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## **Report Name:** Agricultural Biotechnology Annual

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**Prepared By:** Thilani K. Kankanamge, Agricultural Specialist

**Approved By:** Joanna Brown, Agricultural Attaché

### **Report Highlights:**

Sri Lanka's agricultural biotechnology policies remain unchanged. Over the past year, there has been no progress in the approval of its draft Biosafety Act, which establishes a system to protect biodiversity, the environment and human, plant and animal health while minimizing the risks of biotechnology. The draft Act is still with the Legal Draftsman's Department, awaiting further approvals from the Attorney General and the Cabinet.

**DISCLAIMER:** Some information contained in this report is retrieved from various Sri Lankan government websites. [Note: Use Google Chrome to access the links that do not open in Microsoft Edge. Sri Lankan host sites will geo-block site access on a rolling basis].

## *EXECUTIVE SUMMARY*

Sri Lanka's agricultural biotechnology policies remain unchanged. A new legal framework for biosafety will become effective with the enactment of the National Biosafety Act, which has been undergoing review for several years but has yet to be finalized. The Food and Agriculture organization (FAO) in partnership with the World Bank's Global Equipment Facility and Sri Lanka's Ministry of Environment completed the Strengthening Biosafety in Sri Lanka project in 2023, which built Sri Lanka's capacity to implement its National Biosafety Framework (NBF). Specifically, it enhanced the system's risk assessment standards, developed technical capacity for the detection of "living modified organisms" (LMOs) and strengthened biosafety-related infrastructure.

The lack of a legal framework, however, and proper biosafety procedures are major challenges. The policies are at varying stages of development and implementation and include the National Biosafety Act, the National Biosafety Policy, and the Control of Import, Labeling and Sale of Genetically Modified Foods Regulation (2006) and its Amendment (2023). The development of the NBF which includes the Act and Policy fulfilled the country's commitments under the Cartagena Protocol (signed May 24, 2000, and ratified July 26, 2004).

Sri Lanka does not have genetically engineered (GE) crop production. Some GE research, however, occurs at the laboratory level. As of June 2023, Sri Lankan regulations require that all food imports with a content greater than 0.9 percent (by volume) of GE-derived ingredients require prior approval and labeling. GE-free certification is required for crops with "genetically modified" ("GM") varieties. The absence of a functioning approval mechanism has effectively led to a ban on the sale of GE-derived agricultural products. Despite Sri Lanka effectively not permitting the import of GE agricultural products, the United States exported \$144 million in food and agricultural products to Sri Lanka in 2023.

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## CHAPTER 1: PLANT BIOTECHNOLOGY

### PART A: PRODUCTION AND TRADE

#### a) RESEARCH AND PRODUCT DEVELOPMENT

Sri Lanka does not have genetically engineered (GE) plants or crops under research or product development available for near-term commercialization. However, some GE crop research is underway at the laboratory level. Generally, there are ribonucleic acid (RNA)-level expression studies on selected crops such as rice, vegetables, roots and tubers, oilseeds, fruits and other row crops. Additionally, Sri Lankan biotech research focuses on genome studies. The research aims to improve yields through the development of varieties resistant to biotic (bacteria, parasites, and pests) and abiotic stress (drought, salinity, and floods). Specifically, the current biotech research on crops includes:

- Research on optimization of protoplast regeneration, with the long-term objective of gene editing in rice.
- Diagnosing resistance to anthracnose in chilies, yellow vein virus in mung beans, and bruchid beetles in cowpeas.
- Transgenic development of chilies and other field crops including finger millet, onion, and maize.
- Marker-aided selection on rice (e.g., BG 250), mainly for development of higher yielding rice varieties with tolerance to salinity, drought, and bacterial leaf blight disease.
- Developing paddy varieties resistant to brown plant hopper and stem borer.
- Disease diagnosis of cowpea weevil and viruses on chilies and tomatoes.
- Genomic identification of locally available microbial consortia that can assist with biodegradation and biofertilizer production (see, [GAIN-SRI LANKA | CE20221-0007 | Sri Lanka Restricts and Bans the Import of Fertilizers and Agrochemicals](#)). (With the Sri Lankan government's 2021 decision to shift national agricultural production from conventional to organic farming, this new research has been initiated)

Conducting field research requires prior approval from relevant sectoral competent authorities, and no such approvals are granted so far. As such, the application of GE technologies is limited to the laboratory research level. However, there is some application of technologies outside of the research stage. The most prevalent are Polymerase Chain Reaction (PCR)-based detection of pathogens and genes and Marker Assisted Selection technologies. Modern biotechnologies, such as recombinant deoxyribonucleic acid (DNA) and RNA, are used to a limited extent. Tissue culture and the following biotech applications are also used commonly:

- DNA fingerprinting
- Molecular detection of plant pathogens
- Molecular characterization
- Disease diagnosis
- Marker-aided selection
- Gene identification

## **b) COMMERCIAL PRODUCTION**

There are no GE plants or crops under commercial production or under development for near-term commercialization. Tissue culture production with biotechnological applications is widely used at a commercial level for several crops such as bananas, strawberries, flowers, and ornamental plants.

## **c) EXPORTS**

Sri Lanka neither produces, nor exports GE products.

## **d) IMPORTS**

Sri Lanka restricts the import of GE products. The country does, however, import some GE products, namely a few pharmaceutical products that contain GE microbes and drugs produced from excretions of GE organisms. Food products containing GE ingredients in amounts less than 0.9 percent can be imported for human consumption if the presence of such “genetically modified organisms” (GMO) are considered technically unavoidable and the organisms have been subjected to a scientific risk assessment.

