

A Study on Strengthening the Laws on Genetically Modified Organisms in Sri Lanka with Special Reference to the Proposed Regulatory Mechanism

J. D. Wimalasiri^{1#} and R. S. Ranasinghe²

¹Faculty of Law, General Sir John Kotelawala Defence University, Ratmalana, Sri Lanka

[#]jithwim@gmail.com

Abstract—The agricultural and fisheries industries have traditionally been supportive of technological innovation, particularly in the field of genetic improvement. For decades, these industries have been mixing naturally the genetic traits of seeds and animals in the search of varieties that are able to express a desired trait. Genetically Modified Organisms (GMO) is a noteworthy step forward in the production of agricultural crops. Although this method is more efficient, a number of scientific evidence manifest the fact that "novel gene combination" may have health and environmental impacts that are not being adequately addressed at present. Thus a proper legal framework should be established to ensure that the quality of the imported and domestically produced GMOs are harmless to the human health and bio diversity of Sri Lanka. Despite the significance of this requirement, proposals for precise legislation are still in discussion stages. Hence, the main objective of this research is to evaluate whether the existing legal framework can be effectively utilised to ensure that the biodiversity and human health of Sri Lanka are not negatively affected by the importation and domestic synthesis of GM seeds and other products. The secondary objectives are to analyse the impact of GMOs to various facets of a country, to analyse the steps taken in the international arena to combat the above mentioned issues, to examine the factors that may be prompting the delay of the enforcement of the said law and to give recommendations to the domestic legal framework in light of international standards. This research is carried in the form of a library based research and a qualitative research design is adopted. Case laws, statutes, conventions are used as primary sources whereas books, journal articles, conference papers, research papers, internet-web related information, newspaper articles and other legal instruments and resolutions of international/ regional institutions are used as secondary sources. The key findings of this research show that the existing laws can be utilized to a considerable extent in fortification of bio diversity and human health in Sri Lanka. Furthermore, this study seeks to propose several additions in light of the precautionary principle to achieve the ends that cannot be accomplished by utilizing existing domestic laws alone.

Keywords— Bio-safety policy, Genetically Modified Organisms (GMO), Living Modified Organisms (LMO), Biotechnology, Human Health

I. INTRODUCTION

"When it comes to owning the seed for collecting royalties, the GMO companies say, 'it's mine'. But when it comes to contamination, cross-pollination, health problems, the response is 'we're not liable.'"

-Vandana Shiva

In the modern world, technological development has been enhanced unprecedentedly. Genetic Modification of plants and other living organisms is one of such developments which has largely buttressed the agricultural arena in producing crops with a number of beneficial features. High yield, higher growth rate, high resistance to pesticides and high resistance to weather conditions are a few of such features. However, scientific evidence have manifested serious adverse effects to the bio diversity and human health due to farming and consumption of GM products (Bakshi, 2003).

Under normal circumstances, a plant or animal can only acquire genetic material from other plants or animals of the same or closely related species. This mechanism does not allow the existence of life forms that are not suitable for the natural conditions (Environmental Foundations Limited, 2001). Application of biotechnology allows selected individual genes to be transferred from one organism into another, also between non-related species. It is therefore one of the methods to introduce novel traits or characteristics into micro-organisms, plants and animals (Plan & Eede, 2010). One such example is the insertion of anti-freezing proteins of fish species into strawberry plants to induce freeze-resistance traits in strawberries (Khammuang, et al., 2005).

Cartagena Protocol on Biosafety of 2000 defines 'Modern Biotechnology' as the application of:

- a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used

in traditional breeding and selection; the same Protocol defines Living Modified Organisms as 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology' (Cartagena Protocol on Biosafety, 2000). The Secretariat of the Convention on Biological Diversity states that LMOs are usually considered to be the same as GMOs (Genetically Modified Organisms) in general usage (CBD Secretariat, 2013).

The ability of GM crops to produce higher and more reliable yield at a cheaper cost than their non-GM counterparts is believed to aid in reducing domestic and international hunger (Angelo, et al., 2013). Americans and Europeans are fortunate in that they have not experienced wide scale hunger in decades. Yet, the improved production and the process of globalization has not marked an end to the scarcity of food provisions in certain developing countries thus rendering the citizens of developing countries the main consumers of GM products (Blaustein, 2008). However, not only of low income countries, but also of high income countries many consumers are unaware of the GM substances that they consume (Tassel, 2009).

