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Report Highlights:

Sri Lanka does not produce genetically engineered (GE) crops or animals. There is some GE research at the laboratory level, but there is no commercialization. The lack of a legal framework and biosafety procedures are a major setback; the country is in the process of finalizing regulatory biotechnology policies. Policies remain at varying stages of development and implementation, and include the National Biotechnology Policy, the National Biosafety Framework (that encompasses the National Biosafety Policy and National Biosafety Act), as well as the Control of Import, Labeling and Sale of Genetically Modified Foods Regulation of 2006. Development of the National Biosafety Framework conforms to commitments made under the Cartagena Protocol (signed in 2000 and ratified in 2004). The new legal framework for biosafety will become effective with the enactment of the National Biosafety Act. The draft act is with the Legal Draftsman's Department, awaiting further approvals from the Attorney General and the Cabinet.

EXECUTIVE SUMMARY

The United States and the Democratic Socialist Republic of Sri Lanka (Sri Lanka) enjoy a mutually beneficial agricultural trade relationship. Despite Sri Lanka not effectively permitting the import of food, crops, animals, or agricultural products derived from genetic engineering (GE), the United States exported \$179 million in food and agricultural products to Sri Lanka in 2021.

Sri Lankan trade regulations require the mandatory labeling of imported goods with GE ingredients. All food product imports with a content greater than 0.5 percent (by volume) of GE-derived ingredients require prior approval. GE-free certification is required for crops with “genetically modified” (“GM”) varieties. However, the absence of a functioning approval mechanism has led to a ban on the sale of agricultural products derived from genetic engineering.

There is no GE crop production in Sri Lanka. Some GE research, however, occurs at the laboratory level but no biotechnology (biotech) events have been marketed. The lack of a legal framework and proper biosafety procedures are major challenges.

Sri Lanka is developing regulatory biotechnology policies. These policies, however, remain at varying stages of development and implementation. Policies include the National Biotechnology Policy, the National Biosafety Framework (that includes the National Biosafety Policy and National Biosafety Act), as well as the Control of Import, Labeling and Sale of Genetically Modified Foods Regulation of 2006. Development of the National Biosafety Framework conforms to the country’s commitments under the Cartagena Protocol (signed May 24, 2000, and ratified July 26, 2004).

The new legal framework for biosafety will become effective with the enactment of the National Biosafety Act, which has been undergoing review for several years. Steps have been taken in support of the implementation of the act through the National Biosafety Project. The recently completed National Biosafety Project facilitated in strengthening policy, institutional and regulatory frameworks for biosafety, enhancing the system for risk assessment, developing technical capacity for detection of “living modified organisms” (“LMOs”) and strengthening biosafety-related infrastructure, and developing awareness materials.

FAS Colombo (Post) issued GAIN-SRI LANKA biotech reports include: [GAIN-SRI LANKA | CE2021-0010 | Agricultural Biotechnology Annual – 2021](#); [GAIN-SRI LANKA | CE2022-0011 | FAIRS Annual Country Report Annual – 2022](#); and [GAIN-SRI LANKA | CE2022-0012 | FAIRS Export Certificate Report Annual – 2022](#).

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

The application of biotechnology (biotech) in Sri Lanka is limited. The most common technologies are Polymerase Chain Reaction (PCR)-based detection of pathogens and genes and Marker Assisted Selection. Modern biotechnologies, such as recombinant DNA (deoxyribonucleic acid) and RNA (ribonucleic acid) technologies, are used to a limited extent in Sri Lanka. The country does not have genetically engineered (GE) plants or crops under development available for near-term commercialization. However, some GE crop research is underway at the laboratory level. In addition, tissue culture with biotech applications is common.

Biotechnology technologies commonly utilized include the following:

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

There are RNA-level expression studies on selected crops such as rice, vegetables, root and tuber crops, cucumber, field crops, oil seeds, and fruits.

Sri Lankan biotech research focuses on genome studies. Research aims to improve yields through the development of varieties resistant to biotic and abiotic stress (bacteria, parasites, and pests, or drought, salinity, and floods). The application of GE technologies in plants remain at the laboratory research level; however, there is some greenhouse production testing. Conducting field research requires prior approval from relevant sectoral competent authorities.

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. Other field crops undergoing biotech research are finger millet, onion, and maize.
- Marker-aided selection on rice, mainly for development of rice varieties with tolerance to salinity, drought, and bacterial leaf blight disease. New varieties are pending release.
- Developing paddy varieties resistant to brown plant hopper and stem borer.
- Disease diagnosis of cowpea weevil and viruses on chilies and tomatoes.

- With the Sri Lankan government’s 2021 decision to shift national agricultural production from conventional to organic farming, new research has been initiated on 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](#) and [GAIN-SRI LANKA | CE2021-0008 | FAIRS Annual Country Report Annual – 2021](#)).

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 banana, strawberry, 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 0.5 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, governs animal feed imports. The Act does 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 by means of other provisions in the existing regulation they oversee. If there is a request to import GE animal feed, the DAPH will 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, however, 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.

Products intended for human consumption that contain GE ingredients must receive the approval of Sri Lanka's Chief Food Authority. 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). The absence of a functioning approval mechanism results in a ban on the sale of seeds and other agricultural products derived from genetic engineering.

Under Sri Lanka's GM Food regulation, food products for human consumption containing GE ingredients require labeling. Sri Lanka, however, has yet to approve any food product containing GE-derived ingredients, which creates a trade barrier. Importers lament the burden and complexity of the labeling regulations.

PART B: POLICY

a) REGULATORY FRAMEWORK

Except for the Control of Import, Labeling and Sale of Genetically Modified Foods Regulations of 2006 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 legal biosafety framework will become effective with the enactment of the National Biosafety Act. The act has undergone several stages of review and the revisions. The draft Act is currently with the Legal Draftsman's Department and waiting for further approvals from the Attorney General Department, the Cabinet, and the Parliament. Implementation 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 is extensive, as it 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.
- All measures to ensure public health and environmental safety regarding biotechnological application in Sri Lanka.

The policy intends that biotechnology:

- Support economic development.
- Provide an economic and legal framework to facilitate development of research and commercialization of biotechnology.
- Provide an institutional framework; proposing establishment of 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: 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) enhance opportunities for biotech related industries; 7) and the establishment of centers of excellence and biotechnology parks. Implementation of the policy is inconsistent, with neither the National Biotechnology Council nor the National Biotechnology Strategy being yet in place.

