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Biotechnology

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Approved by:
Holly Higgins
U.S. Embassy

Prepared by:
Adrian Mendis

Report Highlights:
Biotechnology in Sri Lanka is largely limited to research and testing. Although agricultural biotechnology is widely accepted among the scientific community, some government officials and NGOs are less convinced of the benefits of the technology. Tissue culture is the only aspect of biotechnology that is applied on a commercial scale. A draft national policy on biotechnology has been compiled. GM labeling regulations were introduced in January 2007 and are moving toward full implementation, likely to the detriment of U.S. food and agriculture imports.

Includes PSD Changes: No
Includes Trade Matrix: No
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SECTION I: EXECUTIVE SUMMARY

Biotechnology is not widely practiced in Sri Lankan agriculture, with tissue culture being the major feature of biotechnology in local agriculture. Advancing biotechnology in agriculture is discussed at various agricultural scientific forums. However, there is little applied implementation of programs in the field. Support for biotechnology in terms of research, development and human resources is lacking in universities, institutes and government. The country has yet to progress to commercial trials of crops beyond laboratory tests and private sector involvement in biotechnology is limited. Although a biotechnology regulatory system was compiled as part of the National Biosafety Framework for Sri Lanka (NBFSL), there has been no implementation of the NBFSL thus far. The NBFSL was developed in conformity to the country's commitments as a signatory to the Cartagena Protocol, to regulate the import of biotech foods, and to ensure the safe utilization of modern biotechnology in domestic agriculture. The U.S. has provided comments on the framework and expressed concern at certain clauses included therein that are not scientifically based.

SECTION II: BIOTECHNOLOGY TRADE AND PRODUCTION

The GM labeling regulation that was published in January 2007 is moving toward full implementation and U.S. agricultural exports will be affected by this regulation. As a result, some importers have stopped importing GM products. Food imports with a GM content of 1 percent or less do not require prior approval. There is no commercial production of biotechnology crops in Sri Lanka, nor are any biotechnology crops under development in the country. Sri Lanka imports soybeans, corn flour, planting seeds, lentils, cotton, and tobacco. Although Sri Lanka requires non-GMO certification for soybeans and corn, the country does not have a mechanism to test whether the imported products are bioengineered.

SECTION III: BIOTECHNOLOGY POLICY

Sri Lanka is drafting a national policy on biotechnology. According to this policy, agricultural biotechnology is identified as a means to make a substantial contribution in a diverse range of applications such as agriculture, livestock, fisheries, pharmaceutical, environment management, biofertilizer and waste management. In August 2005, the Ministry of Environment and Natural Resources (MENR) published the National Biosafety Framework for Sri Lanka (NBFSL), www.biosafety.lk/pub/policy/policy.doc). However, it is not implemented and there is no regulatory framework in force in Sri Lanka for agricultural biotechnology. The framework was launched to regulate imports of bioengineered food and the application of biotechnology in domestic agriculture. The NBFSL website, www.biosafety.lk, contains various clauses pertaining to biotechnology, such as the Legal Report on Biotechnology and Biosafety; Technical and Technology Aspects of Biosafety; and Institutional Aspects of a National Biosafety Framework.

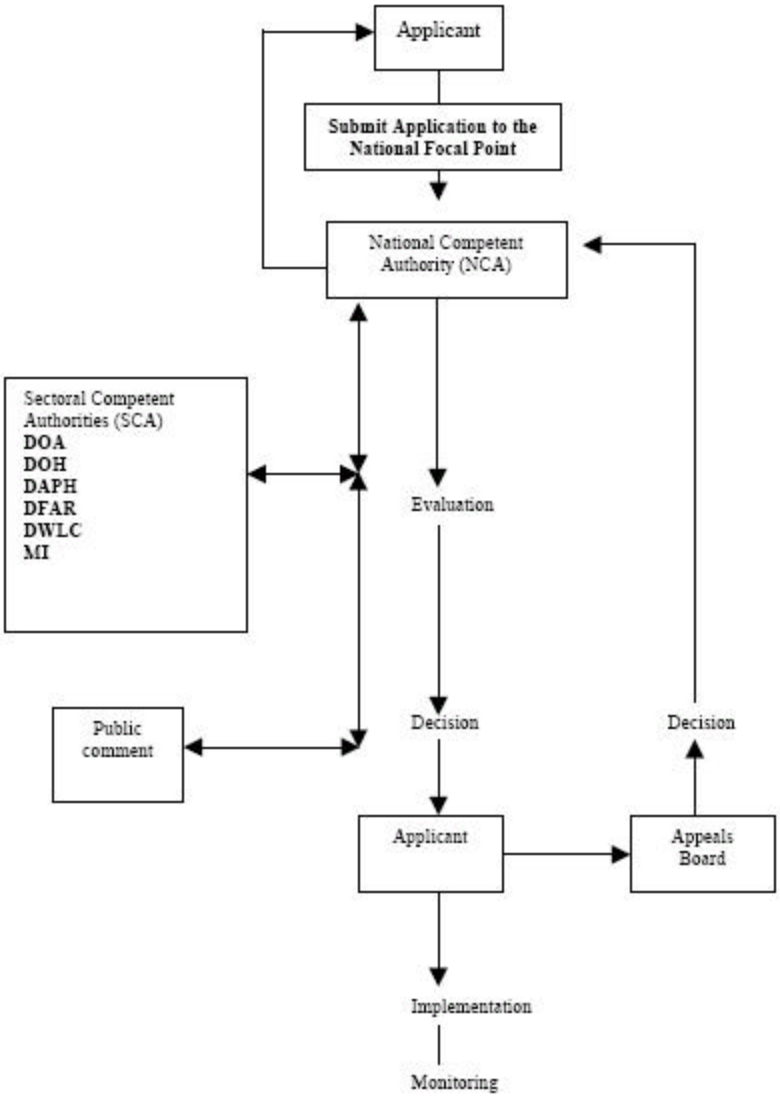
Currently, there is no single regulatory authority to oversee biotechnology products. The MENR was designated by the government to establish the NBFSL, and to interact with the Cartegena Protocol Secretariat. The NBFSL recommended the formation of a national competent authority, to be known as the National Council for Biosafety (NCB), as the apex body on biotechnology. The council, comprised of representatives of various concerned Ministries and civil society, will be tasked with a wide range of responsibilities, such as developing research and development-industry linkages to promote biotech industries, and establishing legislation, protocols, and guidelines. The council will have to be established by a framework law or an Act of Parliament. However, this council is yet to be named.

The council will be required to: (a) screen applications and forward them to the relevant Sectoral Competent Authorities (SCA) and; (b) make them available for public comment.

These Authorities are required to have their own mechanism to carry out risk assessments and report back to the council. SCAs may involve the following agencies:

Department of Agriculture (DOA):	Agricultural and non-agricultural (e.g. forest species, ornamentals) plants, and planting material
Department of Health Service (DOH):	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 (DWLC):	Wild animals and tropical aquarium fish.
Department of Fisheries & Aquatic Resources:	All aquatic animals and aquatic plants.

Following is the NBFSL's proposed flow chart for the evaluation of biotech applications:



The National Science Foundation recommended the establishment of an authority under the Ministry of Science & Technology that would be responsible for initiating, promoting, regulating, and monitoring biotech industries. It would also regulate the resultant activities with respect to safety, quality, and ethical issues.

The labeling of packaged food is required under the "Food (Labeling & Advertising) Regulations 2005," for consumer awareness, health, safety, and nutrition reasons. A labeling and control regulation of biotech products was introduced in January 2007. Implementation of the regulation is affecting U.S. food exports as the regulation is burdensome and costly. Additionally, some of the details required by regulators such as genetic sequence is proprietary and will not be divulged by companies. Importers have also expressed concern about the excessiveness and complexity of the labeling regulation. Although the general public is not familiar with biotechnology, the regulatory systems established by policy makers may cause consumers to be unnecessarily skeptical of GM products.

Sri Lanka has signed and ratified the Cartagena Biosafety Protocol, which is affecting trade due to the GM regulation which is part of the framework. Sri Lanka has limited capabilities (personnel and facilities) to test for biotech food. Under the proposed monitoring and enforcement criteria of the NBFSL, approval of biotech products for import and use in Sri Lanka will be subject to rigorous testing and risk assessments.

SECTION IV: MARKETING ISSUES

At present, market acceptance for agricultural biotechnology products is not an issue. GM products are consumed without reservation.

SECTION V: CAPACITY BUILDING

The Council for Agriculture Research Policy (CARP) and the Sri Lankan National Science Foundation (NSF) have identified biotechnology as a means to improve the domestic agricultural sector's productivity, profitability, and to lessen the harmful environmental effects of chemical fertilizers currently in use. The NSF is looking to partner with universities to train local scientists on biotechnology and facilitate technology transfer. Several workshops on biotechnology have been conducted, with the most recent being a FAO/CARP sponsored conference. Key stakeholders, including the government, private sector, universities, and NGOs participated in the workshop.