Legal framework with respect to Biosafety in Sri Lanka

R.H.M.P. Abeykoon

Background

The United Nations Convention was instituted by the entire world community including Sri Lanka as it was realized that biodiversity is being threatened due to the development activities taking place very fast all over the world. This convention was instituted with the objective of biodiversity conservation, sustainable use of the components of biodiversity, access to genetic resources and for reasonable, equitable and lawful sharing of the resulting benefits.

Sri Lanka signed this convention in 1992 and became a ratified party in 1994, a country becoming party to an international convention is bound to act according to the agreements tagged down by the convention, within the principles of the local institutions as well as the legal framework.

Biosafety is one of the important factors embodied in the biodiversity convention. Here attention has been drawn to possible harmful effects of the products of modern biotechnology on human health and environment. At the same time it has been accepted that modern biotechnology has an immense potential to enhance the benefits for humans. In this respect attention has been drawn also to the importance of food production, agriculture, health, facilities etc.

Clause 8 of the biodiversity convention has put forward the facts to be considered when *in-situ* conservation of biodiversity is carried out. Clause 8(g) of the Convention has pointed out the necessity to institute procedures for the regulation and arrangement for control of possible adverse effects on biodiversity conservation, sustainable use of biodiversity, conservation, and on human health of using genetically modified organisms produced through modern biotechnology and releasing them.

Cartagena Protocol on Biosafety

Cartagena Protocol on Biosafety was instituted on 29th January 2000 as an outcome of prolonged discussion and arguments between the parties to the biodiversity convention as well as all the relevant governmental, non-governmental organizations and community groups. It was instituted as a supplementary protocol to the biodiversity convention. This Protocol was instituted based on the exchange of genetically modified organisms and their use and handling while at the same time providing sufficient protection to biodiversity conservation, its sustainable use and human health.

The clauses 2.1 and 2.2 of the Cartagena Protocol states that the parties should certify that adequate national principles, laws and administrative procedures have been instituted to prevent or minimize the possible effects on biodiversity or human health when carrying out activities such as handling, transporting, exchanging, and releasing of genetically modified organisms.

Sri lanka signed this Protocol in 2000, and is a party to it. Therefore Sri Lanka should adopt the existing national principles, laws and administrative procedures so that Sri Lanka will acquire the capability to abide by the Cartagena Protocol as relevant to biosafety. Here it is necessary to identify a focal point in order to coordinate with Cartagena Protocol all activities relevant to biosafety. It is also necessary to identify the competent authorities for activities such as risk assessment, and monitoring with respect to the various groups of organisms that have been genetically modified. The Ministry which handles environmental affairs acts as the focal point institution. Department of Agriculture, Department of Marine and Aquatic Resources, Department of Health, Department of Wildlife Conservation and Department of Animal Welfare and Health have been identified as the competent authorities.

The present background policy and legal aspects as relevant to biodiversity conservation in Sri Lanka

The national policy regarding biosafety

The formulation of the national policy regarding biosafety, and obtaining the ministry approval for it in 2005, can be regarded as one of the steps that Sri Lanka has taken to implement the binding obligations regarding biosafety in the Cartagena Protocol.

The national policy regarding biosafety reconfirms the commitment of the government to ensure adequate security based on the Precautionary Principles and within a sustainable development plan when using modern biotechnology for the benefit to the present and future generations. Only the six main objectives of the policy are given below so as to be kept informed of the content of the policy.

1. Implementing the biosafety step in order to ensure the prevention of any adverse effect on health of the population, the environment, and biodiversity.

2. Ensuring the regulation and management in an effective manner the genetically modified organisms or food nutrients obtained from them, and any products prepared from them which are likely to be imported to Sri Lanka in keeping with an advance informed agreement as directed by the Precautionary Principle.

3. The regulation and management of any locally produced genetically modified organisms, or food nutrients obtained from them and products prepared from them.

4. Promoting the dissemination of knowledge regarding the use of modern biotechnology in a safe manner and its potential adverse impacts.

5. Development and adaptation of modern biotechnology while ensuring biosafety, and the bioethical expectations.

6. Developing the institutional framework to take decisions relevant to the subject of biosafety at the national level, and for supervision of research and development for international coorporation.

According to the 1st, 2nd and 3rd objectives stated above, the regulation and management of the

genetically modified organisms, food and nutrients obtained from them, whether they are imported to Sri Lanka or produced in Sri Lanka is possible. Here national laws and regulations are necessary. For this purpose provisions have been made available through laws and acts which are implemented under the supervision of various competent authorities mentioned above in the brief introduction. These are given below for your information.

