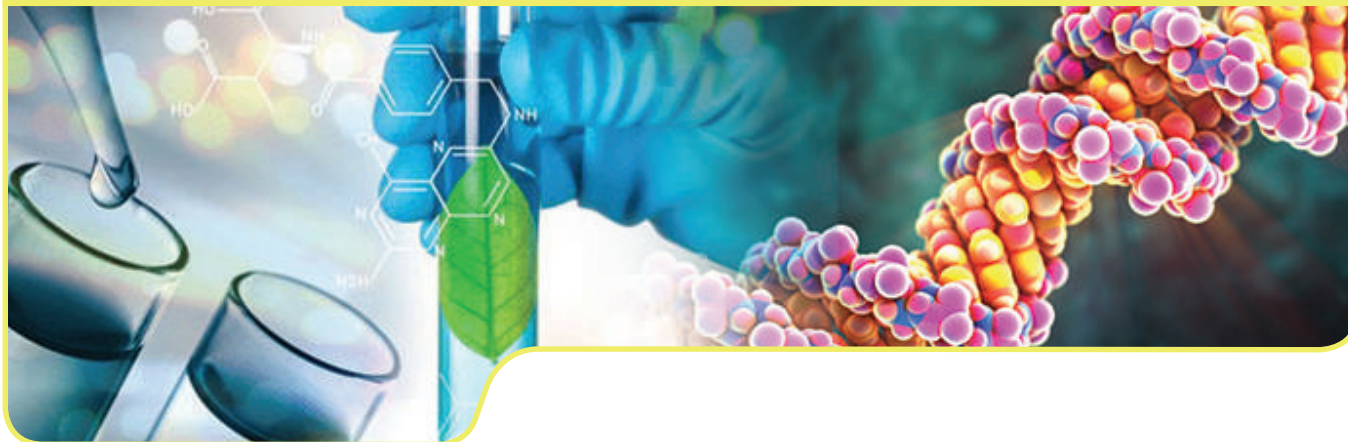


## Safety First: Are we ready?

Prof. Pradeepa C. G. Bandaranayake



Crop and animal production needs to be increased locally and globally to assure food and nutritional security of the growing population while reducing its impact on the environment. Advancements in biotechnological tools over the last three decades have revolutionized crop and animal improvement programs. It has broadened the agricultural research area, bringing in new opportunities to develop novel varieties by transgenic or cisgenic approaches and deletion of

detrimental traits or the addition of significant characters with RNA-guided genome editing technology (Figure 01). Further, advances in genome sequencing give access to the large and complex genomes of domesticated species and their wild relatives, helping to identify a wide spectrum of genetic variation and association of genetic diversity with diverse agronomic phenotypes.

Nevertheless, like any other technology, modern biotechnology is also not completely risk-free.

Considering the rapid development and commercialization of biotechnology and its products including living modified organisms (LMOs), recognition of the potential contribution that biotechnology can make to improving human well-being, and uncertainties regarding potential risks of LMOs on biodiversity and human health, international governments came together to negotiate a treaty to address issues of concern including mechanisms to address the concerns (Figure 02

