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Pakistan

Biotechnology - GE Plants and Animals

Annual

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Report Highlights:

In 2010, Pakistan formally approved eight Bt cotton varieties for general cultivation. While a biotech framework and necessary legislation have been put in place, the government's capacity to evaluate and monitor new biotech crops is weak. Another major development is the signing of MOU's between public and private sector institutes with U.S and the Chinese biotech seed companies. Implementation of the Plant Breeder's Rights Act and amendments to the Seed Act are still pending in the parliament. Aside from traditional vaccines and some genomic studies there is little Genetically Engineered (GE) animal activity in the country.

Section I. Executive Summary:

The administration and farmers in Pakistan are generally pro-biotech. In May 2010 eight Bt cotton (MON 531) varieties were finally approved by the Government of Pakistan (GoP) for general cultivation. A number of Genetically Modified (GM) crops are currently under development with public/ private / multinational seed companies in Pakistan.

Bt varieties now account for almost 100% of cotton area cultivated (8.5million acres) in Pakistan. All components such as crop co-coordinated trials, biosafety evaluation and Intellectual Property Rights (IPR's) systems are in place.

The major U.S. agricultural trade interests related to biotechnology in Pakistan at this time are related to cotton, corn, soybeans and animal feed.

There are no laws banning the import of biotech products (i.e. bulk agricultural commodities, snack foods and processed items).

Pakistan has ratified the Cartagena Protocol of Biosafety (CPB) and maintains a framework of handling Genetically Modified Organisms (GMO's).

International seed companies are actively engaged in meeting greater demand for GM cotton and corn seeds in the country.

A significant development in 2010 is the entry of Chinese seed/ biotech companies into Pakistan. These companies made contract agreements with private companies as well as with public sector institutes for the importation of GM seeds. It is unclear whether Pakistan's biotech regulatory requirements were followed in the case of these imports.

Pakistan has an official regulatory framework for agricultural biotechnology in place; however, its ability to inspire private sector investment is nascent. The Plant Breeders' Rights and Amendments to the Seed Act of 1976 are still awaiting approval from the parliament.

Animal biotechnology in terms of genomics (DNA finger printing) and vaccine for livestock are gaining strength, while animal cloning is still at the planning stage. Some work on Embryo Transfer Technology is under way.

Section II. Plant Biotechnology Trade and Production:

Commercial Production of Biotech Crops

Bt cotton (MON 531) was NOT patented in Pakistan, however, it was widely cross bred with Pakistani varieties by public as well local private seed companies. In May 2010, the Punjab Seed Council (PSC), a provincial/state seed authority formally approved eight biotech cotton varieties for cultivation in Punjab, which is a key cotton producer in Pakistan. Out of Pakistan's total cotton acreage of over eight million acres, Punjab accounts for 70 percent of the cotton growing area.

The Bt varieties under cultivation are Open Pollinated Varieties (OPVs), thus seed is also utilized for the next season's planting. Local seed companies are employing conventional breeding tools for seed multiplication. Seed certification is conducted by Federal Seed Certification and Registration Department (FSC&RD), MINFA, GoP.

Biotechnology Crops under Development

Pakistan has established a comprehensive biotech framework, so far, 35 Institutional Biosafety committees (IBC's) have been notified. A Technical Advisory Committee (TAC) has convened 13 meetings and the National Biosafety Committee (NBC) has held eight meetings. A number of GM crops are in the development stages in Pakistan. These are being developed by public sector as well as private sector (national and foreign) seed companies. At present, these institutes are mainly engaged in plant tissue culture; only six research centers are capable of performing DNA recombination to develop bioengineered plant varieties.

A reported 36 cases of GM crops have been submitted to the National Biosafety Committee (NBC), of which 26 have been notified by the Environmental Protection Agency (EPA) for laboratory/ green house / field testing and commercialization.

Table 1: Genetically modified crops in Pakistan

GM Crop	Genetically Engineered traits	Stage
Cotton	Insect resistance with biotech and other genes, virus resistance, salinity tolerance, fiber modification, drought, herbicide tolerance	Experimental/field trials/ready for release.
Rice	Bacterial blight resistance, insect resistance	Field trial/ ready for release
Corn	Drought, herbicide and insect resistance.	Experimental
Potato	Virus resistance, salt tolerance, insect resistance	Experimental
Sugarcane	Insect resistance	Experimental
Chickpea	Insect resistance, virus resistance	Experimental
Sunflower	Drought and herbicide resistance	Experimental
Chilies	Virus resistance	Experimental
Tomato	Virus resistance, male sterility, salinity tolerance	Experimental
Cucurbits	Virus resistance	Experimental
Tobacco	Virus resistance	Experimental
Groundnut	Fungal resistance, herbicide tolerance	Experimental

In addition to Bollgard II cotton and Round up Ready Flex (herbicide tolerant) cotton, Bt /heat tolerant

corn is also undergoing trial and expected to be released in 2011/12.

Imports of Crops and Products of Biotechnology

Pakistan imports large quantities of cotton from the United States and other sources. Much of this is BT cotton. Pakistan also imports GM cotton and corn seed from multi national companies of USA, Germany and India. Import approval was granted to multinational seed companies for a period of 5 years. Monsanto imported 22 hybrid cotton varieties, while DuPont and Bayer crop sciences imported 4 and 10 hybrid varieties of corn and cotton respectively.

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Public sector entities such as the Punjab Seed Corporation (PSC) and Pakistan Agriculture Research Council (PARC) Islamabad imported GM cotton seed (OPV as well as hybrid) from Silver Land Biotech Company, China and Farm No148 Xiaiang Province, China respectively. A number of domestic seed companies (Ali Akbar, Four Brothers (4B), Guard, Auriga and Sitara seed companies) have signed MOU's with various Chinese seed companies for the import of GM seed of various crops. Some of these companies also imported Bt cotton seed. The import of Chinese cotton seed by PARC, PSC and by private companies sparked controversy as there were allegations that Pakistan's biotech regulatory requirements were not followed.

Imports of biotech bulk commodities include feed corn, soybeans and soybean meal from India, the United States, Brazil, Argentina and other sources. Pakistan also imports GM canola/rapeseed and sunflower seed from Canada and Australia.

U.S. soybean oil derived from biotech soybeans is also imported into Pakistan. Snack foods and other processed products containing U.S. soybean oil are imported into Pakistan without difficulty.

Food Aid

There are no issues related to imports of GM food aid to Pakistan.

Pakistan is a major food aid recipient. Since 2003, Pakistan has received significant quantities of soybean oil, wheat, non-fat dry milk and tallow from the United States under various USDA-funded assistance programs.

Non-U.S. Biotech Crops in Export Channels

In public sector, a number of crops like cotton, rice, wheat, corn, potato, ground nut are being developed locally or with the collaboration of Chinese seed companies which have not passed through

Pakistan regulatory system.

The raw cotton produced by GM cotton seed is being exported to a variety of destinations including USA. Pakistan's major export items include cotton yarn, cotton fabric and items manufactured from cotton. These products are derived from illegal BT cotton grown in Pakistan or from bioengineered cotton imported from other trading partners. Cotton textiles and apparel are major export items from Pakistan to the United States.

Section III. Plant Biotechnology Policy: Regulatory Framework

Pakistan ratified the Cartagena Protocol of Biosafety (CPB) and maintains a framework for handling GMO's. However, the capacity in terms of infrastructure and human resources is lacking.

The proposed regulatory guidelines are built upon on a three-tier system composed of the National Biosafety Committee (NBC); a Technical Advisory Committee (TAC); and Institutional Biosafety Committees (IBC).

The Secretary of the Ministry of Environment heads the NBC, and is responsible for oversight of all laboratory work and field trials, as well as authorizing the commercial release of GM products. The three monitoring and implementing bodies administer enforcement of the National Biosafety Guidelines. The IBC may make recommendations to the NBC regarding the awarding of exemptions for laboratory and fieldwork related to products of bioengineering. These recommendations may be accepted, and formal approval granted, if sufficient information and grounds exist to consider the risk as being minimal or non-existent. After permission for deregulation is granted by the NBC, approval can still be withdrawn provided sufficient technical data and other evidence later becomes available that warrants a review.

The other important ministry dealing with production and release of GM crop is Ministry of Food and Agriculture (MINFA). The ministry developed several Standard Operating Procedures (SOP's) for handling of cases of import/approval/release of GM crops; however, all these have yet to be promulgated.

Responsible Government Ministries/Institutes

The NBC at the National Biosafety Directorate in the Ministry of Environment is responsible for all Biosafety work related to biotechnology. There are nearly 20 members of the NBC from the ministries of Environment, Science and Technology, Health, Agriculture, Education, the Pakistan Agriculture Research Council, the Pakistan Atomic Energy Commission, and representatives from the Provinces, Azad Jammu and Kashmir. The NBC discusses, evaluates and make decisions regarding submissions from the IBC and/or the TAC.

Pakistan's biotech research institutes, multinational firms and local companies marketing pesticides and seeds follow agricultural biotechnology issues closely. They monitor changes in the structure of the regulatory framework, the formation of biotechnology policy and the implementation of action

plans and procedures.

The National Commission on Biotechnology (NCB) was established in 2001, with the purpose of focusing on policy issues in the field of biotechnology. The NCB is functioning on borrowed time as project funds have expired and the GoP has been unable to shift the NCB from project status to regular institute. NCB organized several seminars with various Chamber of Commerce and public sector institutes for commercialization of Biotech products. In that capacity, the NCB has funded 34 domestic and international seminars and conferences at various universities and institutes. Unfortunately, the NCB has so far been ineffective in gaining consensus in resolving issues related to biotech intellectual property rights, plant breeder's rights and Biosafety laws.

The Ministry of Food and Agriculture (MINFA) has taken lead in public/private sector cooperation with Monsanto in the aftermath of an MOU signed between the two parties. The Government of Punjab also signed various MOU's with Chinese companies looking for cooperative arrangements in biotechnology to enhance agricultural production at the provincial level.

Unresolved Political Factors – IPR and Seed Policy

On the policy and legislative side, the Seed Act of 1976 Amendment and the Plant Breeders' Rights Bill have yet to be approved by the parliament.

The current Seed Act is outdated and limited to public sector seed companies only. Proposed amendments to the Seed Act would allow Research and Development (R&D) in national centers to transfer genetic material to private companies. Punitive measures and fines have been proposed to deter the illegal sale of seed.

The Plant Breeders' Rights (PBR) Bill would allow for the registration of varieties and the payment of royalties bring Pakistan into compliance of its WTO commitments under the TRIPS - IPR. Farmers would be allowed to exchange seed but could not sell the seed on a commercial basis.

The delay in seed and plant breeder legislation is perceived as a major impediment to investment in Pakistan by multinational seed companies. Reluctance in finalizing this legislation is due, in part; to the desire of Pakistan's public seed facilities to dominate the seed market. Moreover, potential investors are wary that their proprietary rights will be fully protected under the current proposals.

Approved Biotechnology Crops

During May 2010, GoP approved eight biotech varieties of cotton for their commercial cultivation.

Although the genes of the approved eight varieties are unknown, it is expected that their approval will bring some sanity in the seed business as owners will be held liable for any illegal activities. Moreover, the GoP can start Resistance Monitoring Programs after official approval of Bt varieties.

The Bollgard II (stacked gene technology) seed is patented in Pakistan and as a result, seed companies who want to use the technology will have to enter into a licensing arrangement with Monsanto. The licensing process is expected to minimize pilferaging. The GoP agreed to provide compensation to third parties negatively impacted by any unapproved biotech planted acreage.

Field Testing of Biotechnology Crops

The over all situation of GM crop in the country as per record of NBC/EPA, GoP is given in the table 1. In addition to Bollgard II cotton and RR Flex (herbicide tolerant) cotton, Bt /HT corn are also under trials and expected to be released in 2011/12.

Treatment of Stacked Events

National Biosafety Committee allowed stacked gene (Cry 1A and Cry 2Ab) in cotton developed by Centre of Excellence in Molecular Biology (CEMB), Lahore. Several other stacked gene products are in the pipe line and will be put for approval soon.

The National Biosafety Committee considers each event as a separate case and would consider combined “stacked events” as a unique event.

Product Registration

This system is making use of an old approval system with an additional requirement of obtaining approval of NBC/EPA for Biosafety issue. However, there are still many un-resolved issues and SOP's are still to be approved / published by MINFA. Despite much confusion, many public institutes and private sector companies are struggling to obtain commercial approval/import permits from the chaotic and lethargic system.

Policy on Coexistence

At present, the GOP has not formulated a policy on coexistence between biotech and non biotech crops.

Labeling of Packaged Foods or Feed

Pakistan has not made any decision regarding of packaged food or feed originating from GM foods/ additives/crops. GM derived edible oil and food is being imported without any restrictions. The country has in place GMO testing facilities for import and export of food commodities, and this facility is being utilized by the clients- importers and exporters.

Biosafety Protocol

Pakistan has ratified the Cartagena Protocol on Biosafety (CPB). Now, Pakistan is the full fledged member of CPB, its rules are fully applicable but capacity to implement its policy is badly lacking. The National Biosafety Directorate is still not a permanent body and facing chronic shortage of funds and trained human resource.

Biotechnology-Related Barriers to Trade

Pakistan has just approved eight cotton biotech varieties for commercial cultivation. However, there are no laws banning the import of biotech cotton for further processing, biotech oilseeds and meal, biotech feed corn, soybean or other edible oil derived from biotech oilseeds or products containing such oil.

Delayed implementation of seed act, plant breeder's right and amendments in quarantine laws are impediments to physical and intellectual investment in Pakistan. MNC's and local private companies

are reluctant to invest in seed industry infrastructure and in R&D activities in developing GM crops in the country.

Legislation for Commercially Planted Biotech Crops

Regulatory system and the necessary legislation have been put in place but the working scientists need capacity building in legislation, regulatory and policy issues relevant to diversified crops under development in Pakistan.

Section IV. Plant Biotechnology Marketing Issues: Market Acceptance of Biotech Products

U.S. agricultural and processed products exports to Pakistan are on the rise as these are very much accepted by all the segments of the society.

Government of Pakistan and Agriculture ministry is pro-biotech. Industry and consumers currently accept GM soybeans, soybean meal, soy oil and other processed food products without opposition. NGO's have raised their voices against agricultural biotechnology with minimal impact on the public debate.

Pakistan's agricultural community advocates the utilization of GM technology to increase productivity. As evidence, nearly 100 percent of the 2010/11 cotton crop is estimated to be planted to Bt cotton varieties.

Section V. Plant Biotechnology Capacity Building and Outreach: Recent U.S. Government or USDA-funded Activities

The U.S. Government has funded the following capacity building and outreach projects in Pakistan related to agricultural biotechnology.

- During 2009/10 USDA funded international conferences on wheat stem rust, Foot and Mouth Disease (FMD). The USDA has also indicated a willingness to support development of Pakistan's biotechnology framework.
- Biotechnology has been considered as an important area for funding under trilateral collaboration among U.S. Pakistan and Afghanistan. A Pakistani delegation headed by Federal Minister for Agriculture (FAM) visited Washington D.C in May 2009 and discussed broad areas of collaboration under trilats.
- Two groups- a seed technology group and a dairy genetics group consisting of six fellows for each participated in a 2009 Cochran program.
- During 2009, three scientists received training at CIMMYT Mexico for management of wheat stem rust under Borlaug program and three more scientists will receive similar training during 2010.
- Under a 2003 PL-480 Food for Progress grant with USDA, the University of Agriculture

Faisalabad received and agreed to disburse \$50,000 per year to fund Borlaug Fellows to conduct research on issues of agricultural biotechnology.

- Post-doctoral research on biotechnology and related agricultural issues will be funded under a Young Scientists Program, as part of the USDA-funded sustainable endowment to support the Agricultural Linkages Program at the Pakistan Agricultural Research Council.
- An MOU for \$7.5 million has been signed under the Pakistan-U.S. Science and Technology Program between Pakistan's Higher Education Commission (HEC) and the Ministry of Science and Technology and the U.S Agricultural Research Service (ARS) for scientific collaboration and capacity building of scientists.
- A Pak-U.S. Project USNAS with the Higher Education Commission and Ministry of Science and Technology covers 3-5 projects on GM crop development.
- Agricultural Linkages Program at the Pakistan Agriculture Research Council, Islamabad and Faculty Development, Technology Transfer and Product Commercialization (FDTTPC) funding to University of Agriculture, Faisalabad – ongoing activity to fund projects on biotechnology for crop and livestock improvement.

Areas for Potential Future Capacity Building Efforts

- Pakistan is looking to build the capacity of its young scientists in the legislative, regulatory, and policy areas related to agricultural biotechnology, biosafety and nanotechnology.
- Other areas for future biotechnology collaboration include with the National Biosafety Directorate at the Ministry of Environment, the Federal Seed Certification and Registration Department at MINFA, specialists at Pakistan's National Animal and Plant Health Inspection Service (NAPHIS), and scientists involved in biotechnology applications for crops and livestock in MINFA and Ministry of Livestock.

Section VI. Animal Biotechnology: Development and use

Aside from traditional vaccines and PCR technologies for genomic studies of pathogen and food animals there are no GE animal activities in the country. Limited quantities of chemical based veterinary pharmaceuticals are formulated from imported raw materials. However, little work on Embryo Transfer Technology is underway.

Nanobiotechnology

The GoP has established a National Commission on Nanotechnology. Several projects have been awarded, mainly in the field of Material Sciences in PIEAS, COMSATS (academic institutes). However, a small project has been funded in Agricultural Nanobiotechnology related to the use of nanoparticles for plant genetic engineering utilizing a Bio-Rad biolistic gene gun at National Institute for Biotechnology and Genetic Engineering (NIBGE), Faisalabad. The group received heavy funding and is well equipped to carry out R&D studies but suffers from a severe shortage of trained

human resources.

Regulations

Biosafety Rules of Government of Pakistan-2005 encompass GE animals. Some issues are dealt with by the Ministry of Livestock, PARC (Animal Sciences Division) as well as by NAPHIS, MINFA etc.

A specific regulation of export control list was promulgated in 2004.

In 2005, GOP notified Export Control List of goods, materials, equipment subject to export control.

In March 2007, Strategic Export Control Division (SECD) was established in Ministry of Foreign Affairs (MOFA).

SECD functions as licensing body for export control of sensitive dual-use goods, technologies, materials & equipment.

Relevant government entities involved in the regulation of the genetic engineering of animals are Ministry of Foreign Affairs, Ministry of Commerce, Ministry of Food & Agriculture and Ministry of Livestock

Stakeholders/Public Opinions

There is no public campaign against the genetic engineering of agriculturally-relevant animals. Actually, there is little public awareness in this regard. Use of lactating hormones in milking animals is a routine activity.

Dairy industry (packed milk, dairy products, ice cream etc) is flourishing in Pakistan and demand is on the rise. Public opinion is in favor of healthy products. There is no preference for organic nor is there any opposition to GM products. Basic demand is to have high productivity with less input.

International Organizations

In Pakistan National Plant and Animal Health Inspection Service (NAPHIS) and National Biosafety Committee (NBC) are responsible for these activities. Ministry of Livestock was separated from Ministry of Food and Agriculture is also looking after GM animal issues.

USDA is partly helping in genomic studies of food animals. Pakistan is a member of FAO, OIE and several multilateral bodies. Pakistan developed efficient system of management of Bird flu and declared free of rinder pest and looking to implement a progressive control program for FMD.

Outreach, Needs and Strategies

Expertise and capacity building from USDA is required in following areas:

- Quality Assurance/ Biosafety of Animal Vaccines
- Genomic studies of Food Animals as well as Animal pathogens.

The share of livestock as a percentage of agricultural Gross Domestic Product (GDP) is increasing at a rapid rate. Numerous bodies have been established to support dairy development i.e. Dairy Development Board, Pakistan Livestock and Dairy Development Board, and many regional organizations are involved in overall improvement of livestock and also dairy industry.

US Aid- Pakistan has identified Livestock and Dairy Development as the key sector to improve livelihoods of the rural masses. It is in the process of devising a comprehensive strategy with a focus on nutritional and health management, genomics improvement and the products value chain development.

Pakistan's country specific requirement is "Halal" by origin.