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Agricultural Biotechnology Annual

Agricultural Biotechnology Annual 2012

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Report Highlights:

In 2012, Pakistan formally approved eight Bt and six conventional 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 was put on hold since last year's devolution of key ministries. 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 2012, eight Bt cotton (MON 531) and six conventional (Non Bt) cotton varieties were 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 nearly three million hectares of the total cotton area cultivated (8.5 million 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, corn, and canola seeds in the country.

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. The situation was further aggravated due to last year's devolution of federal ministries that had stakes in plant and animal biotechnology.

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

The appearance of Pakistan as 5th largest GM crop growing country in the International Service for the Acquisition of Agricultural Biotechnology Applications (ISAAA) report 2011 is testimony of the successful plantation of GM crop in the country. At present (2012-13) nearly 3 million hectares is under Bt cotton crop in the country.

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. During 2012 eight Bt cotton and six conventional varieties were approved by the respective state seed councils. Last year, the Punjab Seed Council (PSC), formally approved nine biotech cotton varieties for cultivation in Punjab.

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), Ministry of National Food Security and Research, Government of Pakistan.

Biotechnology Crops under Development

Last year, the National Biosafety Committee (NBC) of Environment Protection Agency (EPA), Pakistan had approved 104 cases of GM crop development for labs, green houses and field evaluations (Table-1). Since devolution the whole system was put on hold because the Federal Government has still not notified the Secretary NBC. The R&D sector of crop biotechnology acquired expertise in various aspects of genetic engineering in some important commodities like cotton, corn, rice, wheat, sugarcane and groundnut. The first generation of GM crops (single gene) is at advanced levels of evaluation while 2nd generation of GM crops (2-5 genes) is in the process of development. Pak-US wheat and cotton productivity enhancement projects under the Kerry Lugar Berman bill are progressing well.

Table-1: APPROVAL OF GM CASES WITH NBC/ PAK-EPA, GOVERNMENT OF PAKISTAN

IBC	38 (notified) Public Sector + Private (National / Multinational)
TAC	16 Meetings Held
NBC	09 Meetings (Last meeting held 15 February, 2011)
Total Cases Submitted	155
Cases notified	104
Labs + GH + Field Studies	98
Commercial approval	14 (08 Bt + 06 Conventional Cotton Varieties)

As noted in the table 1, 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. The public sector in Pakistan, despite an acute financial crunch, is still providing considerable funds for agri-biotech development in the country. For example, the higher Education Commission (HEC) and Punjab Agriculture Research Board (PARB) have provided substantial funds for GM crop development. It is encouraging to note that many projects are on GM wheat which is staple food of the locals. In addition to Bollgard II cotton and Roundup Ready Flex (herbicide tolerant) cotton, Bt /heat tolerant corn is also undergoing trials and is expected to be released as soon as it completes requisite formalities.

Imports of Crops and Products of Biotechnology

Pakistan imports large quantities of cotton from the United States and other sources, much of it Bt cotton. Pakistan also imports GM cotton, canola and corn seed from multinational companies of USA, Australia, Canada, Germany, Brazil 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. 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 No. 148 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 over allegations that Pakistan's biotech regulatory requirements were not followed and in some cases, the imported material did not perform at all.

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 (NFDM) and tallow from the United States under various USDA-funded assistance programs.

Non-U.S. Biotech Crops in Export Channels

In the 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 reportedly 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 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. Last year's devolution of Federal Ministries of Environment, Food and Agriculture, Health, among others, have shattered the existing set up. The government's lackluster attitude to revamp the existing institutes has put the whole system on hold and it will take time to adjust to the new situations.

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 National Biosafety Committee (NBC) 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.

Responsible Government Ministries/Institutes

The NBC at the National Biosafety Directorate in the newly created Ministry of Climate Change is responsible for all Biosafety work related to biotechnology. There are nearly 20 members of the NBC from the ministries of Science and Technology, Commerce, Planning, Textile, the Pakistan Agriculture Research Council, the Pakistan Atomic Energy Commission, Capital administration and Development Division (CADD) 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.

Unresolved Political Factors – IPR and Seed Policy

Implementation of the Plant Breeder's Rights Act and amendments to the Seed Act are still pending in the parliament. Their implementation is further aggravated due to last year's devolutions of Federal Ministries of Environment, Food and Agriculture, Health, among others. The important functions performed by these ministries have been assigned to other ministries/ divisions, most of which lack specific expertise. So, under changed scenario the implementation of above mentioned Acts seems to be a time lag process to adjust to new situations. The approval of these legislations will help boost investment in human and capital resources.