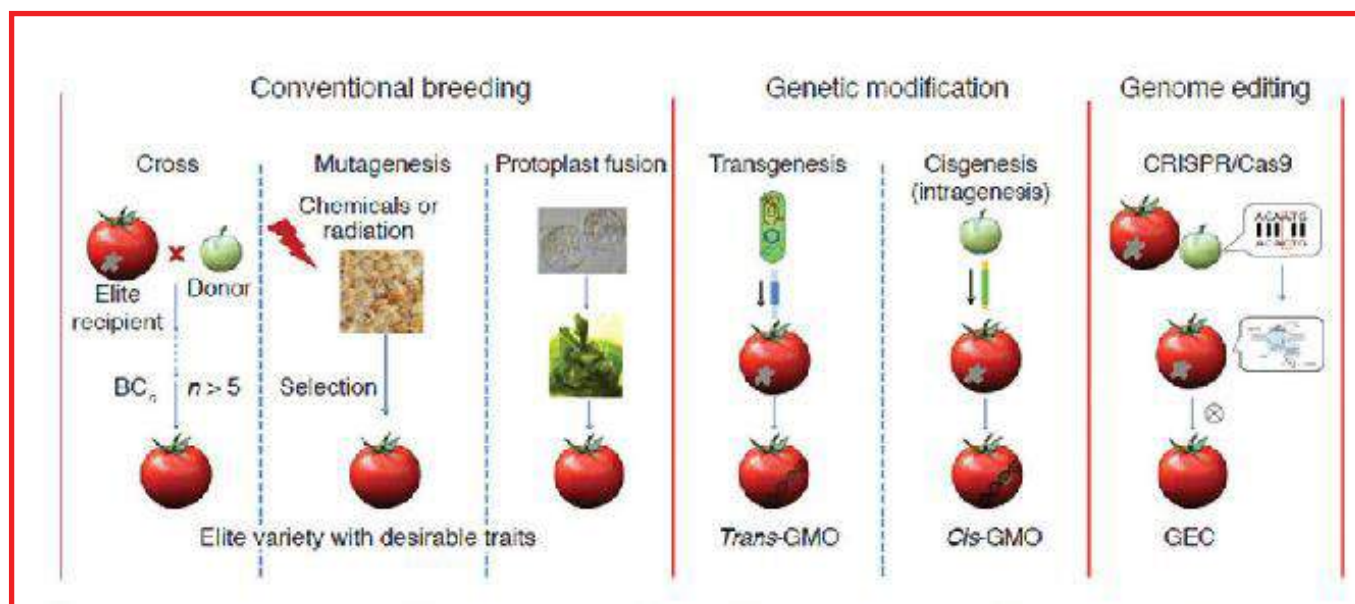
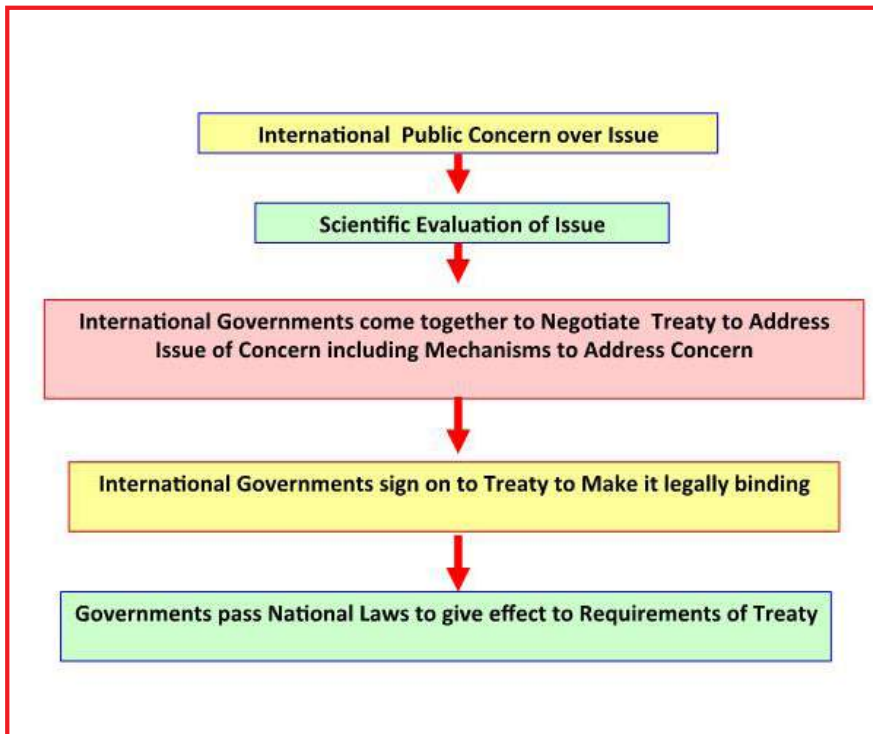


