USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

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Voluntary - Public

Date: 11/29/2018
GAIN Report Number: CE8002

Sri Lanka

Post: Colombo

Agricultural Biotechnology Report 2018

Report Categories:

Biotechnology - GE Plants and Animals
Biotechnology and Other New Production Technologies
Agriculture in the Economy

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Report Highlights:

Sri Lanka does not produce genetically engineered (GE) crops or animals. Some GE research is carried out at the laboratory level, but no development exists at a commercial level. The country does not allow import of GE food, crops, or animals. Sri Lanka signed and ratified the Cartagena Protocol on Biosafety in 2004. Sri Lanka is in the process of developing policies to regulate and promote biotechnology. Most of the policies are incomplete, or not fully implemented.

Executive Summary:

The United States and Sri Lanka enjoy a healthy agricultural trade relationship. Although the country does not allow imports of food, crops, animals, or agricultural products derived from genetic engineering, the United States exported 148 million U.S. dollars' worth of agricultural commodities to Sri Lanka in 2017.

Sri Lankan trade regulations require mandatory labeling of GE ingredients, GE-free certification for imported goods, and approval of imports for food products containing more than 0.5 percent (by volume) of GE-derived ingredients. However, the absence of a functioning approval mechanism in effect leads to a ban on the sale of agricultural products derived from genetic engineering.

No GE crops are produced in Sri Lanka. Some GE research is carried out at the laboratory level, but the research does not reach commercialization.

Sri Lanka is developing multiple policies to regulate and promote biotechnology. These include the National Biotechnology Policy, the National Biosafety Framework (which includes the National Biosafety Policy and the National Biosafety Act), and the Control of Import, Labeling and Sale of Genetically Modified Foods regulation of 2006. Sri Lanka's National Biosafety Framework has been developed in conformity with the country's commitments to the Cartagena Protocol, which it has signed and ratified. However, these policies are still at various stages of development or implementation.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

Biotechnology applications in Sri Lanka are quite limited. Of those, molecular biotechnologies, such as recombinant DNA and RNA technologies, are the most commonly used techniques in Sri Lanka. The country does not have GE plants or crops under development that can be commercialized in the near future, however, some GE crop research is underway at the laboratory level. In addition, tissue culture with biotech applications is common.

Biotechnology is mainly used for DNA finger printing, molecular detection of plant pathogens, molecular characterization, disease diagnosis, marker-aided selection, gene identification, and RNA level expression studies on select crops: rice, vegetable crops, root and tuber crops, cucumber, field crops, oil seeds, fruit crops, and on some less common crops. Biotech research is mostly conducted for genome studies and to improve yields through development of varieties which are drought and saline resistant, or resistant to flooding. The applications of genetically engineered plants is limited to laboratory research, although green-house production has been tested in a handful of instances.

Current biotech research on crops includes:

- Diagnosing resistance to: anthracnose in chilies, yellow vein virus in mung beans, and bruchid in cow peas.
- 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. The new varieties are not yet released.
- Developing varieties resistant to brown plant hopper and stem borer.
- Disease diagnosis of cowpea weevil, and viruses on chilies and tomatoes.

b) COMMERCIAL PRODUCTION:

Genetically engineered crops are not being produced at a commercial level; however, tissue culture production with biotechnological applications is widely used at a commercial level for several crops.

c) EXPORTS:

Sri Lanka does not produce GE products, so accordingly does not export GE products.

d) IMPORTS:

Genetically engineered products are effectively banned from import into Sri Lanka. The country does not import GE products except for a few pharmaceutical products that contains GE microbes

and drugs produced from excretions of GE organisms. Food which contains 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.

Imports of animal feed are governed by the Animal Feed Act No. 15 of 1986. 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 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 has been a food aid recipient from the United States and other countries. Nevertheless, regulations prohibit importing of 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 regulation of 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 genetically engineered (GE) products. As a result, the importation or sale of GE products, including ingredients for human consumption, is banned in Sri Lanka. Products intended for human consumption that contains GE ingredients must receive the approval of Sri Lanka's Chief Food Authority. The general quarantine procedure for import of plant and plant products states that "genetically modified organisms (GMOs)" and "living modified organisms (LMOs)" are not allowed to be imported into Sri Lanka. However, the absence of a functioning approval mechanism in effect leads to bans on the sale of seeds and other agricultural products derived from genetic engineering.

Under the GM Food regulation of Sri Lanka, food products for human consumption containing GE ingredients must be labeled, but Sri Lanka 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. As a result, uninformed consumers are needlessly being made skeptical of GE products, causing no pressure to improve the process.

PART B: POLICY

a) REGULATORY FRAMEWORK:

Except for the Control of Import, Labeling and Sale of Genetically Modified Foods regulation of 2006 under the Food Act, No. 26 of 1980 (GM Food regulation), Sri Lanka has not yet passed any laws to specifically deal with genetically engineered products. Sri Lanka is developing multiple

policies to regulate and promote biotechnology. These 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 country is expecting the new legal framework to take effect with the enactment of the National Biosafety Act, which is expected to be in effect by 2019.

National Biotechnology Policy:

Sri Lanka's National Biotechnology Policy (NBP) was promulgated in July 2010, although its enforcement remains inconsistent. The NBP acknowledges the importance of biotechnology in the economic development of Sri Lanka, and identifies several sectors that could significantly benefit from biotechnology, including field crops, livestock, fisheries, forestry, and the food and feed industries. The NBP sets the following priorities:

1. To create public awareness of biotechnology in order to enable informed decision-making.
2. To enhance opportunities through biotechnology in the following broad categories:
    a. Agriculture
    b. Health
    c. Industry
    d. Energy
    e. Environment

3. To build human resources and establish biotechnology parks and centers of excellence.
4. To establish a National Biotechnology Council to plan, coordinate, monitor and evaluate all activities related to biotechnology, including facilitating and supporting bio-industries.

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). The NBFSL was created to ensure an adequate level of protection for the safe transfer, handling, and use of LMOs. Specifically, the NBFSL aims to minimize risks caused by modern biotechnology to biodiversity, human health, and the environment by regulating transboundary movements through use of relevant policies, regulations, technical guidelines and establishment of management bodies and supervisory mechanisms. The NBFSL is a first step towards a more permanent legislative framework for biosafety.

The National Biosafety Policy and The National Biosafety Act:

The Government of Sri Lanka has created a National Biosafety Policy as part of the National Biosafety Framework of Sri Lanka (NBFSL). The National Biosafety Policy "provides for the safe application of modern biotechnology and ensures that no adverse effects would impact conservation and sustainable use of biological diversity in the country." The National Biosafety Policy differs

from the NBFSL; the NBFSL is the Cartagena Protocol-mandated framework of legal, technical and administrative mechanisms for the regulation of biosafety, whereas the National Biosafety Policy implements specific aspects of the NBFSL. The draft National Biosafety Act also intends to implement the NBFSL, which is expected in effect in 2019. No current draft of the National Biosafety Act is publicly available.

The new Act will regulate and monitor the applications of modern biotechnologies, including all "GMOs", "LMOs", and products that would affect food consumption, research, commercial production, and imports and exports. The new Act will detail procedures for approval, monitoring, and enforcement of penalties for violations.

Regulations for Import, Labeling, and Sale of Genetically Modified Food:

The Control of Import, Labeling and Sale of Genetically Modified Foods regulation of 2006 comes under the Food Act of Sri Lanka, No. 26, 1980. This is the only regulation that applies to import of products 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 of "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 requires importers to declare food products with more than 0.5 percent GE content for prior approval by the Ministry of Health. According to the regulations, a risk assessment should be conducted by a technical evaluation committee as defined in the Act, but Sri Lanka lacks capacity to conduct monitoring or risk assessment. Although no GE foods have been approved to date, lack of capacity to monitor could mean Sri Lanka has GE food products in retail stores which are not labeled as such.

Plant Protection Act 1999 No. 35

The Plant Protection Act No. 35 of 1999 replaced the Plant Protection Ordinance. The existing Act does not contain restrictions on the import of GE plants. However, the general quarantine procedure for importing plants and plant products states that "GMO" and "LMO" are not allowed to be imported into Sri Lanka. The importer is requested to declare if the products have GE components when applying for import permits. Such requests are forwarded for review to the Director General of Agriculture or, in the case of animal feed, to the Department of Animal Production and Health. The regulations under the Act are being revised to regulate importing of GE plants and plant products.

Sri Lankan Ministries and Their Policy Roles (Table 1): There is no single regulatory authority to oversee biotechnology products. The NBFSL recommended the formation of a national

competent authority on biotechnology, to be known as the National Biosafety Council. The recommended council, comprising representatives of various concerned Ministries and civil society, will be required to:

a. screen applications and forward them to the relevant Sectoral Competent Authorities (SCA) and;
b. make the applications available for public comment. These authorities are required to carry out risk assessments and report back to the council. SCAs may involve the following agencies:

Table 1. Sri Lanka: National Council for Biosafety Sectoral Competent Authorities, National Biosafety Framework, 2005

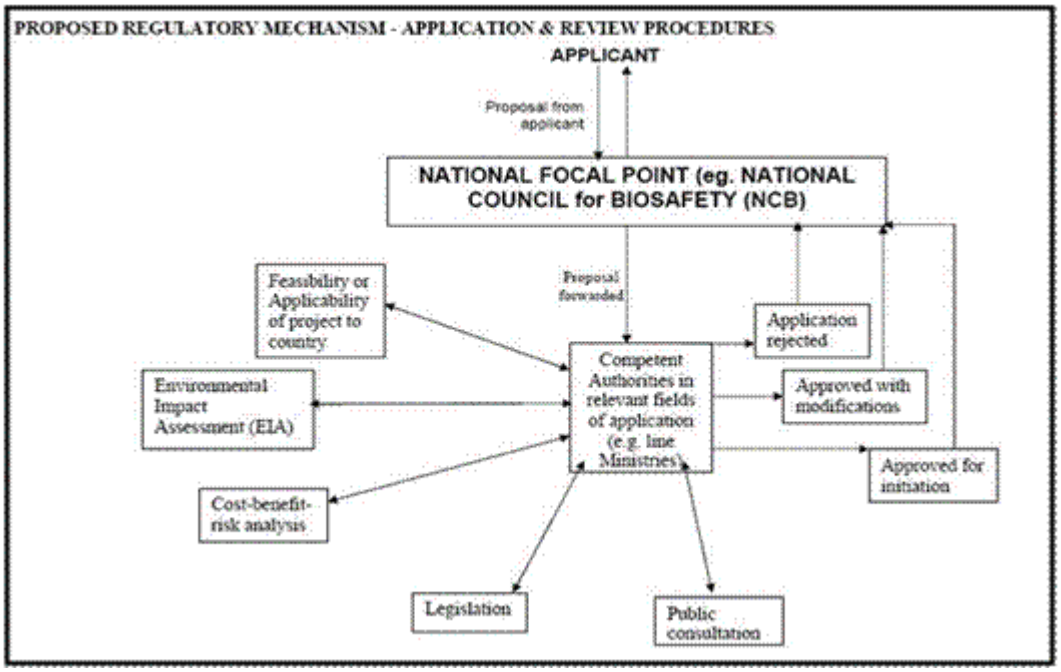
TITLE AGENCY	AREA OF OVERSIGHT
Ministry of Environment (MOE)	The controlling authority for all issues relating to biosafety in Sri Lanka, including research and development, the development of industry linkages, and the establishment of relevant legislations, protocols, and guidelines. The MOE was designated by the government to establish the NBFSL and to interact with the Cartagena Protocol Secretariat.
Department of Agriculture	Agricultural and non-agricultural (e.g. forest species, ornamentals) plants and planting material.
Department of Health	Biotech 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. Biotech fish and/or veterinary pharmaceuticals. Animal feed including biotech feed ingredients.
Department of Wildlife Conservation	Wild animals and tropical aquarium fish.
Department of Fisheries & Aquatic Resources	All aquatic animals and aquatic plants.