According to scientific research, negative effects of cultivation and use of GMOs include allergies, bio pollution, etc. The concept of biosafety refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. It describes efforts to reduce and eliminate the potential risks resulting from modern biotechnology and its products. In the present circumstances an urgent need to establish biosafety measures for Sri Lanka can be observed.

Regulations made under Section 32 of the Food Act No. 26 of 1980; Food (Control of Import, Labelling and Sale of Genetically Modified Foods) Regulations 2006 has set out regulations to be followed in the importation of GMOs to Sri Lanka. Apart from these regulations the only Act which

Makes reference to the terms "genetically modified" (GM) and "living modified" (LM) is the Plant Protection Act.

Other legislation such as Fisheries and Aquatic Resources Act. No 2 of 1996, Water Hyacinth Ordinance Act No, 9 of 1909, Consumer Affairs Authority Act No. 9 of 2003, Animal Disease Act No. 59 of 1986, Fauna and Flora Protection Ordinance No. 2 of 1937 can be interpreted to a certain extent in the protection of human health and bio diversity in this regard. However, all adverse effects of modern bio technological activities are not directly addressed by these laws. The proposal made considering this position, by a Special Committee which included representatives from all relevant ministries is still in its

discussion stages (Ministry of Environment and Natural Resources Colombo, 2005).

Although there remains considerable uncertainty about potential risks associated with modern biotechnology, the possible costs of mitigating or reversing any harm that may occur as a result of the use of modern biotechnology may also prove to be immense, and far-reaching, especially to the government who are ultimately responsible for assuring the health status and food security of the Sri Lankan population (Ministry of Environment and Natural Resources Colombo, 2005).

In this paper, Section II explains the potential threats to Human Life as well as the Bio Diversity of Sri Lanka due to the domestic synthesis, importation and consumption of GMOs in Sri Lanka. Section III analyses the existing legal framework that can be utilised to prevent environmental and health hazards caused by GMOs. Part IV examines the delay of the enforcement of the biosafety laws in Sri Lanka and Section V provides the conclusion and recommendations to the domestic legal framework in light of the examined international standards

II. POTENTIAL THREATS TO HUMAN LIFE AND BIO-DIVERSITY DUE TO GMOs

A. Threats to Human Life

"If you think organic food is expensive, have you priced cancer lately?"

- Joel Salatin

A number of laboratory studies have confirmed that some GM products could cause various negative effects such as extremely toxic contaminants and unknown allergens to human health. (Bakshi, 2003). One such example the Canadian research which successfully identified the presence of pesticides associated with GM foods in maternal, fetal and non-pregnant women's blood (Arisa & Leblanc, 2011). Another study conducted in France using mice revealed that the consumption of GMO maize treated with roundup herbicide (a product of the American agrochemical corporation Monsanto) caused tumours and multiple organ damage, including severe liver and kidney damage (Séralini, et al., 2012).

B. Threats to Bio Diversity

1) Fisheries and Aquatic Resources

The introduction of GMOs into Sri Lanka may not be limited to Genetically Modified Foods and crops. The techniques of genetic engineering had been used by scientists to make a number of new fishes so that they are able to express a desired trait thus being beneficial in the fisheries industry.

Larger size and other desired traits would cause the GM fish to have better performance over their non-GM counterparts. Consumption of larger-sized prey, resistance to various environmental conditions are a few of such features that would cause greater competition that might result in the extinction of the non-GM species (Kapusinski & Hallerman, 1990). Some scientists argue that GM fish species can be created to be sterile, greatly reducing environmental risks that would result from interbreeding in the wild (Fletcher et al., 2001). Achieving 100% sterility, however, is next to impossible. (Logar & Pollock, 2005). Furthermore, the development of transgenic fish species is in its relative infancy and the science examining their potential effects on the natural environment is still emerging. In such circumstances, letting the citizenry and the ecosystem fall into risk is not a prudent decision a State can make.

