOs and GM Food ensuring protection of the environment and human health are more important than just to foster international trade in them. It can undoubtedly be said that protection of the environment is much more important than the short-term economic interest of exporting countries. If anything contrary to this is practiced, the biodiversity might adversely be affected and because of that we might have millions of environmentally displaced people and a large number of people might suffer from GMOs related diseases, including gastric irritation (commonly) and cancer (exceptionally).

It is notable that the WTO is augmenting efforts to fuse environmental law and international trade law. For

achieving this, a Committee on Trade and Environment (CTE) was initially set up. This got support from the Special Session of the Committee on Trade and Environment (CTE Special Session), but the irony is that even after several years of efforts made by them, there are no concrete results so far. Perhaps, it is for this reason that experts at the WTO have insight only in international trade law; and as a matter of fact, their mind set was in favour of international trade law. A balanced approach can only be expected by persons who have expertise in both domains of knowledge. There are a number of suggestions offered by such experts, but they have not been paid attention to by the WTO. The authors are of the opinion that there can be compatibility among the two laws, if international trade law is suitably amended so that both laws can co-exist and do their assigned tasks without encroaching upon one another (Baly, 2004; Ansari, 2004; Ngobese, 2003; Micheal et al., 2002; Steen, 2005). In spite of this, a similar trend in the WTO dispute settlement continued. This is evident from the reports of the Panel and Appellate Body in *Australia — Measures Affecting the Importation of Apples from New Zealand* (*Australia Apple* Case, DS 367). The notable points in the Panel Report are: The Panel ruled that all sixteen of Australia's quarantine measures along with their current Import Risk Analysis were inconsistent with their legal obligations as a WTO member under the SPS Agreement. The Panel found that the 16 measures were not based on a proper risk assessment and, accordingly, were inconsistent with Article 5.1 and 5.2 of the SPS Agreement. The Panel also concluded that by implication, these 16 measures were inconsistent with Article 2.2 of the SPS Agreement, which requires that SPS measures should be based on scientific principles and should not be maintained without sufficient scientific evidence. It was also found that the measure against fire blight and ASCM within Article 5.6 of the Agreement was trade restrictive.

Australia appealed against the decision of the Panel. The Appellate Body, in its report released on 29 November 2010, upheld almost all reasoning given in support of the decision in favour of New Zealand. The Appellate Body upheld the Panel's finding that the 16 measures that are currently discussed, both as a whole and individually, constituted SPS measures within the meaning of Annex A(1) and were covered by the SPS Agreement. The Appellate Body also upheld the panel's finding that the 16 measures were not based on a proper risk assessment and, accordingly, were inconsistent with Articles 5.1 and 5.2 of the SPS Agreement. Thus, by implication, those measures were also inconsistent with Article 2.2 of the SPS Agreement.

The Appellate Body did not agree with the Panel's finding on the issue that Australia's measures, regarding fire blight and ALCM, were inconsistent with Article 5.6 of the SPS Agreement. It is notable here that this ruling of the Appellate Body might create impediment in applying the provisions of section 5.1 of the SPS Agreement. It also reversed the Panel's finding that New Zealand's claims of undue delay, pursuant to Annex C(1)(a) and Article 8 of the SPS Agreement, were outside the Panel's terms of reference. The Appellate Body then completed the legal analysis and found that New Zealand had not established that the 16 measures at issue were inconsistent with Australia's obligations under these provisions of the SPS Agreement.