The current legal framework regarding biosafety in Sri Lanka

1. The rules and regulations with respect to the regulation and management of food and products from genetically modified organisms are given in clause 32 of the Food Act Number 26 of 1980. The gazette notification bearing number 1456/22 and dated 2006.08.03 which has been made by the Minister of Health Security and Nutrition, after consultation with the Food Advisory Committee has given instructions regarding the control of import, labelling and sale of genetically modified food. Instruction number 2 states that no person should import, store, transport, distribute, sell or present for sellng purposes any genetically modified organisms; food produced from genetically modified organisms or food containing constituents obtained from genetically modified organisms as a food meant for human consumption without the approval of the main food authority. According to the instructions numbered 6 and 7, the approval for the use of genetically modified food and products will be given only after obtaining a scientific risk assessment report from a technical evaluation committee, and on the recommendations of this report. Also here the relevent regulations regarding the appointment of the technical evaluation committee on the recommendation of the advisory committee for scientific risk assessment and for the cost to belevied, apparels to be used have been clearly stated.

2. The Minister has been provided with the provisions to formulate the regulations by clause 12 of the Plant Protection Act Number 35 of 1999. The subjects for which provisions are available to make these regulations are given in clause 12 (2). It is possible to formulate regulations related to the import of plants, plant products and living organisms as indicated in the clause 12 (2). It is possible to use these provisions regarding genetically modified organisms. These regulations should be formulated as relevant, to be applied for the genetically modified organisms.

3. It is possible to apply clause 3 of the (revised) Animal Food Act Number 15 of 2016 for the regulation of the import of any food for animals. Here again these regulations should be formulated as relevant to be applied for the genetically modified organisms.

4. For this purpose it is possible to use clauses 37 and 38 of the Wild Animals and Plant Protection Act. The regulation of the import of mammals, birds, reptiles, amphibians, fishes and invertebrates is done by clause 37. It is not allowed to import animals without a licence to do so. Here again regulations should be formulated as relevant to be applied for the genetically modified organisms.

5. It is possible to regulate by clause 10(1) of the Consumer Affairs Authority Act the producers and the sellers who produce anything for consumption; who produce the finished product, package it or sell it.

6. Clause 30 of the Fisheries and Water Resources Act Number 2 of 1996 indicates that it is possible to enact regulations to regulate the import of fish. Here again regulations should be adapted as relevant to be applied for genetically modified organisms. Because the above mentioned acts do not cover all the requirements regarding biosafety, the new Biosafety Act and regulations have been drafted with the objective

of regulating and monitoring the national production, import and final use of genetically modified organisms using modern biotechnology. Information contained in the clauses of the Biosafety Act and regulations are yet in the draft stage. However given below is a summary of the proposed activities in the regulations.

Here research and development activities associated with genetically modified organisms conducted by government institutions, universities, government industries, international institutions, private institutions, non governmental institutions are regulated. The draft of the Biosafety Act has provided the powers pertaining to the risk assessment of the possible adverse effects of genetically modified organisms on biodiversity conservation, sustainable use and on human health.

In the draft Biosafety Act provisions relevant to the following are included.

i. The approving institution, its responsibilities and duties
ii. The methodology of granting approval
iii. The methodology for monitoring
iv. Powers for putting the Act into effect
v. Powers relevant to formulating regulations

The draft Biosafety Act has been prepared with the objective of regulating the following activities

i. The research and development activities in the laboratories associated with genetically modified organisms.
ii. Field studies conducted under safe conditions
iii. Introduction to the environment
iv. The impact and release to the environment of genetically modified organisms which have been produced for research, food and for the production of animal feed
v. Export
vi. Exchange of genetically modified organisms between institutions

The draft Act does not regulate the genetically modified materials used as human or animal food not possessing the ability to germinate or not having the capability to produce offspring, research studies carried out in the laboratories of government institution, research work carried out without commercial objectives.

Given below are the procedures that should be followed according to this draft Act and draft regulations

Any person intending to carry out research on genetically modified organisms, import them, use them, or want to release them to the environment etc. should make an application using the attachment of the Act to the local institution that has been authorised by the Act. The focal institution will direct these applications to the institution competent in the relevant subject. Prior to granting approval, the institutions with the relevant competencies should carryout a risk assessment with respect to the likely adverse effects on biodiversity conservation, sustainable use and on biodiversity, by the genetically modified organisms due to the relevant activity being applied to organisms to be approved. Risk assessment report should include the method of exchange of the genetically modified organisms, their use, the validity of the information submitted by the applicant, the risk and the recommendations to overcome the risks. The draft regulations indicate that in order to make decisions regarding the genetically modified organisms it is necessary to get the views of the public also, in addition to these recommendations. The recommendation of the risk assessment report should be forwarded to the advisory committee appointed in accordance with the provisions of the public opinion Act. The advisory committee after considering all these facts, should give a report stating whether the application is recommended or rejected giving reasons. The decision to grant approval or rejection is determined accordingly. There is also provision to appeal if the application is rejected.

Mrs. R.H.M.P. Abeykoon
Director (Biodiversity)
Ministry of Environment
pathma66a@gmail.com
0714442902