An attempt by the Ministry of Fisheries and Aquatic Resources to introduce a Tilapia modified by human genes into mountainous streams of Sri Lanka in the year 2000 failed due to protests of environmentalists. These protests were based on scientific research indicating the potential dangerous effects on other species living in the same habitats and the consumers of the fish. Being a voracious and invasive species by nature, genetic modification can aggravate their ability to take over habitats thus creating an imbalance in the ecosystem. (Environmental Foundation Ltd, 2001).

2) Bio

. Sri Lanka's unique biodiversity has a very high global significance. It has been classified by Conservation Pollution

Sri Lanka possesses a very rich wealth of biological diversity, reportedly the richest per unit area of land in the Asian region International (CI) as one of the "biodiversity hot spots" together with the Western Ghats in India based on the number of endemic plants and vertebrates. Therefore, it should be of utmost concern of the government and citizens equally to protect the country's bio diversity.

In Diamond V. Chakrabarty (1980), the United States Supreme Court approved the first patent application exclusively for a living organism. The patented microbe, however, was never developed beyond laboratory use in part because of the ecological uncertainties associated with releasing large quantities of Genetically Engineered Microorganisms into the environment.

Ecological concerns over the release of Herbicide Resistant Crops are twofold. One concern is that the transgenic crops might invade natural habitats if their germination, root growth, resistance to abiotic stresses or dispersal has been enhanced. Secondly, genes

transplanted to the crop for herbicide tolerance might transfer to other plants, thereby spreading herbicide tolerance in ways that are ecologically undesirable. Thirdly, successes of Herbicide Resistance Crops can result in the increased use of herbicides and/or compromise efforts towards incorporating integrated pest management. Fourthly, by building herbicide resistance into a few widely used low toxicity herbicides, the rate of weed resistance is likely to increase requiring the use of more toxic herbicides (Whitman, 2000).

3) Super Weeds

Another concern is that crop plants engineered for herbicide tolerance and weeds will cross-breed, resulting in the transfer of the herbicide resistance genes from the crops into the weeds. These "super weeds" would then be herbicide tolerant as well. Other introduced genes may cross over into non-GM crops planted next to GM crops (Whitman, 2000).

II. EXISTING LEGAL FRAMEWORK ON GMO'S IN SRI LANKA

A National Bio Safety framework was prepared in April 2005. The overall objective of this framework is 'to ensure that the risks likely to be caused by modern biotechnology and its products will be minimized and biodiversity, human health and environment will be protected in a maximum way, regulating the transboundary movements through formulation of relevant policies regulations, technical guidelines and establishment of management bodies and supervisory mechanisms'.

The draft of the Biosafety Act of Sri Lanka is being reviewed at Legal Draftsman's Department at present. Until the said Act comes into force, several legislations already existing in Sri Lanka are utilized to be interpreted in preventing the hazards occurring from the use and planting of GMOs.

The draft Act stipulates that release of LMOs or GMOs should be undertaken in a manner that prevents or reduces risks to biological diversity and human health. It requires any exporter to notify the National Competent Authority in writing prior to the transboundary movement of LMOs/GMOs. It is a legal requirement to provide complete and accurate information of all required particulars in the application. The National Competent Authority, if it is deemed necessary, requires Sectoral Competent Authorities to carry out risk assessment on a case by case basis. The current position on GMOs is governed under several national legislations and international treaties.

Fauna and Flora Protection Ordinance No. 2 of 1937 in its section 37 and 38(b) allows GM animals only for research purposes.

Section 21 of the Animal Disease Act No. 59 of 1986 prohibits the import of animals, animal products, veterinary drugs or veterinary biological products, animal semen or embryo except under the authority of a permit issued by the Controller of Imports and Exports on the recommendation of the Director of Animal Production and Health. Furthermore, Section 17 prohibits The manufacture of any veterinary drug or veterinary biological product in Sri Lanka except under the authority of a licence issued on that behalf by the Director of Animal Production and Health. Effective interpretation of this Section can be used to prevent the import and domestic creation of Genetically Modified versions of the above mentioned components.