The [Animal Feed Act No. 15 of 1986](#) and [Animal Feed \(Amendment\) Act, No. 15 of 2016](#), govern animal feed imports. These Acts do not restrict the import of animal feed with GE content; however, the Department of Animal Production and Health (DAPH) prevents the imports of GE animal feed (particularly GE soybeans and corn) by means of other provisions in the existing regulations. If there is a request to import GE soybean or corn for animal feeds, the DAPH can decide to allow for the import in concurrence with the Department of Agriculture and the Ministry of Environment.

## **e) FOOD AID**

Sri Lanka is a food aid recipient of the United States and other countries. Nevertheless, regulations prohibit importing GE food items, even as food aid.

## **f) TRADE BARRIERS**

Sri Lanka has passed the [Control of Import, Labeling and Sale of Genetically Modified Foods Regulations \(2006\)](#) under the [Food Act, No. 26 of 1980](#) (“GM” Food regulation), which deal with the issue of genetic engineering. Some provisions in the existing laws are used to control, check, and even ban the introduction of certain GE products. As a result, the import or sale of GE products, including ingredients for human consumption, is highly restricted.

In June 2023, Sri Lanka's Ministry of Health, however, did amend the existing [Food \(Control of Import, Labeling, and Sale of Genetically Modified Foods\) Regulations \(2006\)](#) with the [Food \(Control of Import, Labeling, and Sale of Genetically Modified Foods\) Regulations \(2006\) - Amendment](#). As per the new regulation, food which contains, or has “genetically modified organisms” or materials with less than 0.9 percent, is exempt from prior approval of the Chief

Food Authority when other importing and labeling requirements are met. Earlier, the exemption threshold had been 0.5 percent. The change in the GE acceptance threshold level from 0.5 percent to 0.9 percent will help facilitate trade, as certain products can now be imported without prior approval from the Chief Food Authority and mandatory labeling (see, [GAIN-SRI LANKA | CE2023-0016 | Sri Lanka Enacts New Regulation on Genetically Engineered Food Imports](#)).

Outside of the above exception, products intended for human consumption that contain GE ingredients must receive the approval of Sri Lanka's Chief Food Authority. Further, under Sri Lanka's "GM" Food regulation, food products containing GE ingredients require labeling. Sri Lanka, however, has yet to approve any food product containing GE-derived ingredients.

Relatedly, Sri Lanka's general quarantine procedure for the import of plant and plant products does not permit the entry of "genetically modified organisms" and "living modified organisms" (LMOs). This results in a ban on the sale of GE seeds and other GE agricultural products.

## **PART B: POLICY**

### **a) REGULATORY FRAMEWORK**

Except for the Control of Import, Labeling and Sale of Genetically Modified Foods Regulations of 2006 and its amendment under the Food Act, No. 26 of 1980 (GM Food regulation), Sri Lanka has not yet passed laws that deal with GE products. Some policies that regulate biotechnology include the National Biotechnology Policy, the National Biosafety Framework of 2005 (which includes the National Biosafety Policy and the National Biosafety Act), and the GM Food regulation.

The new biosafety framework will become effective with the enactment of the National Biosafety Act. The act has undergone several stages of review and the draft is currently with the Legal Draftsman's Department and waiting for further approvals from the Attorney General, the Cabinet, and the Parliament. The implementing regulations for the Act are already being prepared. The Act will provide guidelines for contained and confined laboratory and field trials.

**National Biotechnology Policy:** In July 2010, Sri Lanka promulgated the National Biotechnology Policy, although its enforcement, to date, remains inconsistent. The National Biotechnology Policy, however, does acknowledge the importance of biotechnology in the economic development of Sri Lanka. Sri Lanka's National Biotechnology Policy defines biotechnology as "technologies involving the use of organisms, cells and biomolecules leading to industrial, agricultural, medical, energy, and environmental applications." The policy is extensive, as its scope covers:

- All areas of agriculture, livestock, fisheries, forestry, human and animal health, food production, energy, and the environment,
- All research and development in biotechnology,
- All product development and commercialization regulatory and promotional activities, and

- All measures to ensure public health and environmental safety regarding biotechnological application in Sri Lanka.

The policy has multiple objectives, which include the following:

- Support economic development.
- Provide an economic and legal framework to facilitate development of research and commercialization of biotechnology.
- Provide an institutional framework that establishes a National Biotechnology Council to plan, coordinate, monitor, and evaluate biotechnology activities, including facilitating and supporting bio-industries while ensuring safe and ethical practices.
- Promote ethical and biosafety considerations of biotechnology, support research and human resource development related to biotechnology.
- Ensure that biodiversity innovations are environmentally sustainable.
- Safeguard intellectual property rights and traditional knowledge.
- Promote public-private-partnership in biotechnology.

The National Biotechnology Policy highlights the government’s commitment to various priorities that include: 1) research development and commercialization of biotechnology; 2) promotion of public awareness of biotechnology; 3) human resource development; 4) biotech capacity building; 5) sustainable use of biodiversity; 6) enhanced opportunities for biotech related industries; and 7) the establishment of centers of excellence and biotechnology parks.