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 bringing Pakistan into compliance of its WTO commitments under the Trade Related Intellectual Property Rights (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 to finalize 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

On the multinational company front, field testing of corn by Monsanto, Pioneer and Syngenta is in process, while Monsanto, Nath Seed/Guard and Bayer is in the process of field testing for Bt cotton.

On domestic front, during 2012 eight Bt cotton varieties and six conventional (Non Bt) varieties were approved by state seed councils. Last year, the Punjab Seed Council (PSC), formally approved nine biotech cotton varieties for commercial cultivation in Punjab.

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

Field Testing of Biotechnology Crops

The overall situation of GM crops in the country, according to the NBC/EPA, GoP is outlined in 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 the ensuing year.

Treatment of Stacked Events

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

to be submitted 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

The product registration system still makes use of an old approval system but with an additional requirement to obtain approval from NBC/EPA for Biosafety issues. However, there are still many un-resolved issues and SOP’s are still waiting approval / publishing by the Ministry of Science and Technology and Ministry of Commerce. Despite much confusion over product registration, many public institutes and private sector companies keep struggling to obtain commercial approval/import permits from the chaotic and lethargic approval 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 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 a 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 after the devolution regime the Directorate is attached to the newly created Ministry of Climate Change. Stakeholders hope the new ministry will properly take care of the funds and the capacity building of the staff.

Biotechnology-Related Barriers to Trade

Pakistan has just approved eight cotton biotech varieties and six conventional varieties for commercial cultivation in Punjab and Sindh. 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 the seed act, plant breeder’s rights and amendments in quarantine laws are impediments to physical and intellectual investment in Pakistan. Multinational Companies (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

A regulatory system and the necessary legislation have already 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.

The GoP and Agriculture institutions are pro-biotech. Industry and consumers 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 three million hectares of the 2012/13 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 2010/11 USDA launched \$20 million program to combat Ug-99 in wheat, CLCV in cotton and FMD in animals.
- 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 funds to Borlaug Fellows for conducting 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 Climate Change, the Federal Seed Certification and Registration Department at Ministry of National Food Security and Research, specialists at Pakistan's National Animal and Plant Health Inspection Service (NAPHIS), and scientists involved in biotechnology applications for crops and livestock in the Ministry of Science and Technology and Ministry of Commerce.

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 substantial funding and is ready to carry out R&D studies but suffers from a severe shortage of trained human resources.

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 major GE animal related initiatives in the country. Limited quantities of chemical based veterinary pharmaceuticals are formulated from imported raw materials. However, some work on Embryo Transfer Technology is underway.

Regulations

Biosafety Rules of Government of Pakistan-2005 encompass GE animals. The relevant ministries and organizations are; Ministry of Commerce, a new counterpart after the devolution of Ministry of Livestock, PARC (Animal Sciences Division) and National Plant and Health Inspection Service (NAPHIS), Ministry of National Food Security and Research .

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

In 2005, the GOP notified Export Control List of goods, materials, equipment subject to approval by the ministry of

Commerce, Government of Pakistan.

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 and equipment.

Relevant government entities involved in regulation of genetic engineering of animals are; Ministry of Foreign Affairs, Ministry of Commerce, Ministry of Science and Technology, Ministry of Climate Change & Planning and Development Division.

Stakeholders/Public Opinions

There is no public campaign against the use of genetic engineering in the livestock sector. The general awareness to understand genetic engineering related issues is extremely limited. Use of lactating hormones in milking animals is a routine activity.

The 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 minimal input cost

International Organizations

The Pakistan National Biosafety Committee (NBC) and the National Plant and Animal Health Inspection Service (NAPHIS) are responsible for Animal biotech activities. Under new set up the functions of Pakistan Environmental Protection Agency (Pak EPA), earlier working under the devolved Ministry of Environment has been assigned to a newly created Ministry of Climate Change.

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 with the support of international organizations.

Outreach, Needs and Strategies

On various forums GOP has expressed its desire and willingness to jointly work with the USDA in the 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, including the dairy industry.

US Aid- Pakistan has identified Livestock and Dairy Development as the key sector to improve livelihoods of the rural masses. It is working with Government, private and multinational bodies 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.

Section VII. Author Defined: