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Report Highlights:

Sri Lanka does not produce genetically engineered (GE) crops or animals. Some GE research, however, occurs at the laboratory level, but that research does not reach commercialization. The lack of a legal framework and proper biosafety procedures are a major setback. The country is in the process of developing regulatory biotechnology policies. 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 and ratified in 2004). The new legal framework for biosafety will become effective with the enactment of the National Biosafety Act, but that has been undergoing review for several years.

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 did export $152 million in food and agricultural products to it in 2020.

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 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. 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 and ratified in 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. Some steps have been taken in support of the implementation of the act through the National Biosafety Project.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Biotechnology (biotech) applications in Sri Lanka are limited. Of those, the most common are Polymerase Chain Reaction (PCR) based detection of pathogens and genes and Marker Assisted Selection. Molecular biotechnologies, such as recombinant DNA and RNA 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 applications 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 select 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 applications of GE plants remain at the laboratory research level; however, there is some greenhouse production testing.

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 varieties resistant to brown plant hopper and stem borer.
- Disease diagnosis of cowpea weevil, and viruses on chilies and tomatoes.
- With the 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 for that can assist with biodegradation and biofertilizer production.

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.

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 (GMOs)" 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 feeds containing GE content; however, the Department of Animal Production and Health (DAPH) prevents the imports of GE animal feed by means of provisions in the existing regulations. If there is a request to import GE animal feed, the DAPH will make the decision 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 not yet passed any laws to specifically deal with the issue of genetic engineering, except for the Control of Import, Labeling and Sale of Genetically Modified Foods Regulations 2006 under the Food Act, No. 26 of 1980 ("GM" Food regulation). However, 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.

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" ("GMOs") and "living modified organisms" ("LMOs"), and 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, creating 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 any 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 await the Sri Lankan Cabinet's approval. Implementation regulations for the act are already in preparation. 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, acknowledges 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 bio-molecules leading to industrial, agricultural, medical, energy and environmental applications." The policy is extensive, covering the following areas:

- 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.

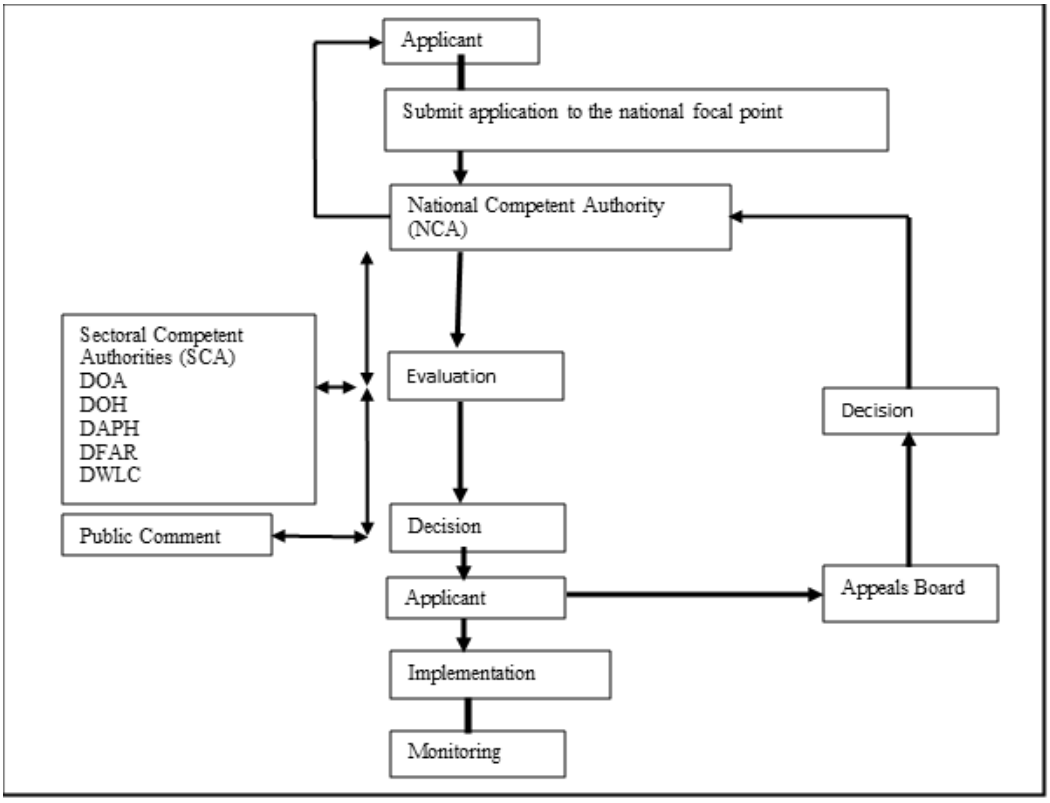
The National Biotechnology Policy's key themes highlight the government's commitment to: Research development and commercialization of biotechnology promotion of public awareness of biotechnology human resource development and biotechnology capacity building sustainable use of biodiversity enhance opportunities for biotechnology related industries, and the establishment of centers of excellence and biotechnology parks.