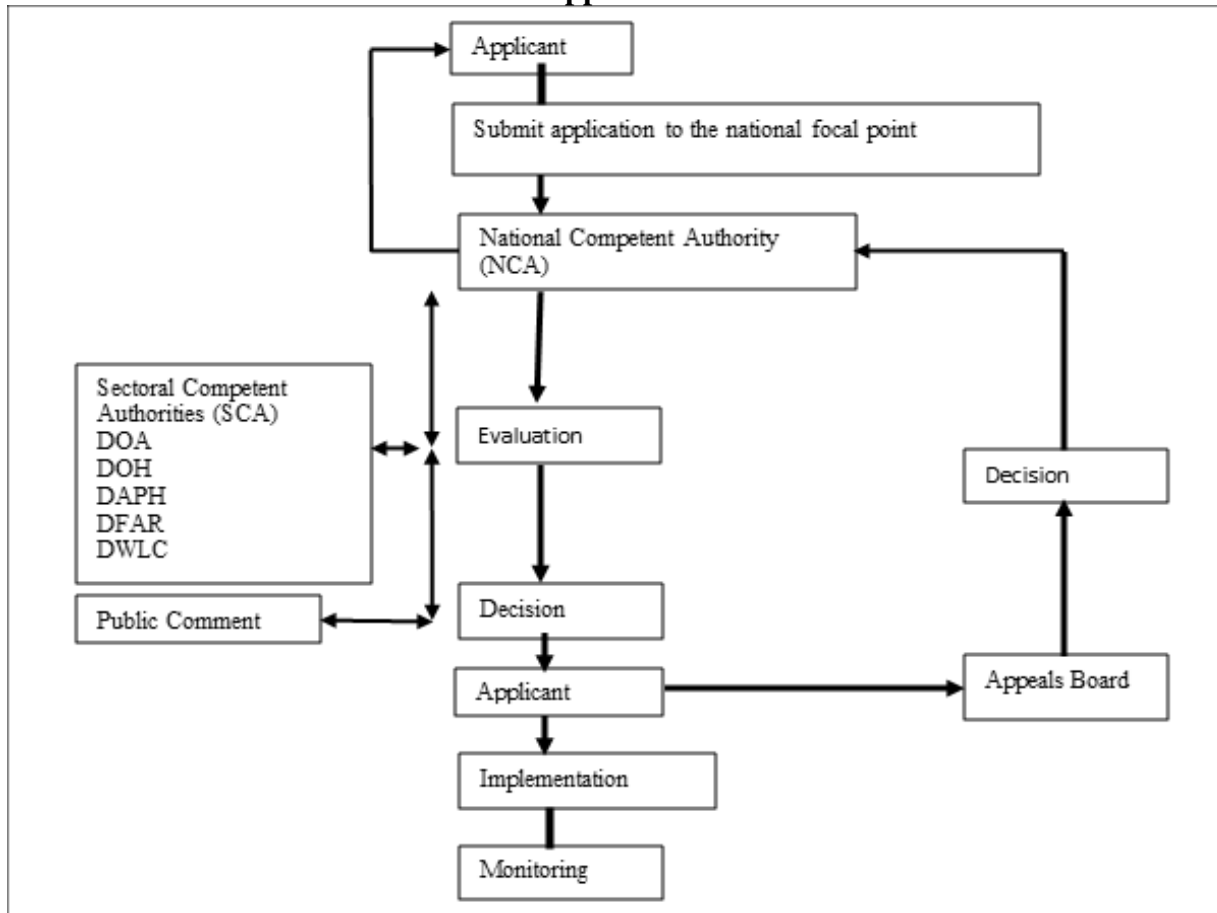
Since neither the National Biotechnology Council nor the National Biotechnology Strategy is established at this point, the implementation of the policy is inconsistent. The National Science Foundation (NSF) is currently reviewing the policy.

On October 12, 2020, the [Sri Lanka Institute of Biotechnology](#) (SLIBTEC) was established as a fully government-owned company under the Ministry of Technology. This institute aims to promote and support biotech industries in Sri Lanka. It has the objective of increasing the availability of products derived from biotechnology for export. The work on the Biotechnology Park is progressing and the Park will eventually encompass a 13.2-acre facility in the town of Homagama within the Colombo district. It would house high-end biotechnology innovation and manufacturing firms. In addition, an on-site research facility will provide a centralized multidisciplinary research and service facility, with initial areas of research in biopharma, biofuels, agricultural biotechnology, and other emerging fields. The park is envisioned to be Sri Lanka’s biotechnology focal point, aiming to attract investments and partnerships from local and international firms.

**The National Biosafety Framework:** In 2005, Sri Lanka developed the National Biosafety Framework of Sri Lanka (NBFSL) in conformity with the country’s commitments under the Cartagena Protocol (see, Part B: Policy, paragraph 1). It was created to ensure an adequate level of protection for the safe transfer, handling, and use of “LMOs.” It is a first step towards a more permanent biosafety legislative framework.

Specifically, the NBFSL aims to “minimize risks caused by modern biotechnology to the environment and human health” by regulating trans-boundary movements through use of relevant policies, regulations, technical guidelines and establishment of management bodies and supervisory mechanisms.<sup>1</sup>

**FIGURE 1: Sri Lanka, Proposed Administrative System for the Circulation and Assessment of the Notifications for GE Applications**



Note: DOA – Department of Agriculture; DOH – Department of Health; DAPH – Department of Animal Production and Health; DFAR – Department of Fisheries and Aquatic Resources; DWLC – Department of Wildlife and Conservation.

Source: National Biosafety Framework, 2005. FAS Colombo office research.

Sri Lanka’s National Biosafety Framework proposes a multi-department GE approval system. The proposed system would require coordination across multiple government institutions responsible for GE assessment and approval. Each government institution would function under their specific legal authority.

<sup>1</sup> It is important to note that modern biotechnology does not “cause” risk to the environment or human health. Rather, risk assessments of the potential hazards new biotech products may present (again, products and not the process that is used to create them) should be science-based and adhere to international standards (i.e., not to be so unnecessarily strict without justification as to cause trade disruption).



**National Biosafety Policy and The National Biosafety Act:** The Sri Lankan government created the National Biosafety Policy as part of the NBFSL. The National Biosafety Policy follows a precautionary approach, reflecting Sri Lanka’s interpretation of the Cartagena Protocol on Biosafety. It defines biotechnology in accordance with the Cartagena Protocol as “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use.”