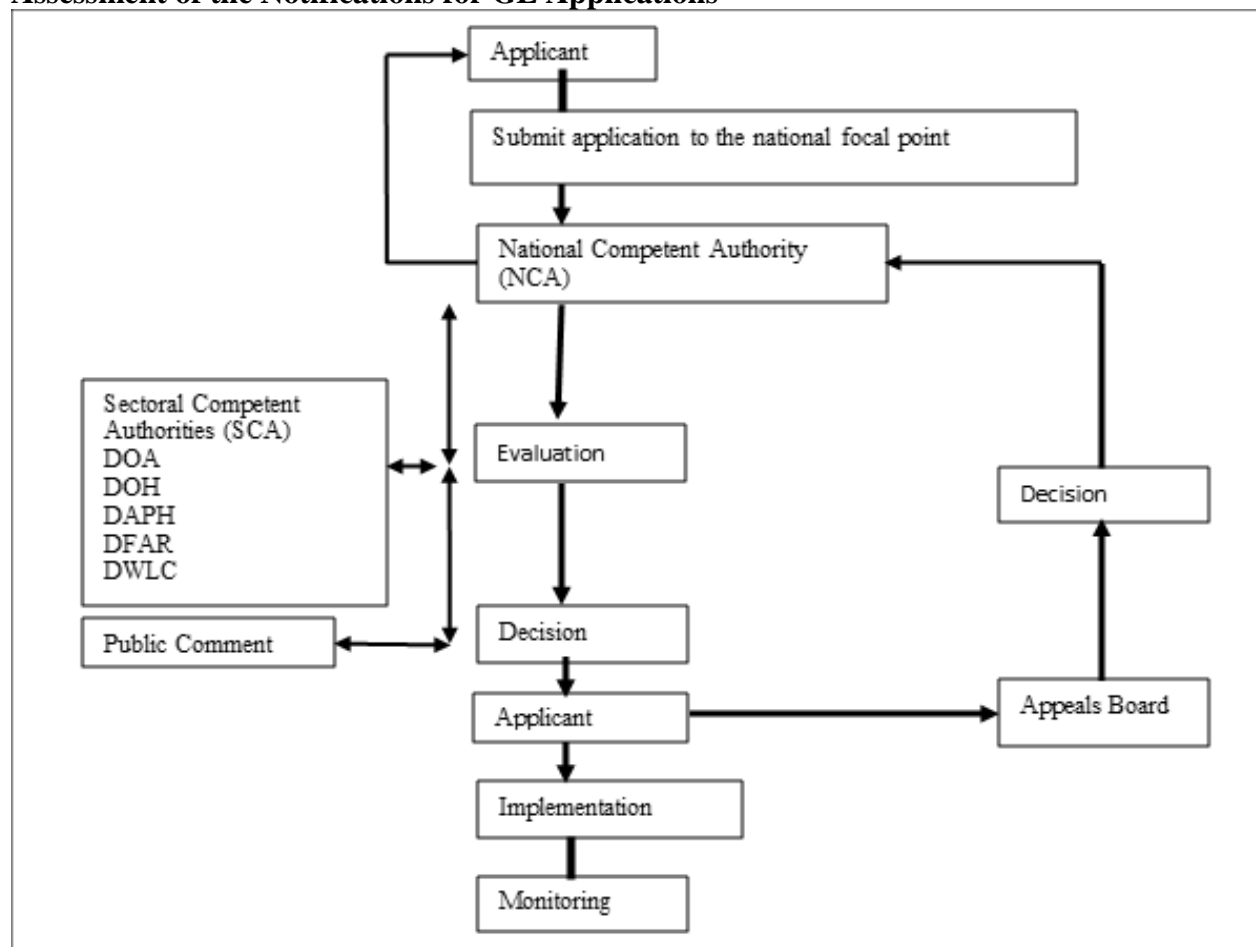
On October 12, 2020, the [Sri Lanka Institute of Biotechnology](#) (SLIBTEC) Private Limited was established as a fully government-owned company under the Ministry of Technology. This institute aims to promote and support biotech industries in Sri Lanka. It has the objective of increasing the availability 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 Homagama, housing 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 central point for biotech; 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.¹

¹ 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

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 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 GE approval system for applications. The proposed system coordinates multiple government institutions responsible for GE assessment and approval. Government institutions, however, function under their specific legal enactment.

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.”

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).

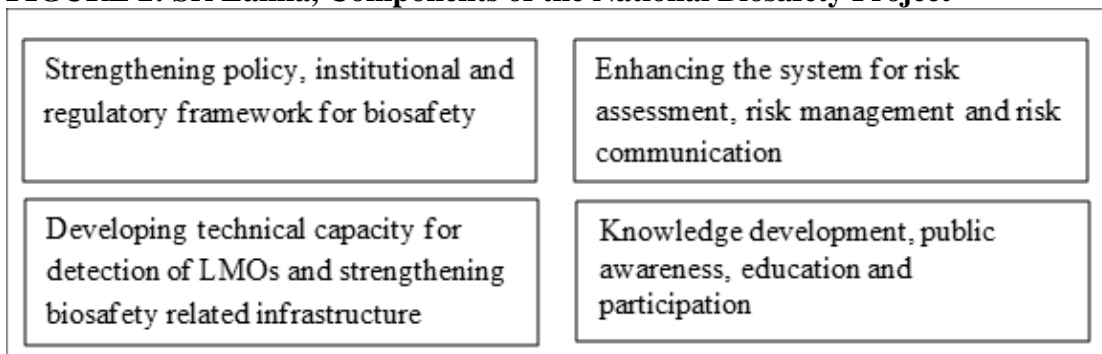
The National Biosafety Policy differs from the NBFSL: The NBFSL is the Cartagena Protocol-mandated framework of legal, technical, and administrative mechanisms for biosafety regulation. Whereas the National Biosafety Policy implements specific aspects of the National Biosafety Framework. The draft National 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 Global Environmental Facility (GEF) has funded the National Biosafety Project with the Food and Agriculture Organization (FAO) from 2017 to 2020, which has been extended through mid-2022, to complete the activities delayed by the COVID-19 pandemic. 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 government counterpart.

