The National Biosafety Project

Shanaka Gunawardena

Sri Lanka possesses a wealth of biological diversity. The country is classified as one of the global "biodiversity hot spots" based on its hosting a large number of endemic plants and vertebrates. Sri Lanka depends heavily on its biological resources to sustain its economy, making it very important to take note of any threats to biodiversity. The country has adopted a proactive approach to formulating environmental policy, and has been one of the first countries to ratify the Convention on Biological Diversity (CBD) in 1994.
Sri Lanka also ratified the Cartagena Protocol on Biosafety (CPB) in 2004, which aims to address the safe transfer, handling, and use of living modified organisms (LMOs) also known as genetically modified organisms (GMOs).

The Government of Sri Lanka has been taking several steps to ensure the safe use of LMOs. Recognizing the need for ensuring adequate levels of protection in the safe use of modern biotechnology, the Biodiversity Secretariat of the Ministry which is assigned the subject of environment, and acting as the national focal point for the CBD and CPB, formulated the National Biosafety Framework (NBF) and the National Policy on Biosafety. Both these documents were approved by the cabinet of ministers in 2005. Additionally, the national focal point drafted the Biosafety Act in 2014; a law to deal with the products of modern biotechnology.
Nevertheless, implementation of the NBF requires sufficient capacity in many aspects including regulations, risk assessment, detection, and awareness on the products of modern biotechnology. Therefore, there was an urgent need to build Sri Lanka's capacity to make greater use of the benefits of LMOs in a safe and sustainable manner.

Fig. 01 : Stakeholder consultative workshop for the drafts of the Biosafety Master Plan, Biosafety Regulations and the Manual on Administrative and Operational Procedure for Biosafety - February 2019

Fig. 02 : Stakeholder consultative workshop to discuss risk assessment guidelines for living modified organisms (LMOs) with technical support from Biotech Consortium India Limited (BCIL) and National Science Foundation (NSF) - September 2019

Understanding this requirement of building the capacity of Sri Lanka to establish biosafety in the country, the national focal point for biosafety partnered with the Food and Agriculture Organization of the United Nations for technical support, and initiated the National Biosafety Project (the implementation of the National Biosafety Framework in accordance with the Cartagena Protocol on Biosafety) in 2017. This ongoing 4-year project is funded by the Global Environment Facility (GEF), an international funding entity helping to tackle our planet's most pressing environmental problems.

The objective of the Biosafety Project is to strengthen the regulatory, institutional and technical capacities for the effective implementation of the NBF in conformity with the Cartagena Protocol on Biosafety. Component 1 of this project focuses on strengthening policy and institutional and regulatory

Fig. 03 : The national laboratories were assessed for their suitability to be upgraded to conduct regulatory testing of LMOs in Sri Lanka – May 2019

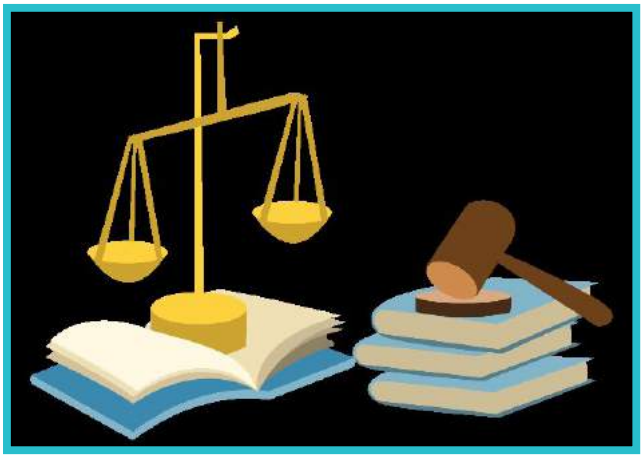
(i) National Plant Quarantine Services (NPQS), (ii) Government Analysist's Department, (iii) Sri Lanka Customs, (iv) Industrial Technology Institute (ITI), (v) Agricultural Biotechnology Centre (AgBC) - University of Peradeniya, and (vi) Institute of Biochemistry, Molecular Biology & Biotechnology (IBMBB).