THE TWO POSSIBLE SOLUTIONS FOR CO-EXISTENCE OF THE WTO RULES AND MEAs

Fundamentally, there are two possible suggestions towards this end. The first one is to amend Article XX of the GATT; and the second one is to make multilateral environmental agreements (MEAs) as an exception to the WTO rules. It is said that both suggestions are not acceptable due to rigidity of the WTO members, economic interests of the Member States and political reasons. It is notable here that the North American Treaty Agreement (NAFTA) has adopted the second one, but this solution might not be acceptable at the bigger body due to the involvement of the economic interests of larger numbers of developed states who, in fact, dominate the WTO. It is evident from the meetings of the WTO that among the Member States, there exist a lot of groupings and each one of them presses its demands as they would, and if they get through, they protect their economic interests. In order to get their proposal approved, they seem to be ready to go to any extent. This state of affair compels us to say that the WTO is highly politicised, there is lack of altruism, collectivism or multilateralism, as no state is ready to accept anything at the cost of their economic interests. It is for this reason that some say that the WTO is a rich countries' club. This is evident from the issue of withdrawal of subsidies given by developed countries on their agricultural produce. The outcome, so far, is that subsidies will continue in coming decades. The United Sates agreed to make a promise to withdraw subsidy from GM cotton in the next thirty years. Every unbiased economist is of the opinion that the practice of the subsidy is not in the interest of developing and least developed countries, where more than seventy percent of the world population lives. However, this figure will increase in future (Ansari, 2008).

In view of this, the authors are of the opinion that the second option, following safety measures contained in the Cartagena Protocol, is a better option. It should be pressed for states to accept it although it might not be acceptable to GMOs producing countries. We should not ignore it only because of this fear. The other solution which the authors subscribe to is that the required risk assessment provisions contained in the SPS Agreement and the Cartagena Protocol should be read together as was ruled by the Appellate Body in the *US – Shrimp*

case. The position was almost the same about the Kyoto Protocol, but it ultimately came into effect after the expected time. It is a different thing that states are agitating their minds to have a better means to fight the problem of global warming (Ansari, 2008). Cases decided by the WTO Panels and the Appellate Body appear to have favoured international trade. Perhaps, it is because they know little about the imperative of conservation of the environment and environmental law made for it. It is for this reason that authors are of the opinion that disputes involving both laws (international free trade law and international environmental law) should be decided by an environmental court having experts in both international trade law and environmental law. This task cannot be given to the UNEP because it is already very much occupied with the task undertaken by it. The United Nations should constitute this court under a global convention. This might not be initially acceptable to developed countries. However, they might ultimately have to succumb to the world opinion in its favour which might take some time.

AGRICULTURAL SUBSIDIES

We have noted that in the field of international trade of agricultural LMOs, the most controversial issue is subsidies given by developed countries on their exports of agricultural produce. They are practicing it for boosting competitiveness of their agricultural produce. This provides an impetus to farmers in these countries to engage with exportable agriculture produce. The European Union countries and the United States are notable among those countries. Efforts are being made by importing courtiers, which are mainly developing and least developed, for getting subsidies abolished so that their agricultural produce may also have international demand, and in turn, their farmers could survive. They have always stressed on abolition of subsidies at all meetings held under the auspices of the WTO, including regular Ministerial Meetings. This is because subsidies affect the livelihoods of their poor farmers. In view of the subsidies and their adverse impacts on farmers and export of their agricultural produce, it is suggested that all agricultural subsidies must immediately be abolished. This is for fostering equity and sustainable development of all farmers in all countries, especially farmers of the developing and least developed countries. This kind of protectionism is not at all warranted in a globalised world; rather, developed countries should think of providing impetus to the agriculture in developing and least developed countries.