Implementation of the policy is inconsistent. Neither the National Biotechnology Council, nor the National Biotechnology Strategy are in place. Nevertheless, the work on the Biotechnology Park is progressing, albeit at a slow 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 has been brought online to promote and support biotech industries in Sri Lanka. It has the objective of increasing the availability of product derived from biotechnology for export.

The National Biosafety Framework: The National Biosafety Framework of Sri Lanka (NBFSL) was developed in 2005, in conformity with the country's commitments to the Cartagena Protocol (see Part B: Policy, paragraph l). It was created to ensure an adequate level of protection for the safe transfer, handling, and use of "living modified organisms." It is a first step towards a more permanent legislative framework for biosafety. Figure 1 illustrates the flow chart for receipt of applications, risk assessment.

FIGURE 1: Sri Lanka, Proposed Administrative System of Circulation and Assessment of the Notifications for the Use of 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.

Specifically, the NBFSL aims to minimize risks caused by modern biotechnology to the environment, human health, and the environment by regulating trans-boundary movements

through use of relevant policies, regulations, technical guidelines and establishment of management bodies and supervisory mechanisms.

The National Biosafety Framework of Sri Lanka is a first step towards a more permanent legislative framework for biosafety. Figure 1 illustrates the recommended flow chart for receipt of applications, risk assessment to the decision making.

Sri Lanka's National Biosafety Framework proposes a system for approval of GMO applications. The proposed system coordinates multiple government institutions responsible for GMO assessment and approval; otherwise, each government institution functions 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 National Biosafety Framework of Sri Lanka (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) i*n vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) 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 Biosafety Policy in this view seeks the safe application of modern biotechnology, no adverse effects on conservation, and sustainable use of biological diversity.

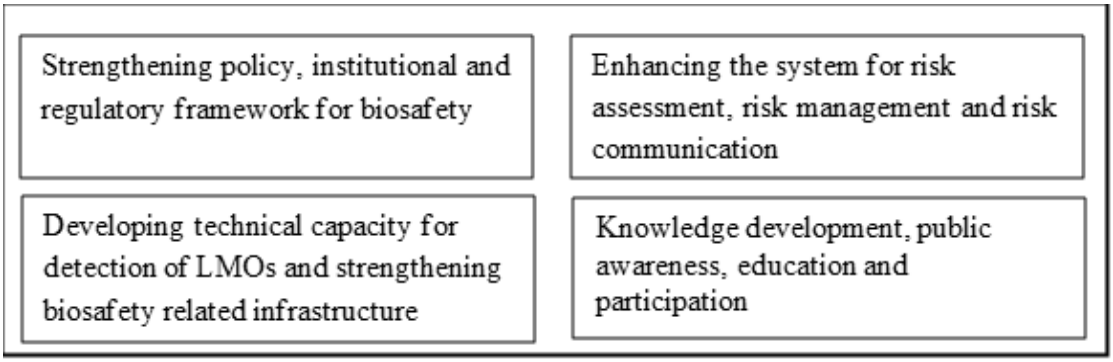
The National Biosafety Policy differs from the NBFSL: The NBFSL is the Cartagena Protocol-mandated framework of legal, technical, and administrative mechanisms for biosafety regulation. Whereas the National Biosafety Policy implements specific aspects of the National Biosafety Framework of Sri Lanka.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

The new Biosafety Act will regulate and monitor the applications of modern biotechnologies, including all "GMOs," "LMOs," and products that affect food consumption, research, commercial production, and imports and exports. The new Biosafety Act will detail procedures for 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. Project funding has now been extended through 2021. The project aims 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 has identified 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 strengthening biosafety related infrastructure; and 4) knowledge development, public awareness, education, and participation (figure 2).

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, which strategizes the implementation of the National Policy on Biosafety. However, the regulatory component can be finalized only with the Biosafety Act in place.

The draft Biosafety Act is recommending that the Ministry of Environment's Central Environmental Authority serve as the regulatory body following the act's implementation. The revisions being made nonetheless still require approval from the Cabinet of Ministers.