Fig. 04 : Focus group discussion with vegetable farmers to assess their understanding on biotechnology, LMOs and biosafety - August 2018

frameworks for biosafety. Component 2 aims to enhance the system for risk assessment, risk management and risk communication. Component 3 focuses on developing technical capacity for the detection and identification of LMOs. Component 4 focuses on supporting targeted education and outreach campaigns to raise awareness about biosafety and enhance public participation in decision-making.

The success of the project is a result of effective technical support provided by FAO through national and international consultants as well as several implementing partners. The Biotech Consortium India Limited (BCIL), New Delhi, India is technically supporting components 1, 2 and 3. The Agriculture Biotechnology Center (AgBC) of the University of Peradeniya is technically supporting component 3 as well as preparing curriculum and educational material on biosafety for secondary and tertiary level education. The National Science Foundation (NSF) is technically supporting component 2 and the development of awareness material for dissemination of knowledge in biosafety among several stakeholder groups. The project has achieved many milestones throughout the past few years in all four components of the project. While it is essential to have an effective regulatory system to implement biosafety in the country, it is also Sri Lanka's national obligation as a signatory to the Cartagena Protocol on Biosafety. The most significant achievement towards strengthening the regulatory system of biosafety in Sri Lanka was the drafting of the Biosafety Act. The draft Biosafety Act outlines the regulatory process of the country identifying key role players and their responsibilities. This Act, which is the first law drafted specially to deal with LMOs in the country, outlines the roles of the national competent authority, sectoral competent authorities and other decision-making bodies to ensure that the LMOs are approved for use only if they are safe to the environment and human health. Since the Biosafety Act was drafted in 2014, the project revised the draft to improve its applicability, and moved it towards enactment. Also the Biosafety Regulations, the Biosafety Master Plan and the Manual on Administrative and Operational Procedure for Biosafety were drafted under the project. This work was technically supported by the international consultant, Dr. Ranjini Warrier from India and national consultants, Dr. Ananda Jayalal from the Ministry of Health, and Mr. Anandalal Nanayakkara (Attorney-at-Law). Under the first component of the project, a dedicated website for biosafety titled "Sri Lanka Biosafety Clearing House (BCH)" was established. The work on BCH was technically supported by BCIL and the national consultant Dr. Maheshi Atapattu.

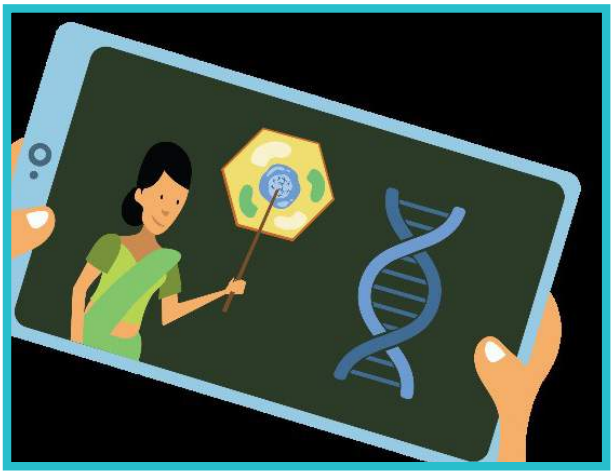
Article 15 of the CPB is about risk assessment of LMOs. This important element is identified in the draft Biosafety Act as a regulatory requirement so that the potential adverse effects of LMOs can be identified prior to their use. Thus, it is essential that Sri Lanka has the expertise to conduct risk assessment of LMOs in a scientifically sound manner. In order to strengthen this capacity in Sri Lanka, the project drafted the guidelines pertaining to risk assessment of LMOs with technical support from BCIL and NSF. They are (i) Guidelines for the safe use of LMOs in the lab, (ii) Guidelines for the environmental risk assessment of LM plants, (iii) Guidelines for the conduct of confined field



1. Strengthening policy and institutional and regulatory frameworks for biosafety

2. Enhancing the system for risk assessment, risk management and risk communication (i)

3. Developing technical capacity for the detection and identification of LMOs



4. Knowledge development, public awareness, education and participation

trials of LM plants, (iv) Guidelines for the safety assessment of foods derived from LM plants, (v) Guidelines for the testing of genetically modified mosquitoes, (vi) Guidelines for the institutional biosafety committees, and (vii) The risk analysis framework. Further, the project is planning to train relevant individuals to conduct risk assessment of LMOs. Some of these trainees will be obtaining foreign training to ensure that they are aware of the international best practices in this area.