Currently, discussions are being held pertaining to the development of Part V Animals Act No.29 of 1958 P, which deals with providing measures for the improvement of the breed of animals, to accommodate control of introducing breeding materials, including GMOs and LMOs, and the need to provide statutory status to the "National Animal Breeding Policy Committee" (Environmental Foundation Ltd, 2001).

Plant Protection Act No. 35 of 1999 prevents the introduction of any organism harmful or injurious to plants or destructive to plants in Sri Lanka. When considering Section 15, the provisions of Plant Protection Act can be used not only to prevent the entry of plants and animals, but also to prevent the import of any GM plasmid that could be potentially harmful to plants.

Consumer Affairs Authority Act No. 9 of 2003 in its Section 10(1)(a) issues general directions to manufacturers or traders to label the goods in respect of price marking, packaging, sale or manufacture of the goods. Since all genetic modifications relate to the manufacture of a good, this Section can be used to label all goods containing GMOs.

The Food Act No. 26 of 1980 amended by Act No. 20 of 1991 in its Section 2 prohibits the manufacture, import, sale or distribution of any food that, inter alia, is unfit for human consumption, is adulterated or is in contravention of the provisions of this Act or any regulation made there under. It is unlikely that the first section could be used any time soon because there is yet no concrete scientific information to prove that such food is unfit for human consumption. However, GMFs could be banned under Sec.2 (d), which refers to adulterated food. "Adulterated" is defined as "the addition of a substance as an ingredient in the preparation for food or subtraction of any constituent from such food or subjection of such food to any other process or any other treatment so as to- render

the food injurious to health, or affect its character, value, composition, merit or safety. Under the third section, the Department of Health has already promulgated regulations to restrict and in some cases ban the entry of GMFs. The Food Act also has provisions relating to the labelling of foods. Section 3(1) says that "no person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading, deceptive or likely to create an erroneous impression, regarding its character, value, quality, composition, merit or safety.

Water Hyacinth Ordinance Act No, 9 of 1909 provide effective means to prevent the entry into or keep in one's possession and GM plants or parts that can be named in a gazette regulation.

Section 30 of the Fisheries and Aquatic Resources Act. No 2 of 1996 empowers the Minister to make regulations in consultation with Minister or Trade, having regard of the need to protect the aquatic resources of Sri Lanka, to prohibit or regulate the export from or import into, Sri Lanka of any species of fish including live fish or any eggs, roe or spawn or any products prepared thereof for a period of time. This Section can be interpreted to mean the power to prohibit importation of GM fish species that might have a negative effect on the human health and bio diversity. Furthermore, Section 35 empowers the Director of Fisheries and Aquatic Resources to permit local fishing boats to be used for research operations, experimental fishing or scientific investigations relating to fish and aquatic resources in Sri Lankan waters. He is further empowered to attach conditions as he may think fit regarding the conduct of such research operations, experimental fishing or scientific investigations. This Section can be interpreted to prevent scientific research focused on creation of harmful GM species in Sri Lanka.

In view of the above Statutory Provisions, it is evident that they can be interpreted to minimise potential harmful effects to a certain extent. However, the absence of a statute which plainly addresses the Biosafety issues can leave a loophole through which an astute importer or creator of GMOs can make his way to cause danger to human health and bio diversity of Sri Lanka solely for personal economic gains.

III. INTERNATIONAL MECHANISMS RELEVANT TO SRI LANKA PERTAINING TO GMOS

Cartagena Protocol on Biosafety recognizes the importance of establishing credible and effective safeguards for LMOs to maximize the benefits of modern biotechnology while minimizing its potential risks. Sri Lanka signed this Protocol in 2000 and entered into force

in 2004. The National Bio Safety Framework of Sri Lanka is a result of this ratification.

The Cartagena Protocol is an addition to the Convention on Biological Diversity. As a protocol, it is more detailed and more importantly, more binding. The Protocol's main aim is to regulate the trans-boundary movement of living modified organisms. Article 2 of the protocol states that it seeks to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements (Article 2).