Both the NBFSL and the National Biosafety Policy identify modern biotechnology as an application of (a) *in vitro* nucleic acid techniques, including DNA and direct injection of nucleic acid into cells or organelles, or (b) the 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, which have the potential to advance the production of different crops, “but with potential adverse effects not yet known.”

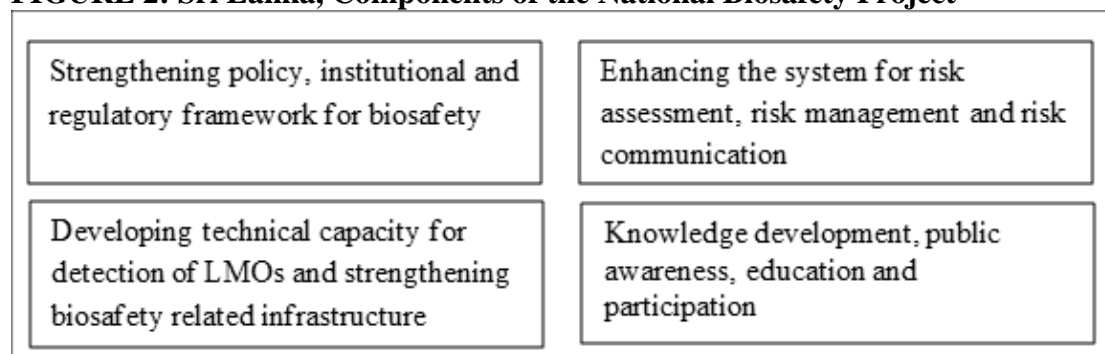
**The National Biosafety Policy differs from the NBFSL:** The NBFSL is the Cartagena Protocol-mandated framework of legal, technical, and administrative mechanisms for biosafety regulation. The National Biosafety Policy implements specific aspects of the National Biosafety Framework. The draft National Biosafety Act intends to implement the NBFSL in the near-term. A draft of the National Biosafety Act is not yet publicly available.

The new Biosafety Act will regulate and monitor the applications of modern biotechnologies, including all GE, “LMO,” and related products that pertain to food consumption, research, commercial production, and imports and exports. The new Biosafety Act will detail procedures for the approval, monitoring, and enforcement of penalties for violations.

The World Bank’s [Global Environmental Facility \(GEF\)](#) funded the National Biosafety Project with the Food and Agriculture Organization (FAO) from 2017 to mid-2022. The project aimed to strengthen institutional, regulatory, and technical capacities for effective implementation of the National Biosafety Framework in conformity with the Cartagena Protocol on Biosafety. The Ministry of Environment is the lead within Sri Lanka.

The project had four components: 1) strengthening policy, institutional and regulatory framework for biosafety; 2) enhancing the system for risk assessment, risk management and risk communication; 3) developing technical capacity for detection of “LMOs” and strengthen biosafety related infrastructure; and 4) knowledge development, public awareness, education, and participation.

**FIGURE 2: Sri Lanka, Components of the National Biosafety Project**



Source: Based on the Workshop on Draft Guidelines for Risk Assessment of Living Modified Organisms, FAO, Ministry of Mahaweli Development and Environment, GEF, 2019. FAS Colombo office research.

The National Biosafety Project has finalized the biosafety masterplan, that provides a strategy for the implementation of the National Policy on Biosafety. However, the regulatory component can only be finalized once the Biosafety Act in place.

The current iteration of the draft Biosafety Act recommends that the Ministry of Environment’s (MOE) Central Environmental Authority serve as the lead regulatory body following the Act’s implementation. However, the draft also requires approvals from the Attorney General’s Department, Cabinet of Ministers, and the Sri Lankan Parliament. There has been no progress in the approval of the draft Act over the past reporting year.

The Ministry of Environment, working through the National Biosafety Project has launched the [Sri Lanka Biosafety Clearing House](#) (BCH), a tri-lingual website in April 2021. It provides information about the authorities, regulations, guidelines, experts, databases of genetically modified organisms, risk assessment, awareness, contacts, approval process, and linkages to the global BCH (i.e., providing a gateway to global biosafety information). The Biodiversity Secretariat of the Ministry of Environment updates the BCH website.

**Regulations for Import, Labeling, and Sale of Genetically Engineered Food:** The Control of Import, Labeling and Sale of Genetically Modified Foods Regulations of 2006 and its Amendment in 2023 come under the Food Act of Sri Lanka, No. 26, 1980 (GM Food regulation). This is the only regulation that applies to food product imports and is binding only for products imported for human consumption. The regulation requires that biotech products for human consumption in Sri Lanka receive rigorous testing and risk assessments.