It is unethical on the part of biotechnologists to develop LMOs, especially GM crops and wish to market it without conducting satisfactory and reliable lab and field safety testing. It is not wise on their part; and for that matter, on the part of the biotechnology companies and countries, where they have been developed to market LMOs and GM food without guaranteeing their safety (Bisupati, 2005). The authors say this because it has been noticed in many cases. Recently, unsuccessful effort was made by the Government of India in marketing *Bt Brinjal* in 2010. The Central Government of India conducted meetings with government officials and the public in each state, which was attended by right minded biotechnologists and environmental NGOs. For safety concerns, the Indian people and biotechnologists did not support the government's idea of marketing it. It was for this reason that the government had to send it for further lab and field testing. Public participation compelled the British Government to establish the Agricultural and Environmental Biotechnology Commission in 2003 which made public participation with government officials and scientists a condition of precedent before introducing any GM product, living or non-living, into the environment or market, followed by farm scale evaluations (FSEs). It is notable here that FSEs of beet, maize and spring and winter oil seed rape conducted in the United Kingdom revealed that which caused adverse impacts on insect and birds and other similar species (Winickoff et al., 2005; Wilkinson et al., 2003; Firebank et al., 2003). Public participation is now widely accepted as a potent part of the precautionary measures used in ensuring risk assessment for protecting the environment and public health. This marks the constructive public participation in introducing any LMO/GMO and GM Food. After all, if any unsafe stuff is marketed for human consumption, they are going to be affected from that stuff. Scientists can play an important role in the whole process by conducting independent safety researches in order to get to know the safety of any LMOs/GMOs already marketed or proposed to be marketed. Biotechnologists must always think about ensuring the interest of the general public and conservation of the environment; as such, they should give it priority over their personal name and fame and short-term monitory interests. Then only, can they serve the present generation and generations to come, that is, maintaining a sustainable world. In view of this, the authors are of the opinion that NGOs and environmentalists belonging to all related disciplines can play significant constructive roles in this direction (Ansari, 2008).

When LMOs/GMOs are marketed, it should be ensured that other species should also remain in use; because if they are not ensured, there might be irreparable loss to the biodiversity. In view of this, it is suggested that all states must maintain a gene-bank containing genetic materials of all species so that whenever they need to carry out further research on them, they will be available to scientists and technocrats. Although we have the experience of the Cambodian rice species, there were very few varieties in use, while others had vanished. When scientists wanted to conduct a research on the indigenous rice varieties in order to make them more

productive and capable in the adverse environmental conditions, they luckily found genetic materials in the International Rice Research Institute (IRRI) of the Philippines. Otherwise, it would have been a detriment to further biotechnology researches and protecting the interests of the farmers of the country. It would, in turn, also have been loss to the traditional use of different varieties of rice. It is also necessary to emphasize here that the use of LMOs in agriculture must be used in controlled conditions. On the contrary, they might contaminate other similar varieties. For ensuring the safety of other varieties, the idea of an effective buffer zone has to be practiced (Ansari, 2003).

TRADITIONAL KNOWLEDGE

We have noted in the foregoing that biotechnological researches must be in the interest of the public. Among the public's interests, farmers' interests are central. However, we know the story of patenting of *Basmati* rice, *Neem* and the traditional knowledge of farmers (TK) and rural folks. At national and international levels, patent laws are already there. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is there. Before the TRIPs came into being and got a normative value, the Paris Convention for the Protection of Industrial Property and the Bern Convention for the Protection of Literary and Artistic Works were already in existence; although some areas were not covered by these Conventions. In some cases, the standards of protection prescribed were thought as inadequate. So the TRIPS Agreement added a significant number of new and higher standards to these conventions. When TRIPs was signed, developing and least developed countries did not realize that it might go against their economic interests. The World Intellectual Property Organization (WIPO) is doing its best to enforce the rules contained in TRIPs in a flexible way in order to protect the interests of these countries also [http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html, (8 July 2011); Oliva et al., 2005], but it has been a quite debatable legal instrument (Oliva et al., 2005).

It is notable that the role of intellectual property (IP) systems in relation to traditional knowledge (TK) and how to preserve, protect and equitably make use of TK has recently received increasing attention in a range of international policy discussions. These address matters that are diverse as food and agriculture, the environment (notably the conservation of biological diversity, health, including traditional medicines), human rights and indigenous issues and aspects of trade and economic development. According to the WIPO, while the policy issues concerning TK are broad and diverse, the IP issues break down into two key themes: Defensive protection of TK, or measures which ensure that IP rights over TK are not given to parties other than the customary TK holders. These measures have included the amendment of WIPO-administered patent systems. Some countries and communities are also developing TK databases that may be used as an evidence of the prior art to defeat a claim to a patent on such TK, in which the positive protection of TK or the creation of positive rights in TK empowers TK holders to protect and promote their TK. In some countries, *sui generis* legislation has been developed specifically to address the positive protection of TK. Providers and users may also enter into contractual agreements and/or use existing IP systems of protection [http://www.wipo.int/tk/en/tk/ (7 December 2011)]. In order to make it useful to all, it underwent amendments. Even after that, it was considered as favouring the developed countries, which are ahead in conducting biotechnology related researches. Local laws for protection of intellectual property are supposed to be in line with the provisions of the TRIPS. Patenting under the TRIPS cannot override the traditional knowledge of TK. However, if any new species has been developed via gene manipulation, it can be patented by the researcher. The *Basmati* rice case clearly demonstrates this.