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 regulatory body following the act’s implementation. The revisions being made nonetheless still require approvals from the Attorney General’s Department, Cabinet of Ministers, and the Sri Lankan Parliament.

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. The launching of the BCH is in fulfillment of the Cartagena Protocol on Biosafety. 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).

Regulations for Import, Labeling, and Sale of Genetically Engineered Food: The Control of Import, Labeling and Sale of Genetically Modified Foods Regulations of 2006 comes 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, storing, transportation, distribution, selling or offering for sale 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.

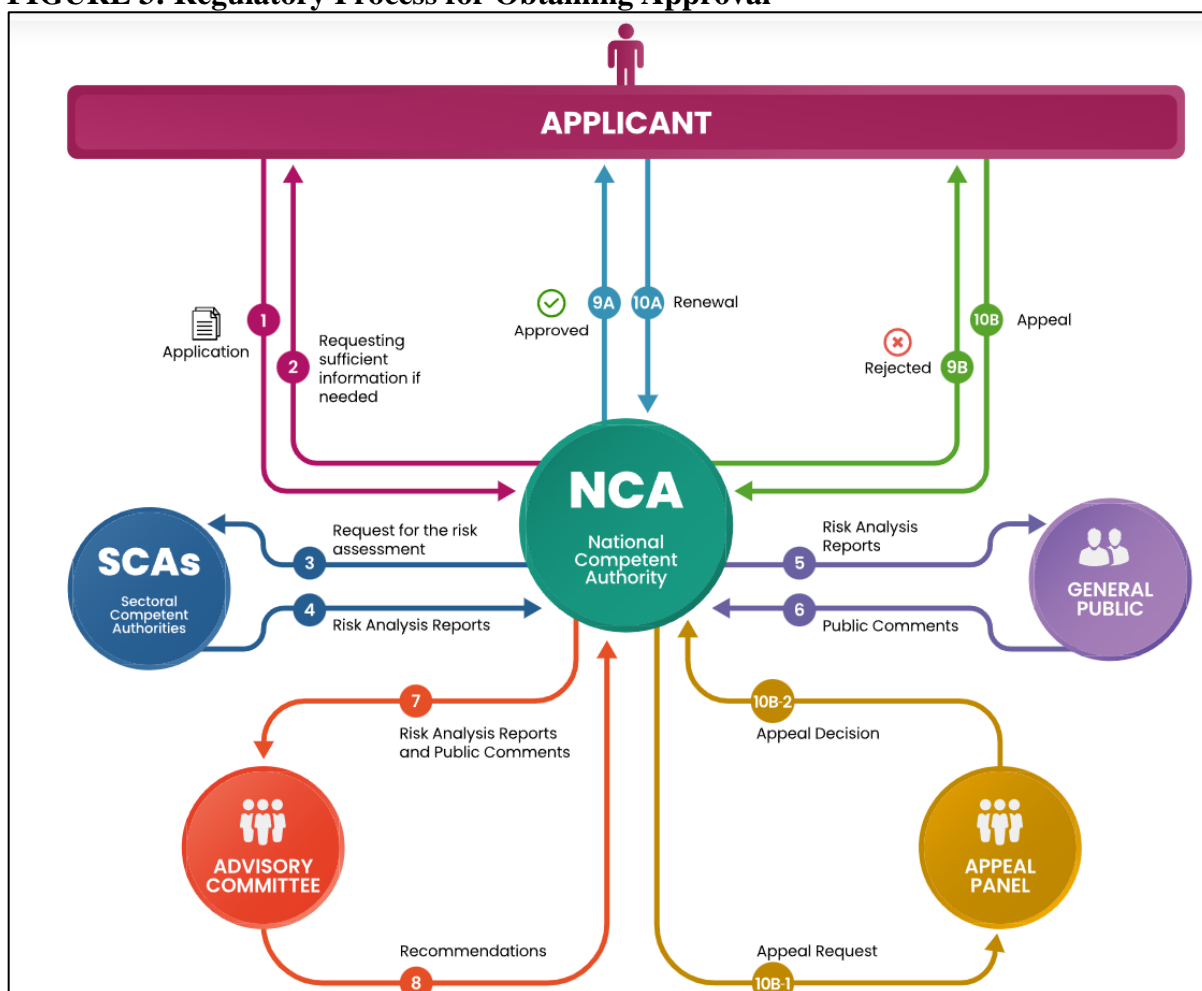
The regulation also calls on importers to declare food products with more than 0.5 percent GE content for prior approval by the Ministry of Health. The regulation requires a risk assessment by advisory committee (as per the act's definition). The National Biosafety Project established the guidelines 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.