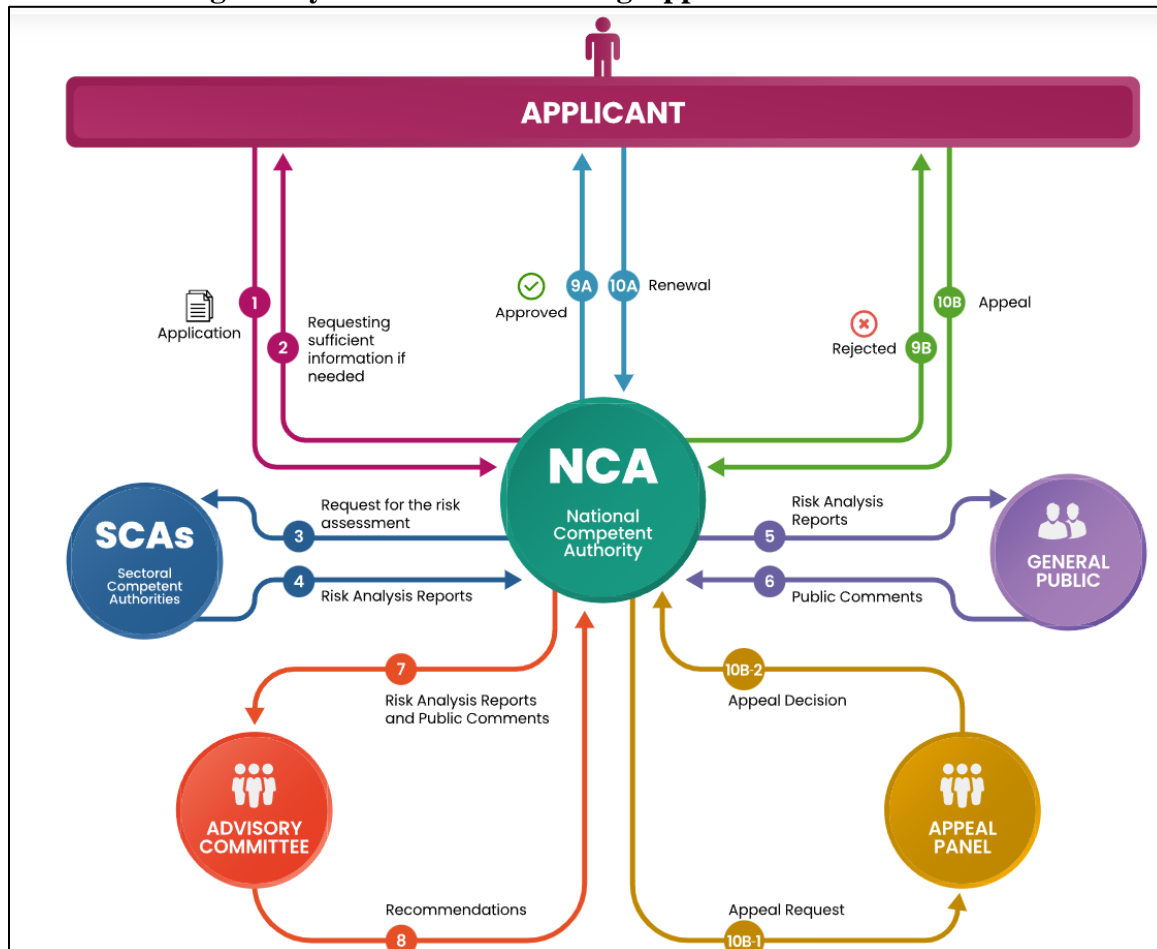
The regulation prohibits the import, storage, transportation, distribution, or sale of any GE product for human consumption, that is without the expressed permission of the Chief Food Authority. This includes any food produced from or containing ingredients produced from genetic engineering.

The regulation also calls on importers to declare food products with more than 0.9 percent GE content for prior approval by the Ministry of Health. The regulation requires a risk assessment by advisory committee (as per the Act’s definition). The National Biosafety Project established the

guidelines for risk assessment, and online trainings were conducted for key stakeholders on how to conduct a risk assessment.

The BCH website illustrates the procedure for obtaining the approval for the importation of “LMOs” and “GMOs” into Sri Lanka or their release into the environment. The [Application Forms](#) are available: 1) to obtain permits for the production and introduction of “Genetically Modified Organisms” and products and 2) to obtain import permits. However, in the absence of a National Biosafety Act, this approval process is not functioning.

**FIGURE 3: Regulatory Process for Obtaining Approval**



Source: Sri Lanka Biosafety Clearance House Website

Note: Currently, National Coordinating Committee on Biosafety (NCCB) is acting as the advisory committee.

The National Competent Authority (NCA) has yet to be identified under the Biosafety Act. The NCA is responsible for handling applications and communicating to the applicant and to the Biosafety Clearing House (BCH) on the regulatory functions.

Sectoral Competent Authorities (SCA) are considered as expert technical bodies for analysis of specific categories of “LMOs” and provide support to the NCA and implementation of relevant sectoral acts on biosafety. Sectoral Competent Authorities are: 1) the Central Environmental Authority (CEA); 2) the Department of Health Services; 3) the Department of Animal

Production and Health; 4) the Department of Fisheries and Aquatic Resources; 5) the Department of Agriculture; and 6) the Department of Wildlife Conservation.

**Plant Protection Act 1999 No. 35:** [The Plant Protection Act No. 35 of 1999](#) replaces the Plant Protection Ordinance. The existing Act does not contain restrictions on the import of GE plants, but based on the powers vested by the Act, the Director General of Agriculture can impose regulations. The general quarantine procedure for importing plants and plant products does not permit GE and “LMO” imports.

When applying for import permits, the importer must declare whether the requested product contains a GE component. The Director General of Agriculture reviews these import permit requests. In the case of animal feed, the Department of Animal Production and Health reviews the requests. The Plant Protection Act’s regulations are under consideration for review for regulating GE plants and products imports.

**Sri Lankan Ministries, Policy Roles:** There is no single regulatory authority overseeing biotechnology products. The National Biosafety Framework recommends the establishment of the National Biosafety Council (as the national competent authority). The council would be composed of representatives from different ministries and civil society. Its functions would include the screening of applications, forwarding applications to the SCA, and preparing public comments. The SCA would carry out risk assessments and reporting outcomes to the council.

**TABLE 1: Sri Lanka, National Council for Biosafety Sectoral Competent Authorities**

TITLE AGENCY	AREA OF OVERSIGHT
Department of Agriculture	Agricultural and non-agricultural (e.g., forest species, ornamentals) plants and planting materials, microorganisms, and animals.
Department of Health	“GM” food and pharmaceuticals.
Veterinary Drug Control Authority (Department of Animal Production and Health)	Domestic animals, including fish, birds, bees, and any other domesticated or wild animals kept in captivity. “GM” fish and/or veterinary pharmaceuticals. Animal feed including “GM” feed ingredients.
Department of Wildlife Conservation	All animals, except listed tropical aquarium fish and domestic animals (“GM” fish are not in the excluded list.)
Department of Fisheries and Aquatic Resources	All aquatic animals and aquatic plants.