It has very well been demonstrated by the World Intellectual Property Organization (WIPO) in these words: "The role of intellectual property (IP) systems in relation to traditional knowledge, and how to preserve, protect and equitably make use of TK, has recently received increasing attention in a range of international policy discussions. These address matters that are diverse as food and agriculture, the environment (notably the conservation of biological diversity, health, including traditional medicines), human rights and indigenous issues and aspects of trade and economic development. While the policy issues concerning TK are broad and diverse, the IP issues are broken down into two key themes-defensive protection of TK, or measures which ensure that IP rights over TK are not given to parties other than the customary TK holders. These measures have included the amendment of WIPO-administered patent systems" [(http://www.wipo.int/tk/en/tk/, (2 January 2011)].

In the *neem* and *basmati rice* cases, we can see the positive and constructive approach which protects the interest of farmers at large. Some countries are also developing TK databases that may be used as an evidence of prior art to defeat a claim to a patent on such TK; in which case, the positive protection of TK, or the creation of positive rights in TK may empower TK holders to protect and promote their TK (Ong, 2008). In some countries, *sui generis* legislation has been developed specifically to address the positive protection of TK. Providers and users may also enter into contractual agreements and/or use existing IP systems of protection (Chambers et al., 2005).

GEOGRAPHICAL INDICATIONS

The goods of a specific geographical origin and its use

are also to be protected in the general interest of the public. They are known as goods of geographical indications (GI). The WIPO has given its meaning and scope in these words: “A geographical indication is a sign used on goods that have a specific geographical origin and possess qualities, reputation or characteristics that are essentially attributable to that place of origin. Most commonly, geographical indications include the names of the places of origin of the goods. Agricultural products typically have qualities that are derived from their place of production and are influenced by specific local factors, such as climate and soil. Whether or not a sign is recognized as a geographical indication is a matter of national law. Geographical indications may be used for a wide variety of products, be it natural, agricultural or manufactured” [http://www.wto.org/english/news_e/news10_e/trip_28oct10_e.htm, (8 January 2011); http:///www.wto.org/english/news_e/trip_ss_27jan11_e.htm (27 January 2011); http://www.wipo.int/geo_indications/en/about.html, (2 January 2011)].

It is notable that in the latest George Larson Goerra Policy Brief no. 3 of November 2010 of the International Centre entitled: “Geographical Indications of *in situ* Conservation and Traditional Knowledge” for Trade and Development (ICTSD), after conducting a study on GI in 31 countries, it was concluded that protection of GI in many countries, mainly in developing and least developed countries, has proven to be essential for conservation of the biodiversity and eradication of poverty among farmers of these countries. It will also promote discussions on CBD and WTO law [http://ictsd.org/i/publications/100736/; http://ictsd.org/downloads/2011/02/larsen_v4.pdf19, (February, 2011)]. It is also notable here that the WTO is now working on making a comprehensive register (GIs) comprising all goods under the geographical indications which are supposed to be completed by the end of March 2011. The register will contain opposing opinions rather than rival documents. This will end future disputes among the Member States over geographical indications. If any innovation via gene manipulation in any of the products is made, it will not be covered under the geographical indication. Thus, the researcher will be entitled to get it patented.