The national competent authority (NCA) has yet to be identified under the Biosafety Act. The NCA is responsible for handling of the 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) Department of Health Services; 3) Department of Animal Production and Health; 4) Department of Fisheries and Aquatic Resources; 5) Department of Agriculture; and 6) Department of Wildlife Conservation.

FIGURE 3: Regulatory Process for Obtaining Approval



Note: Currently the National Coordinating Committee on Biosafety (NCCB) is acting as the advisory committee.
Source: Sri Lanka Biosafety Clearance House Website.

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 is composed of representatives from different ministries and civil society. Its functions include the screening of

applications and forwarding of these to the SCA, preparing applications for public comment. The SCA will carry out risk assessments, 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 Definition

Legal term (Official language)	Legal Term (English)	Laws and Regulations	Legal Definition (English)
N/A	Genetically Modified Organism	<ul style="list-style-type: none"> Control of Import, Labeling and Sale of Genetically Modified Foods Regulations 2006 under the Food Act, No. 26 of 1980 National Biosafety Policy National Biosafety Framework, 2005 	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"> Plant Protection Act, No. 35 of 1999 	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"> • National Biotechnology Policy 	Biotechnology is defined as “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"> • National Biosafety Framework of Sri Lanka • National Biosafety Policy 	Modern biotechnology is the application of (a) <i>in vitro</i> 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.”

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 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 of 2006 falls 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 0.5 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 their 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 of 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 subject to appropriate labeling.

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 0.5 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. 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 and the University of Peradeniya/Biotechnology Center are testing for the presence of “GMOs” and “LMOs” in exports. The cost per test varies from Sri Lankan rupees (LKR) 13,000.00 (\$36.00) to LKR 14,000 (\$39.00). 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 the upcoming year. 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 Biosafety Project has equipped the country with sufficient technical and human capacity for the implementation of regulatory testing.²

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 0.5 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.

² Biosafety Newsletter (2022). Food and Agricultural Organization of the United Nations and Ministry of Environment. Vol. 4, Issue 1.

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 genetic engineering of plants.

n) RELATED ISSUES

Nothing to report.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

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 about 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.³

³ Kandanaarachchi, M. (2019), “A Preliminary Survey on Sri Lankans’ Knowledge and Understanding of Biosafety and GMOs,” 7th Annual South Asia Biosafety Conference, Dhaka, Bangladesh.

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. In addition, three certificate courses on biotechnology and biosafety are developed for tertiary education. The audiovisual and other electronic [awareness material](#) are available on the Biosafety Clearance House website.⁴

b) MARKET ACCEPTANCE/STUDIES

Nothing to report.

⁴ 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 that for 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 IPR for animal biotechnology.

g) INTERNATIONAL TREATIES AND FORUMS

Sri Lanka is a member of World Organization for Animal Health (OIE). The Director General of the Department of Animal Production and Health is an OIE 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

Like those regarding 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 regulations on microbial biotechnology. The Control of Import, Labeling and Sale of Genetically Modified Foods Regulations of 2006 (GM Food regulation) regulates food produced from or containing GE ingredients. The GM Food regulation prohibits imports, storing, 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 0.5 percent or greater.

b) APPROVALS/AUTHORIZATIONS

The Control of Import, Labeling and Sale of Genetically Modified Foods Regulations of 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 0.5 percent or greater.

c) LABELING AND TRACEABILITY

There are no specific labeling requirements for microbial biotech derived products at present. Sri Lanka has 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. Labs have limited GE content testing capacity and are not accredited. Labs with GE content testing capabilities are the National Plant Quarantine Service, the ITI, and the University of Peradeniya/Biotechnology Center. 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