Source: National Biosafety Framework, 2005. FAS Colombo office research.

**Local Funding Agencies for Biotechnology:** Only a handful of agencies fund biotechnology research in Sri Lanka. The main institutions are the National Science Foundation (NSF), the Sri Lanka Council for Agricultural Research Policy (SLCARP), and the National Research Council (NRC). Sri Lanka’s Council for Agricultural Research Policy has a National Agricultural Research Plan (NARP), which identifies biotechnology research priorities for Sri Lanka. Identified priority areas determine the actual awarding of research grants.

**TABLE 2: Sri Lanka, Legal Terms and Definitions**

Legal Term (Official language)	Legal Term (English)	Laws and Regulations	Legal Definition (English)
N/A	Genetically Modified Organism	<ul style="list-style-type: none"> <li>• Control of Import, Labeling and Sale of Genetically Modified Foods Regulations 2006 under the Food Act, No. 26 of 1980</li> <li>• National Policy on Biosafety</li> <li>• National Biosafety Framework, 2005</li> </ul>	Any living organism that possesses a novel combination of genetic material obtained using modern biotechnology.
N/A	Genetically Modified	<ul style="list-style-type: none"> <li>• Plant Protection Act, No. 35 of 1999</li> </ul>	An organism derived from any activity which has involved or resulted in the formation or derivation of new combinations of heritable material by the insertion of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid, or other vector system, to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.
N/A	Biotechnology	<ul style="list-style-type: none"> <li>• National Policy on Biotechnology</li> </ul>	Technologies involving the use of organisms, cells and biomolecules leading to industrial, agricultural, medical, energy and environmental applications.
N/A	Modern Biotechnology	<ul style="list-style-type: none"> <li>• National Policy on Biotechnology</li> </ul>	An application of (a) in vitro nucleic acid techniques, including DNA and direct injection of nucleic acid into cells or organelles, or (b) the 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, which have the potential to advance the production of different crops, “but with potential adverse effects not yet known.”
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**b) APPROVALS/AUTHORIZATIONS**

Sri Lanka is not approving GE crops for cultivation or import. There are no regulations that mandate prior approval for GE research. Nonetheless, the National Science and Technology Commission is assigned by the Science and Technology Development Act, No. 11 of 1994 to review the science and technology activities in the country, carried out by both public and private sector institutions. The main function of the commission is to advise the government on policies and plans for the development of science and technology. The commission is empowered to request and receive information relating to scientific and technology activity. The commission analyzes and recommends priority areas for future development, as well as monitors progress of projects and programs in science and technology institutions; it has no mandate to approve.

The Control of Import, Labeling and Sale of Genetically Modified Foods Regulation (2006) and its Amendment fall under the Food Act of Sri Lanka, No. 26 (1980) (GM Food regulation). It requires prior approval from the Ministry of Health for imports of food products with GE content of 0.9 percent or greater. A technical evaluation committee conducts risk assessments.

**c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS**

Existing regulations do not address the approval of stacked or pyramided events.

**d) FIELD TESTING**

The existing regulatory framework does not allow field-testing of GE crops in Sri Lanka.

**e) INNOVATIVE BIOTECHNOLOGIES**

Sri Lanka has not discussed or determined its position on the research, development, application, or regulation of innovative biotechnologies.

**f) COEXISTENCE**

As there is no cultivation of GE crops, there are no coexistence guidelines.

## **g) LABELING AND TRACEABILITY**

According to the Control of Import, Labeling and Sale of Genetically Modified Foods Regulations (2006) (GM Food regulation), if the application has been approved, and permission is granted in accordance with the regulation, the product is permitted to be placed in the market.

The label of a food product containing GE ingredients, or food ingredients used in the preparation of food, must include the statement “genetically modified” in conjunction with the name of that food or ingredient or processing aid irrespective of the size of the label or package. If the product is for retail sale without packaging, similar information must be on an accompanying label as on packaged food labels. Food that has GE content of less than 0.9 percent is exempt from these regulations, if the presence of such GE content is technically unavoidable, and the organisms have been subject to a scientific risk assessment. In Sri Lanka, the acronyms “GM,” “GMO,” and “LMO” are widely used.

## **h) MONITORING AND TESTING**

Sri Lanka lacks testing facilities at the ports-of-entry/exit to test for GE products. Laboratories have limited GE testing capacity and are not accredited in this competency. However, actions are being taken to receive accreditation. Laboratories upgrading GE content testing capabilities include the National Plant Quarantine Service, the Industrial Training Institute (ITI), and the University of Peradeniya/ Biotechnology Center. Currently, the ITI, the University of Peradeniya/Biotechnology Center, and a few private labs are testing for the presence of “GMOs” and “LMOs” in imports and exports. The cost per test is approximately Sri Lankan rupees (LKR) 18,000.00 (~\$60.86).<sup>2</sup>

There are no reports of interceptions of import consignments containing unapproved GE events. There is no routine marketplace monitoring of products for GE content. The last marketplace monitoring was conducted in 2015 and found no GE products. The Ministry of Environment aims to conduct random market testing in future; however, there are budget constraints. In addition, authorities do not regularly monitor field crops for unapproved GE events, as regulations prohibit the entry of GE seeds or plants.