Fig. 1 : Comparison of Conventional breeding, Genetic modifications and Genome editing (From Huang S, Weigel D, Beachy RN, Li J (2016) *Nature Genetics*, 48, 109)



**Fig. 2 : How does an international treaty work?**

shows how does an international treaty works). The Convention on Biological Diversity (CBD) adopted a supplementary agreement to the Convention known as the Cartagena Protocol on Biosafety (CPB). This Protocol entered into force on 11<sup>th</sup> September 2003 and currently, 172 parties have signed the Protocol. Sri Lanka signed the CPB on 24 May 2000 and ratified it on 28<sup>th</sup> April 2004. As a signatory to the CBD and CPB, Sri Lanka is obliged to implement the articles of the CPB and develop its own national regulatory framework for the safe transfer, handling, use, and release of LMOs.

As defined in the CBP, the objectives of the Protocol are to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling, and use of LMOs, often referred to as genetically modified organisms (GMOs), 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.

Recognizing the need for ensuring the regulation of biotechnology research and development activities, the Biodiversity Secretariat of Sri Lanka implemented the National Biosafety Framework Development Project in 2005, which led to the formulation of the National Biosafety Framework (NBF) in 2005. As part of the project, a National Policy on Biosafety was prepared to renew the commitment of the government to ensure adequate levels of protection in the safe use of modern biotechnology based on the precautionary principle, within the overall framework of sustainable development for the benefit of present and future generations. The Cabinet of Ministers approved the Policy in 2005.

The NBF is a system of legal, technical, and administrative mechanisms established under the MoEWR for implementation of the articles of the CPB. The National Policy on Biosafety (NPB) is an important element of the NBF and provides for safe application of modern biotechnology. The NPB covers, the need for a national policy for Sri Lanka, policy objectives, policy principles, and policy statements (Table 01). Nevertheless, NPB does not include policy strategies.

The draft Biosafety Act on the other hand clearly defined the approving authority (its composition, powers, and duties), the procedure for granting approval, monitoring mechanism and powers, enforcement powers, emergency powers, offenses and related aspects, and the powers to make regulations to enforce the provisions of the Act. Whereas the draft regulations include, the procedure for review of applications and decision making, risk analysis process, terms and conditions of permits issued, procedures for monitoring and supervision, procedures for export, and procedure for handling appeals.

Nevertheless, until the Biosafety Act and respective regulations are in place, following existing laws and regulations could cover some aspects of the safe transfer, handling, and use of LMOs resulting from modern biotechnology.

- ◆Fauna and Flora Protection Ordinance No.2 of 1937

- ◆Section 37 and 38(b) of this Ordinance has allowed importing of any GM – animal only for research purposes.

- ◆Animal Disease Act, No.59 of 1992c)
- ◆Animal Feed Act, no 15 of 1986
- ◆Plant Protection Act, No 35 of 1999
- ◆Consumer Affairs Authority Act No,9 of 2003
- ◆Food Act, No.26 1980 amended by act no. 20 of 1991.
- ◆Fisheries and Aquatic Resources Act, No. 2 of 1996
- ◆Intellectual property Act, No 36 of 2003
- ◆Water Hyacinth Ordinance, No. 09 of 1909
- ◆Regulations (2006) on GM Food under the Food Act

Among these, the Plant Protection Act has provisions to prevent the introduction of any organism harmful or injurious to plants or destructive to plants in Sri Lanka. These provisions can be used not only to prevent the entry of plants and animals but to prevent the import of any genetically modified plasmids that could be potentially harmful to plants (Section 15).

The Consumer Affairs Authority Act provides provisions to issue general directions to manufacturers or traders to label the goods in respect of price marking, packaging, sale, or manufacture of the goods (Section 10(1) (a)). Since all genetic modifications relate to the manufacture of a good product, this section can be used to label all goods with LMOs or materials derived from LMOs.