Although LMOs are different from their non-LMO counterparts at the molecular level, they appear similar to each other. Therefore, it is important that Sri Lanka has the capacity to detect and identify the LMOs using the necessary tools and techniques. This requires molecular testing laboratories with suitable equipment and human resources in the country. The project visited and assessed several national laboratories to check if they have the prerequisite infrastructure which could be upgraded to conduct regulatory testing of LMOs. This activity was carried out with technical support from BCIL and AgBC. The assessed laboratories are

National Plant Quarantine Services (NPQS),
(ii) Industrial Technology Institute (ITI), (iii) Agriculture Biotechnology Centre (AgBC), University of Peradeniya,
(iv) Sri Lanka Customs,
(v) Government Analyst's Department (GAD) and
(vi) Institute of Biochemistry, Molecular Biology & Biotechnology (IBMBB), University of Colombo.
The assessment criteria included
(i) availability of dedicated space for LMO testing,
(ii) having competent personnel,
(iii) accessibility by users,

(iv) mandate of the organization,
(v) experience in regulatory testing procedures,
(vi) accreditation status and
(vii) willingness to work in this area.
Based on these criteria, NPQS and ITI were selected to be upgraded as national testing laboratories and the AgBC as the national reference laboratory. Additionally, GAD will be upgraded with capacity to test for LMOs at the protein level (through ELISA) and Sri Lanka Customs will be upgraded with capacity to conduct quick detection (through lateral flow strips).
Under the third component, the project conducted the first training workshop for LMO testing at the AgBC in May 2019. There will be more training workshops for LMO testing including foreign training organized through the National Biosafety Project.

Public awareness on biosafety is an integral part of the implementation strategy of the NBF in Sri Lanka. Participation of the general public is part of decision making when it comes to releasing LMOs into the environment or for human consumption. Article 23 of the Cartagena Protocol mentions "consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public." Therefore, it is important that the public is informed with relevant information about LMOs.

Whether people prefer to use LMOs or to avoid them, is a personal choice. However, misinformation and misconception about LMOs may lead to dire consequences in decision making. Therefore, it is important that the public is well aware about modern biotechnology, its products and biosafety. Especially when it comes to approval of an LMO in the country, it is crucial that people participate in informed decision-making. Thus, knowledge development and awareness on biosafety among all stakeholder groups including the public is essential towards successful implementation of the NBF in Sri Lanka.

As the first awareness activity, the project organized a media conference to make the public aware about the project and biosafety related to Sri Lanka.
To determine the level of understanding on LMOs and biosafety among several stakeholder groups, the project conducted a baseline survey through focus group discussions, key informant interviews and a questionnaire. The data collected in this survey indicated that there were many misunderstandings and misconceptions among some individuals of the public. The information collected through this survey is being utilized by the international consultant Dr Mahaletchumy Arujanan for awareness and outreach, in order to prepare the biosafety communication strategy for Sri Lanka.

Under component 4, the project is developing curricula and course material to integrate biosafety into secondary and tertiary education levels in Sri Lanka. This work is technically supported by the AgBC, which is working closely with the National Institute of Education and other relevant entities towards this task. The project has developed several awareness material in all three local languages to disseminate knowledge on biosafety among several stakeholder groups.
The NSF, which is a network of experts in biotechnology and other scientific fields, is providing technical support to this activity. The project initiated the publication of a biannual and trilingual newsletter on biosafety, and has released three issues up to now. The biosafety awareness activities that were initiated by the project will continue across many stakeholder groups to ensure that everyone has sufficient knowledge in biotechnology, modern biotechnology and biosafety to make informed decisions.
The progress of the National Biosafety Project is a result of the commitment of all the implementing partners, consultants, stakeholders and others who have contributed in many ways. The project team is appreciative of the support provided by everyone towards the successful implementation of the project.
Once the National Biosafety Project achieves its objective, Sri Lanka will have sufficient capacity to make greater use of the benefits of modern biotechnology in a safe and sustainable manner.

Mr. Shanaka Gunawardena
Project Manager - National Biosafety Project
Food and Agriculture Organization of the United Nations
shanaka.gunawardena@fao.org
0775780422