As a part of the National Biosafety Project, equipment required for testing of genetically engineered components is being upgraded. The purpose of the upgrades is to increase Sri Lanka’s detection capacity. The University of Peradeniya/Biotechnology Center will serve as the National referral lab, the ITI, and National Plant Quarantine Services labs will conduct the regulatory testing work. In addition, the Government Analyst Department (GAD) received an Enzyme Linked Immunosorbent Assay (ELISA) based facility and the Sri Lanka Customs has received capacity for rapid testing. Officers were trained on GE detection and identification. The University of Peradeniya/Biotechnology Center and the Biotech Consortium India Limited collaboratively trained over 100 food and feed inspectors, seed inspectors, plant quarantine officials, and customs officials on GE inspections, monitoring, and sampling. Overall, the

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<sup>2</sup> Exchange rate, \$1.00 = LKR 295.74 as of October 03, 2024.

Biosafety Project has equipped the country with sufficient technical and human capacity for the implementation of regulatory testing.<sup>3</sup>

**i) LOW LEVEL PRESENCE (LLP) POLICY**

Sri Lanka has a Low-Level Presence (LLP) policy for food products imported for human consumption. Foods with a GE content of less than 0.9 percent are exempt from the regulations if the presence of such content is technically unavoidable, and the organisms are subject to a scientific risk assessment. Sri Lanka has zero tolerance for unapproved GE events, but the LLP policy and/or other regulations do not specify a penalty for undeclared imports of GE products.

**j) ADDITIONAL REGULATORY REQUIREMENTS**

Nothing to report.

**k) INTELLECTUAL PROPERTY RIGHTS (IPR)**

The Intellectual Property Act of Sri Lanka makes it possible to patent GE microbes. However, provisions in the Act allow regulators to deny patents upon recommendation of other relevant authorities. The draft Plant Breeders Rights Act attempts to comply with obligations under the trade related aspects of the Intellectual Property Rights Agreement and international legal agreement between all member nations of the World Trade Organization (WTO). GE plant varieties require approval prior to the granting of plant breeder rights.

**l) CARTAGENA PROTOCOL RATIFICATION**

Sri Lanka signed the Cartagena Protocol on Biosafety on 24 May 2000 (ratified July 26, 2004). The Ministry of Environment is the National Focal Point for the Cartagena Protocol on Biosafety, and responsible for the National Biosafety Framework.

**m) INTERNATIONAL TREATIES AND FORUMS**

Sri Lanka is a member of the International Plant Protection Convention. It is also a member country of the Codex Alimentarius since 1972. It is a WTO member since 1995 and a member of General Agreement on Trade and Tariffs (GATT) since 1948. In international fora, Sri Lanka has not stated its position - either positive or negative - on the genetic engineering of plants.

**n) RELATED ISSUES**

Nothing to report.

**PART C: MARKETING**

**a) PUBLIC/PRIVATE OPINIONS**

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<sup>3</sup> Biosafety Newsletter (2022). Food and Agricultural Organization of the United Nations and Ministry of Environment. Vol 4, Issue 1.



In general, the Sri Lankan public and regulators have negative perceptions or attitudes toward GE products and research. Although the research community recognizes the benefits of GE products, they are constrained by the lack of commercial marketing opportunities, clarity in regulations for GE research, and by the scarcity of basic research funding.

A pilot survey carried out in Sri Lanka on the perceptions of “GM” food and organisms reveals a lack of understanding of biotechnology and biosafety that has led to misconceptions. Most of the participants of the survey (68 percent) believed Sri Lanka can benefit from “GMOs” if proven safe and 60 percent believe “GMO” products are available in the country. Out of the sample group, government officials, academia and the research community showed the highest level of knowledge on “GMOs.” Out of the rest of the sample, more than half had a poor understanding. Growers, importers, biotech-related organizations, media, and the public are often uncertain about the difference between genetic engineering and conventional breeding techniques.<sup>4</sup>

As part of the Biosafety Project, educational material in biosafety is prepared for different educational levels. Two comprehensive resource books were prepared for teachers. The material is shared with the National Institute of Education (NIE) and available to use for in the next school curriculum revision. The Ministry of Education with Agricultural Biotechnology Center in Peradeniya has trained 450 teachers who teach advanced level (A/L) biology on biotechnology. In addition, three certificate courses on biotechnology and biosafety have been developed for tertiary education. Audiovisual and other electronic [awareness material](#) are available on the Biosafety Clearance House website.<sup>5</sup> Further, [University of Peradeniya/Biotechnology Center](#) regularly conducts certificate courses and trainings on [Molecular Biology and Biotechnology](#) targeting students, teachers, academics, and researchers. These programs include theory and practical components and participants are allowed to join virtually.

## **b) MARKET ACCEPTANCE/STUDIES**

Nothing to report.

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<sup>4</sup> Kandanaarachchi, M. (2019), “A Preliminary Survey on Sri Lankans’ Knowledge and Understanding of Biosafety and GMOs”, 7th Annual South Asia Biosafety Conference, Dhaka, Bangladesh.

<sup>5</sup> Biosafety Newsletter (2022). Food and Agricultural Organization of the United Nations and Ministry of Environment. Vol 4, Issue 1.

## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

### **PART D: PRODUCTION AND TRADE**

#### **a) RESEARCH AND PRODUCT DEVELOPMENT**

Genetic engineering research for animals is not taking place in Sri Lanka. Some field trial research exists on nutritional biotechnology such as rumen bypass feed development, digestibility, and rumen microflora quality improvement. Other ongoing research includes optimization for synchronization protocols for reproductive efficiency, disease diagnosis, early pregnancy detection, and vaccine development. Still other research includes molecular characterization, especially genetic conservation. The Sterile Insect Technique (SIT) has been used for Dengue vector mosquito control and a pilot trial for field releasing sterile male mosquitoes has been initiated. There is no research and development on animal cloning.