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 National Research Council (NRC). SLCARP has a National Agricultural Research Plan (NARP), which identifies the biotechnology research priorities for Sri Lanka. The research grants are provided based on the identified priority areas for the country.

The following is the proposed flow chart for the evaluation of biotech applications:

Figure 1. Sri Lanka: Biotech Approval Application, National Policy on Biosafety



Source: National Policy on Biosafety

b) APPROVALS:

No GE crop is approved for cultivation or import in Sri Lanka. There are no regulations that mandate prior approval for GE research. Nonetheless, the National Science and Technology Commission was vested with power 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 institutions.

c) STACKED or PYRAMIDED EVENT APPROVALS:

Existing regulations do not address how stacked or pyramided events would be approved.

d) FIELD TESTING:

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 is no coexistence guidelines.

g) LABELING:

According to the Control of Import, Labeling and Sale of Genetically Modified Foods regulation of 2006, 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 genetically engineered (GE) food, or food ingredients used in the preparation of food, must include the statement 'genetically modified' in conjunction with the name of that food or ingredients, or processing aid irrespective of the size of the label or package. If the product is displayed for retail sale without packaging, the same information must be attached as a label on the food. Food that has GE content of less than 0.5 percent is exempted from these regulations, provided that the presence of such GE content is considered 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. No interceptions have been reported of import consignments containing unapproved GE events. There is no routine monitoring of products in the market place 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.

i) LOW LEVEL PRESENCE POLICY:

Sri Lanka has a Low-Level Presence (LLP) policy only for food products imported for human consumption. Foods that have GE content of less than 0.5 percent are exempted from these regulations, if the presence of such content is considered technically unavoidable and the organisms have been subjected to a scientific risk assessment. Sri Lanka has zero tolerance for unapproved GE events, although the LLP policy 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 if they are considered detrimental.

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. While the Act gives Plant Breeders Rights on new plant varieties, if a variety is a GE plant, it first needs approval under the provisions of the new law before it can be given the Plant Breeders 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 identified as the National Focal Point for Cartagena Protocol on Biosafety and has responsibility for developing 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 has been a WTO member since 1995 and a member of GATT since 1948. Sri Lanka has not stated in international forums its positions -- 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 public and regulators in Sri Lanka have negative perceptions or attitudes toward genetically engineered (GE) products and research. Although the research community certainly recognizes the benefits of GE products, they are constrained both by the lack of commercial marketing opportunities, clarity in regulations for GE research and by the lack of basic research funding.

b) MARKET ACCEPTANCE/STUDIES:

Nothing to report

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. Also, 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. The importers are instructed to declare such imports to the Department of Animal Production and Health which will approve or deny such imports.

e) TRADE BARRIERS:

The trade barriers applicable to plant products are also applicable for GE animal products.

PART E: POLICY

f) REGULATORY FRAMEWORK:

Imports of animals are governed under the Animal Disease Act No. 59 1992. 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.

g) APPROVALS

No regulations detail requirements on labeling or traceability of GE animals and products, including cloned animals.

h) INNOVATIVE BIOTECHNOLOGIES:

Nothing to report

i) LABELING AND TRACEABILITY:

No regulations detail requirements on labeling or traceability of GE animals and products, including cloned animals.

j) INTELLECTUAL PROPERTY RIGHTS (IPR):

No specific regulations exist on IPR for animal biotechnology.

k) 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 a permanent delegate of the OIE. Sri Lanka is also a member of the Codex Alimentarius since 1972. Sri Lanka is not known to have stated positions on GE animals or cloning in international forums.

l) RELATED ISSUES:

Nothing significant to report.

PART F: MARKETING

m) PUBLIC/PRIVATE OPINIONS:

Similar to plant biotechnology

n) MARKET ACCEPTANCE/STUDIES:

Nothing to report