Furthermore, Principle 15 of the Rio Declaration states "In order to protect the environment, a precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." With this view, the Protocol embodies two important principles: the precautionary principle and the advanced informed agreement principle. The precautionary principle says that a State can take certain precautionary measures without having to back these up with scientific evidence. At first glance, it appears that this principle confers a privilege on technically disadvantaged countries. However, the Protocol goes one step further by saying that lack of scientific evidence should not be used as an excuse for avoiding taking measures to prevent environmental degradation. The other principle governs when a party may go ahead with the movement of such LMOs. Advanced informed agreement means exactly that - the party into which the LMOs are to be brought need to know well in advance the nature of the organism, the possible risks involved. Risk assessments - government decide whether or not to import LMOs on the basis of risk assessments, which have to be undertaken in a scientific manner based on recognized risk assessment techniques. However, where there is a lack of relevant information and knowledge, a country can apply the precautionary approach. Under the clearing-house mechanism of the Convention, the protocol has established a Biosafety Clearing-House. This aims to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with LMOs and to assist Parties to implement the Protocol.

IV. THE DELAY OF THE ENFORCEMENT OF THE PROPOSED LAWS

The Food Administration Unit of the Ministry of Health of Sri Lanka has taken steps to regulate GM food related

issues in the year 2001. One major step of this program was to completely ban the import of certain foods without a certificate from an accredited laboratory ensuring that the foods are free of any GMO. However, Sri Lanka revoked the restriction followed by a series of questions raised by the World Trade Organisation whether Sri Lanka had sufficient evidence to prove that GM foods were unsafe (Environmental Foundation Ltd, 2001). State parties to the Sanitary-Phytosanitary agreement are allowed to impose restrictions on the import of products by providing evidence that such products may be cause danger to human health or biodiversity of a country. Article 5 of the agreement provides that these restrictions must be backed with sufficient scientific evidence to justify their imposition (Agreement on the Application of Sanitary and Phytosanitary Measures, 1995). However, Sri Lanka, as a developing country is not barred from applying the "precautionary principle" embodied in Principle 15 of the Rio Declaration. This principle forms the basis for the Cartagena Protocol on Biodiversity, which states that developing countries may enforce this principle to safeguard themselves from GMOs. Therefore WTO involvement in this ban cannot be justified and that it cannot become involved in this action of the Sri Lankan Government, which was totally taken to protect its consumers from possible negative impacts. Furthermore, Sri Lanka has reportedly faced threats from the US Trade Secretary, who criticised the regulation. It should be noted that the unwarranted interference of International Organizations in matters related to the sovereignty of Sri Lanka is extremely inappropriate (Environmental Foundation Ltd, 2001).

CONCLUSION

Modern Biotechnology being one of revolutionary discoveries of the world has created vast developments in many industries. However, the potential threats of such shall not overlooked.

Despite the lack of scientific evidence to clearly establish the exact threats of GMO, Sri Lanka has to adopt the precautionary principle following Principle 15 of the Rio Declaration to ensure the protection of bio diversity and human health of Sri Lanka. However, According to the study done in 2010 on 'Consumer Attitudes towards Labelling of GM food in Sri Lanka', it was revealed that most of the Sri Lankan consumers are not aware of GM foods, and yet perceive GM foods to be risky to human health. (Senarath & Karunagoda, 2012). Given the serious health and environmental hazards caused by GMOs it is high time that Sri Lanka implemented projects to enhance the biosafety framework. However, draft Act conscripted over 12 years ago is still in its discussion stages. Even though existing legislation concerning food

and biodiversity facets can be utilised in prohibiting harmful activities, a strong legal framework is necessary in this regard. Among international legislation Sri Lanka has followed Cartagena Protocol as well as Rio Declaration on Bio Diversity to draft required the biosafety framework and the draft Act. Finally it can be stated that Sri Lanka is long overdue with a bio safety law through which the country's human health and bio diversity can be protected against harmful effects of the domestic synthesis and importation of Genetically Modified Organisms

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Jithmi Wimalasiri is a final year undergraduate at the Faculty of Law, General Sir John Kotelawala Defence University. Her research interests include Environmental law, Human Rights Law, Labour Law and Commercial Law.



Rushitha Ranasinghe is a final year undergraduate at the Faculty of Law, General Sir John Kotelawala Defence University, Ratmalana. Her research interests include Environmental Law, Human Rights Law, Company Law and Commercial Law.