#### **b) COMMERCIAL PRODUCTION**

There is no commercial production of GE animals, insects, birds, or fish in Sri Lanka, nor is there commercial production of cloned animals.

#### **c) EXPORTS**

Sri Lanka does not export any GE animals, animal clones, or products from these animals.

#### **d) IMPORTS**

There is no legal framework governing the controls for importing GE animals or animal products to Sri Lanka. However, some provisions in the existing regulations are used to control, check, and even ban the introduction of certain GE products. Importers must declare such imports to the Department of Animal Production and Health, which will approve or deny such import requests.

#### **e) TRADE BARRIERS**

Trade barriers applicable to plant products are also applicable for GE animal products.

### **PART E: POLICY**

#### **a) REGULATORY FRAMEWORK**

The Animal Disease Act No. 59 of 1992 governs the import of animals. The Act does not restrict the import of GE animals, however, in practice the Department of Animal Production and Health prevents imports of GE animals based on certain provisions in the existing regulations.

**b) APPROVALS/AUTHORIZATIONS**

There are no regulations detailing requirements on labeling or the traceability of GE animals and products, including that of cloned animals.

**c) INNOVATIVE BIOTECHNOLOGIES**

Nothing to report.

**d) LABELING AND TRACEABILITY**

There are no regulations detailing requirements on labeling or the traceability of GE animals and products, including cloned animals.

**e) ADDITIONAL REGULATORY REQUIREMENTS**

Nothing to report.

**f) INTELLECTUAL PROPERTY RIGHTS (IPR)**

No specific regulations exist on Intellectual Property Rights for animal biotechnology.

**g) INTERNATIONAL TREATIES AND FORUMS**

Sri Lanka is a member of World Organization for Animal Health (WOAH). The Director General of the Department of Animal Production and Health is a WOAH permanent delegate. Sri Lanka is also a member of the Codex Alimentarius since 1972. Sri Lanka does not have positions on GE animals or cloning in international forums.

**h) RELATED ISSUES**

Nothing significant to report.

**PART F: MARKETING**

**a) PUBLIC/PRIVATE OPINIONS**

Public and private opinions regarding animal biotechnology is similar those pertaining to plant biotechnology.

**b) MARKET ACCEPTANCE/STUDIES**

Nothing to report.

## CHAPTER 3: MICROBIAL BIOTECHNOLOGY

### PART G: PRODUCTION AND TRADE

#### a) COMMERCIAL PRODUCTION

Nothing to report.

#### b) EXPORTS

Nothing to report.

#### c) IMPORTS

Sri Lanka imports products that may contain microbial biotech-derived food ingredients. Most of the microbial derived products are imported under a single harmonized tariff system (HS) code, which makes effective tracking of each product difficult.

#### d) TRADE BARRIERS

FAS Colombo is not aware of trade barriers that affect trade of microbial biotech-derived food ingredients or processed food products containing microbial biotech derived food ingredients.

### PART H: POLICY

#### a) REGULATORY FRAMEWORK

Sri Lanka lacks specific regulations on microbial biotechnology. The Control of Import, Labeling and Sale of Genetically Modified Foods Regulations (2006) (GM Food regulation) and its Amendment regulate food produced from or containing GE ingredients. The GM Food regulation prohibits imports, storage, transportation, distribution, sale or offer of GE food for human consumption, without the permission of the Chief Food Authority. The regulation applies to food product imports for human consumption; biotech products require testing and risk assessments. Approval from the Ministry of Health is required for food products with a GE content of 0.9 percent or greater.

#### b) APPROVALS/AUTHORIZATIONS

The Control of Import, Labeling and Sale of Genetically Modified Foods Regulations (2006) falls under the Food Act of Sri Lanka, No. 26, 1980 (GM Food regulation). Approval from the Ministry of Health is required for food products with a GE content of 0.9 percent or greater.

#### c) LABELING AND TRACEABILITY

There are no labeling requirements for microbial biotech derived products. Sri Lanka is yet to approve any food products containing microbial biotech derived ingredients. Nevertheless, as

such products are covered under the Control of Import, Labeling and Sale of Genetically Modified Foods Regulations (2006) (GM Food regulation), if the application has been approved and permission is granted, the product is permitted to be placed in the market subject to appropriate labeling. The label of a package of a food product with a GE ingredient or food ingredients used in the preparation of food must include the statement “genetically modified” in conjunction with the name of that food or ingredient or processing aid irrespective of the size of the label or package. If the product is for retail sale without packaging, it requires labeling with similar information as that of packaged foods. Food with GE content of less than 0.9 percent is exempt from these regulations if the presence of GE content is technically unavoidable, and the organisms have been subject to a scientific risk assessment. Nonetheless, Sri Lanka is yet to approve any food products containing microbial biotech derived ingredients.

**d) MONITORING AND TESTING**

Sri Lanka lacks testing facilities at the ports-of-entry/exit for GE products. The facilities have limited GE content testing capacity and are not accredited for this competency. Laboratories with GE content testing capabilities are the National Plant Quarantine Service, the ITI, the University of Peradeniya/Biotechnology Center, and a few private labs. There is no routine marketplace monitoring of products for GE content.

**e) ADDITIONAL REGULATORY REQUIREMENTS**

Nothing to report.

**f) INTELLECTUAL PROPERTY RIGHTS (IPR)**

No specific regulations exist on IPR for microbial biotechnology products. The Intellectual Property Act of Sri Lanka makes it possible to patent GE microbes. However, provisions in the Act allow regulators to deny patents upon recommendation of other relevant authorities.

**g) RELATED ISSUES**

Nothing to report.

**PART I: MARKETING**

**a) PUBLIC/PRIVATE OPINIONS**

Nothing to report.

**b) MARKET ACCEPTANCE/STUDIES**

Nothing to report.

**Attachments:**

No Attachments