RIGHT TO INFORMATION

Right to information is one of the human rights which are stressed by those who want to get complete information about the food they are consuming or can consume in future. It warrants labeling of food that contains GMOs and supply of milk, milk products and meat of animals fed on genetically modified stuff. Likewise, labeling is required on oil and other such things meant for human and animal consumption. Certain LMOs/GMOs must also carry labeling. Requirement of labeling is mainly stressed by Europeans, Australians and New Zealanders, but as a matter of fact, people in other countries also wish to know about what they are consuming. This right is also justified on the basis of constitutionally guaranteed right to life in almost all countries. European Union has taken utmost precaution about allowing import of GM foods. It allows for imports only after a satisfactory lab testing demonstrates them to be safe. It is because people in the EU countries are very much environmental and health conscious. It is for this reason that labeling of LMOs and GMOs and food containing GMOs is more required there than in other countries. The recent case of high dioxin level in animal feed became a big issue in Germany. People stopped buying eggs, poultry and meat of animals fed with that animal feed, although German scientists claimed that they are safe for human consumption. Other countries have also adopted precautionary measures. The matter was considered to be so serious that EU had to set up an enquiry that showed their consciousness for the environment and human health.

Same sentiments of people living in various countries other than EU countries also go the same. There are some others who are not so particular about such labeling. The authors are of the opinion that even if it is not demanded by the people in a country, there is no harm requiring labeling of the aforementioned stuffs. Rather, it is the corresponding duty of the state to honour the ‘right to information’ and ‘right to life’ of its people and enact appropriate law about such labeling. It is better for people to know about what are they consuming and if it is good for their health. Some states are reluctant about such labeling for economic reasons. The authors feel that this is not a correct approach. Health of their people should be given priority over any other considerations. We can quote here one pertinent example to support this. *Bt. Cotton* is mainly for producing more cotton by protecting cotton crops from insects, but its seeds can also be used for producing edible oil or for producing animal feed. Since there is no safety guarantee from *Bt. Cotton* growers, human consumption of the oil produced from its seed or milk or the meat of animals that have consumed feed containing its seed might be harmful. It is notable that because of this reason only; *Bt. Brinjal* could not be marketed in India (News, 2011; The Hindu, 2011).

PROFIT SHARING

The CBD has provisions for access to genetic material and profit sharing (APS), but there has been persistent injustice in profit sharing between the country that provided the required potential genetic materials and the country that conducted the research. Justice requires that there has to be an amicable profit sharing among them. This is essential, with other things, to support the people

of developing and least developed countries as they have rich biodiversity. It is warranted that the monetary gain received by the exporting country should be spent on the wellbeing of the state; while a portion of it should go to the people who are engaged in preserving/ growing such genetic materials. The Nagoya Protocol of 2010 made under the CBD aims at this, but due to lack of appropriate transparency and accountability provisions in the Protocol, it seems it might not come into force. The authors suggest that these provisions should be brought into the Protocol. The authors further suggest that a database of all plant and animal species of every country should be made in order to track down the source of the genetic material. It will work as an inventory of all species. This will also help in alleviating smuggling of genetic materials.