The Ministry of Environment with the assistance of the National Biosafety Project also launched the Sri Lanka Biosafety Clearing House (BCH) 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 "GMOs," risk assessment, awareness, contacts, and linkages to the global BCH (i.e., providing a gateway to global biosafety information).

Regulations for Import, Labeling, and Sale of Genetically Modified 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 import, storing, transportation, distribution, selling or offering for sale any form from "GMOs" in food for human consumption, without the 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 technical evaluation committee (as per the Act's definition). However, Sri Lanka lacks the capacity to conduct monitoring or risk assessments. Lacking monitoring capacity allows for the possibility that Sri Lanka has unlabeled GE content food products in retail stores.

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 imports of "GMO" and "LMO" into Sri Lanka.

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 to regulate imports of GE plants and products.

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 (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 Sectoral Competent Authorities (SCA) and preparing applications for public comment. The SCA (Table 1) will carry out risk assessments, reporting 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 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), 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 the biotechnology research priorities for Sri Lanka. Identified priority areas determine the awarding of research grants.

b) APPROVALS: 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 vested 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 has the power to request and receive information relating to scientific and technology activity from individuals, and bodies of persons. 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 is responsible for conducting risk assessments.

c) STACKED or PYRAMIDED EVENT APPROVALS: 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 genetically engineered 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 "genetically modified" ("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. Laboratories upgrading GE content testing capabilities include the National Plant Quarantine

Service, the Industrial Training Institute (ITI), and the University of Peradeniya/ Biotechnology Center. There are no reports of interceptions of import consignments containing unapproved GE events. There is no routine marketplace monitoring of products for GE content. Similarly, authorities do not regularly monitor field crops for unapproved GE events, as the regulations prohibit 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 at three laboratories just cited. The purpose of the upgrades is to increase Sri Lanka's detection capacity. Accreditation of these laboratories is under discussion.

i) LOW LEVEL PRESENCE POLICY: Sri Lanka has a Low-Level Presence (LLP) policy for food products imported for human consumption. Foods that have GE content of less than 0.5 percent are exempt from these 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, although 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, in Nairobi, Kenya, when it was first open for signatories. Sri Lanka ratified the Cartagena Protocol on 28 April 2004, which took effect on 28 July 2004. The Ministry of Environment is the National Focal Point for the Cartagena Protocol on Biosafety and has responsibility for developing the National Biosafety Framework.

m) INTERNATIONAL TREATIES and FORA: Sri Lanka is a member of the International Plant Protection Convention. It is also a member country of the Codex *Alimentarius* since 1972. It has been 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 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 and the research community were more knowledgeable. 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.[1]

b) MARKET ACCEPTANCE/STUDIES: Nothing to report.

[1] Kandanaarachchi, M. (2019), "A Preliminary Survey on Sri Lankans' Knowledge and Understanding of Biosafety and GMOs", 7thAnnual South Asia Biosafety Conference, Dhaka, Bangladesh.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) **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. There is no research and development happening 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 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 the provisions in the existing regulations.

b) **APPROVALS:** No regulations detail requirements on labeling or traceability of GE animals and products, including cloned animals.

c) **INNOVATIVE BIOTECHNOLOGIES:** Nothing to report.

d) **LABELING AND TRACEABILITY:** No regulations detail requirements on labeling or traceability of GE animals and products, including cloned animals.

e) **INTELLECTUAL PROPERTY RIGHTS (IPR):** No specific regulations exist on IPR for animal biotechnology.

f) INTERNATIONAL TREATIES and FORA: 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.

g) 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 is importing 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 any trade barriers that negatively 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 does not have regulations on microbial biotechnology. However, the Control of Import, Labeling and Sale of Genetically Modified Foods Regulations of 2006 ("GM" Food regulation) regulates food produced from or containing ingredients produced from genetic engineering. The "GM" Food regulation prohibits import, storing, transportation, distribution, selling or offering for sale any form of "GMOs" in food for human consumption, without the permission of the Chief Food Authority.

This is the only regulation that applies to food product imports and is binding only for food products imported for human consumption. Biotech products for human consumption require rigorous testing and risk assessments. Prior approval from the Ministry of Health is required for food products with a GE content of 0.5 percent or greater.

b) APPROVALS: 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). Prior approval from the Ministry of Health is required for food products with a GE content of 0.5 percent or greater. A technical evaluation committee will conduct risk assessments.

c) LABELING and TRACEABILITY: There are no labeling requirements for microbial biotech derived products. Nevertheless, as such products are covered under 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 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 0.5 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 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 to test for GE products. Laboratories have limited GE content testing capacity and are not accredited. Laboratories upgrading to GE content testing capabilities include the National Plant Quarantine Service, the Industrial Training Institute (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