Regulations came in 2006 under the Food Act which prevents import, store, transport, distribute, sell, or offer for sale any LMOs or ingredients from LMOs meant for food unless approved by the chief food authority.

The Water Hyacinth Ordinance provides effective means to prevent the entry, or retain until any GM plants or parts are identified and named in a gazette regulation.

The capacity building both human and physical is important for the implementation of any regulatory system. It is especially true for this highly technical and evolving subject. Sri Lanka has identified this necessity, and currently is in the process of building such capacities. For example, human and physical capacity building on LMO detection, inspection, and monitoring are among the key

expected outcomes of the on-going project on “Implementation of the National Biosafety Framework in accordance with Cartagena Protocol on Biosafety”.

The Agricultural Biotechnology Centre, University of Peradeniya (AgBC) has taken the lead as a local partner organization of the above FAO funded project, and work in collaboration with the Biotechnology Consortium Indian Limited (BCIL). As such the country will be prepared for detection and identification of LMOs/GMOs with;

- a) a fully pledged Accredited National GM referral laboratory at AgBC
- b) two fully pledged Accredited GM testing laboratories at the Industrial Technology Institution (ITI) and the National Plant Quarantine Service (NPQS) of the Department of Agriculture of Katunayake,
- c) a Small Quick detection facility (Strip based) at the Sri Lanka Customs, and ;
- d) an Enzyme Based Immunosorbent Assay (ELISA) based testing facility at the Government Analyst Department, Colombo, Sri Lanka.



**Safety First: Are we ready?**

While few staff members from identified labs will be trained internationally, more members are identified to be trained locally at developed facilities.

Over three hundred (300) relevant officers are already trained on GM inspection, monitoring, and sampling. The methodologies, guidelines, and standard procedures of sampling, inspection, and monitoring of GMOs are being prepared to support the regulatory system of the country.

The preparation of future generations has been identified as a priority. The new Advanced Level Biology curriculum introduced by the National Institute of Education (NIE), includes considerable content on biotechnology and biosafety. Supportive teaching and learning materials are in preparation for both primary and secondary education levels. Similarly, biotechnology and biosafety will also be introduced at tertiary level education through certificate courses. Such programs are already developed and are at the implementation stage.

Several scientific surveys conducted have shown that the general public in Sri Lanka is not aware of LMO/GMO. The same studies have suggested that even the educated population has less awareness



**Table 01: Policy statements of National Policy on Biosafety**

	<p>Recognizing the importance of protecting in people, environment and biodiversity while promoting a sustainable social and economic development through the implementation of biosafety measures</p>
	<p>Recognizing the human health, environment and socio-economic risks that may be incurred by careless or unscrupulous development of modern biotechnology and the use of its products</p>
	<p>Realizing the need for developing our own capabilities in biosafety through research and development and training</p>
	<p>Reaffirming the commitment to the obligations of the CBD and CPB</p>

though they are interested in labeling GM food/products. Therefore, substantial efforts are being taken to improve public awareness of biotechnology and biosafety.

All the above preparatory steps are important for the country adapting the proper regulations and guidelines for safe use of modern biotechnology and to facilitate harnessing benefits while minimizing risks if there are any. Because, the Sri Lankan population is projected to increase by about 18 %, from 20.3 to 23.9 million before plateauing by 2050. Linear progress of 2% genetic gain has to be achieved to sustain the productivity to feed the growing population. It is a huge challenge when crop yields have reached a plateau, due to the narrow genetic base and lack of potential to increase harvest index within elite breeding stocks. The introduction of new promising alleles through rapid breeding cycles seems an efficient mechanism to improve the rate

of gain significantly, and it could help to achieve the goal of feeding the projected population in 2050. There are many biotechnological tools available and applied around the world for the introduction of favorable alleles and to speed up the breeding efforts. It is clear that Sri Lanka has barely exploited the potential of biotechnology for crop improvement while the world is moving faster with new technologies.



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