ETHICAL AND RELIGIOUS ISSUES

Gene manipulation may involve ethical and religious issues also. Producing safe agricultural produce and improved animal species, without impairing the balance in the environment and rights of farmers and other stake holders, are ethical on the part of scientists and technocrats, as it is for the protection of the interests of the public at large. It is also justified by popular religions of the world, especially Islam and Christianity. They do not consider it as interference in the domain of Allah (s.w.t.) – because it is not giving new life, rather it is for improving certain plant and animal species – which is in the interest of the public (In Islam, it is known as *maslalah mursalah*) and is also a necessity (*dharurah*). It is for this reason that OIC decided to augment and provide all supports to biotechnology at the Kuwait Conference. Thus, all technologically advanced Muslim countries, as well as other countries, are boosting research in this direction in accordance with the best of their abilities; but all LMOs have to be supportive to the conservation of the environment which is good for human consumption. These imperatives in Islam are known as *halal* and *tayyeb*. If they are broadly interpreted, they must not adversely affect the environment and must protect human, animal and plant lives and health. Therefore, genetic modification of any plant or animal species to develop diseases for the sake of further research is not acceptable. For example, a transgenic mouse, named *oncomouse*, which could develop cancer cells, was created by the Harvard Medical School. The Harvard researchers had planned to further their research on this mouse. This was considered as an unethical act by a large number of right minded researchers around the world. When the researchers attempted to get this mouse patented, it generated dispute. The matter was also considered by the Canadian Supreme Court in *Harvard College* v. *Canada* (Commissioner of Patent), 2002 SCC 76. The Court ruled that the higher life formed was not patentable because it was not manufactured or a composition of matter within the meaning of the inventor contained in the law. The legal validity of the mouse was considered by the European Patent Office also in 2004. It ruled that it would preclude patents or inventions, that is, 'the publication and exploitation of which will be contrary to *ordre public* or public morality'. It would also exclude patents of 'animal varieties or essentially biological processes…for the production of animals'. The ethical aspect goes the same way with termination seeds, unsafe agricultural produce and other genetically modified plants and animal species. The authors are of the opinion that gene manipulations must be limited only to improving the quality of plant and animal species; otherwise, they might prove to be detrimental to the public. The professional ethics also demand that researches must ensure public interest. As such, they should not conduct research on reproductive cloning, even if it will be done with the intent of reproducing them with improved genes by removing bad genes and or/and adding good genes which seem to be possible if not now, but in future, as it amounts to interference in the domain of Allah (s.w.t). International trade in spurious plant and animal species is wrong ethically, as well as religiously.

In short, all acts of gene manipulation will be acceptable if they are in the public's interest or fall within the premises of necessity. Thus, any research conducted for name and fame or purely for fulfilling economic lust is unethical on the part of the researcher. Likewise, developing any plant or animal species with a predominant sense of exploiting other countries is also an unethical act. There are a number of examples of such acts. Notable among them are: termination seeds and certain Bt. varieties. These acts are unreligious also because religions are for justice, equity and the good of the people of the world. However, no religion prefers individual interests over public interests.

CONCLUSION

Based on the discussions in the foregoing, it can be said that for the sake of ensuring sustainable development and in the interest of the general public around the world, especially in developing and least developed countries, international trade law and environmental law must be made compatible. Otherwise, we might have irreparable environmental damage and a large number of people might be displaced internally and internationally. This also goes with international trade of GMOs, LMOs and foods containing GMOs or their movement from one country to another by way of food aid. It is demanded by the ethical injunctions applicable to biotechnologists that they should work in the public interest rather than for their personal gains, money and fame. This is also applicable to countries that have developed GMOs which is not safe to be introduced in the environment or allowed for human consumption. They cannot opt for exporting them for the sake of mobilising money. This is also warranted by popular religions of the world, especially Islam and

Christianity. Scientists should not engage in cloning activities even though it is justifiable on the ground that clones will not have defective genes if not now but in the future, as giving life is the domain of Allah (s.w.t.). Developed, developing and least developed countries should work together so that benefits from biotechnological breakthroughs should permeate to developing and least developed countries, as the case may be, with a special consideration of profit-sharing with countries from where genetic materials are supplied. There has to be also capacity building efforts by developed and technologically advanced countries via technology transfer and training. It is advisable that individuals and institutions in less technologically advanced, developing and least developed countries should work in collaboration with technologically advanced countries. For this, South-South cooperation can also be considered. There has to be gene-banks and data base in the form of an inventory of all plant and animal species in all countries. Smuggling of genetic materials should be strictly dealt with. In the interest of all countries, it is warranted that a meaningful balance between TRIPS and TK is maintained. It is also required in the interest of both the public and the environment that LMOs, GMOs and food containing GMOs must be properly labeled. These are essential for sustainability of the biodiversity and their use by people of all countries. It is the demand of professional ethics and popular religions, especially Islam and Christianity, that scientists and technocrats should not engage themselves in reproductive cloning. The same logic will go with stem-cell researches if they are predominantly for the good of humanity.

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