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Pakistan

Agricultural Biotechnology Annual

Agricultural Biotechnology Annual 2018

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Report Highlights:
In Pakistan, a developed biotechnology and seed regulatory structure is in place to facilitate the introduction of new technologies in the country. Pakistan's commercialization of GE (genetically engineered) crops remains limited to two cotton events introduced in 2010. The 2005 Federal Biosafety Rules, which approve applications to introduce new technologies, resumed in 2016 after a four-year hiatus. Pakistan introduced new seed rules in 2016 that will facilitate the private sector's role, new rules for an intellectual property regulation called Plant Breeders Rights (PBR) Rules 2018, and a process of establishing a registry to enforce these regulations. Imported GE products require food, feed, and processing (FFP) approval under the Biosafety Rules and Guidelines 2005 in order to meet new import requirements. Pakistan is a significant importer, exporter, and producer (cotton) of biotechnology crops.

Section I. Executive Summary:

Pakistan's biotechnology sector is dependent on three key regulations: the 2005 Biosafety Rules, Seed Amendment Act of 2015 and subsequent Rules, and 2016 Plant Breeders Rights Act and subsequent Rules. Until recently, none of these regulations were operational, either due to uncertainty about their regulatory status or the need for parliamentary approval and rule implementation. However, all three regulations will be fully implemented in 2019, opening Pakistan to the official introduction of modern biotechnology whether from the private or public sector for the first time in its history. Pakistan is a major importer of crops derived from biotechnology and an exporter of textiles made from biotech cotton.

Pakistan initiated or approved the process for GE (genetically engineered) traits contained in multiple crops over the past two years. Pakistan already commercialized cotton, and corn is currently going through the hybrid registration approval process with an expected commercialization in 2019. Research on a variety of other crops is underway. Foreign and domestic companies and public research institutions are conducting biotechnology research on crops such as wheat, corn, rice, sugarcane, potato, and tomato.

Regulatory authorities in Pakistan are in the process of implementing more stringent measures on imported agricultural commodities to regulate GE products. The concerned departments argue for compliance with Pakistan's policies related to GE products under the Biosafety Rules 2005. The Biosafety Rules require food, feed, and processing (FFP) approval, but Biosafety Guidelines do not have standard operating procedures in place, which hinders importation of GE products. During October 2018, a delegation from the Department of Plant Protection and Quarantine visited the United States to discuss quarantine issues and compliance with Pakistan's GE policies. The visit culminated in an agreement to maintain uninterrupted trade while Pakistan completes a pest risk assessment and subsequent bilateral consultations. Pakistan must also implement rules for the trade of FFP products.

Section II.
PLANT AND ANIMAL BIOTECHNOLOGY

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

Since 2016, Pakistan accelerated the pace of product development as the federal government resumed oversight of the biotechnology approval process. Now, public research institutions along with foreign and domestic firms are submitting applications for new product approvals. The approval of the Amended Seed Act 2015 and the enforcement of subsequent new seed rules in 2016 are also helping to facilitate development of the seed sector. The Plant Breeders' Rights Act and Rules that introduces intellectual property protections in the sector has been approved by Parliament; implemented is expected in 2019 and onwards.

Table 1: DEVELOPMENT OF BIOTECH CROPS IN PAKISTAN

Crop	**Trait**	**Status**	**Institute**
Cotton	Diamondback moth resistance with Bt gene	Field trials	CEMB
	Virus (CLCV) resistance with Tr AC gene	Field trials/ready to release	CEMB
	Virus (CLCV) resistance with RNA interference (RNAi)	Field trials	CEMB & NIBGE
	AVP1-H+ for salt and drought tolerance	Field trials	NIBGE
	Cry1Ac and Cry2Ab	Field trials	CEMB/NIBGE + 4 Domestic Seed Companies
	Cry1Ac + Cry2Ab and Glyphosate	Field trials	CEMB/NIBGE+ 4 Domestic Seed Companies

	Fiber improvement	Experimental	CEMB
Wheat	Rust, drought, and salt tolerance	Experimental/Field Trial	NIBGE
	Bio-fortified wheat for increased iron and zinc bioavailability	Field Trial	FCCU/AARI
	Increased phosphorus use efficiency	Field Trial	FCCU+ 1 Domestic Seed Company
	Rust resistance markers	Experimental	AARI
Rice	Bacterial blight resistance with Xa21 gene (through molecular assisted breeding)	Experimental	NIBGE
	Insect resistance with Cry1Ac & Cry2A genes	Experimental	CEMB
Maize	Insect Resistance (Cry1Ac+Cry2A)	Field trials	CEMB/ NIGAB
	CEMB-GTGene	Field trials	CEMB
	CEMB-AFP	Field trials	CEMB
	cp4epsps	Field trials	Monsanto
	cry2Ab2 & cry1A.105 and cp4epsps	Field trials	Monsanto
	cry1F, cry1Ab and cp4epsps	Field trials	Pioneer
	cry1Ab x mESPSPS	Field trials	Syngenta
	mESPSPS	Field trials	Syngenta
Sugarcane	Insect resistance with Cry gene	Experimental	NIBGE
	Chloroplast transformation	Experimental	CEMB
	Drought tolerance	Experimental	AARI
	SIG1+SIG2+SIG3	Experimental	CEMB

	CHiA+CHiB+CHiC	Experimental	CEMB
	Insect resistance with VIP3+ASAL	Experimental	CEMB
	Herbicide tolerant sugarcane	Experimental	CABB
	Biotic stress tolerant sugarcane using SUGARWIN 2 gene	Experimental	CABB
	Abiotic stress tolerant sugarcane using scdr1 gene	Experimental	CABB
	Antifungal sugarcane virus resistance	Experimental	CEMB
Chickpeas	Insect resistance (Bt gene)	Experimental	CEMB/NIGAB
Tobacco	Insect (Helicoverpaarmigera and Heliothesisvericens) resistance with a novel synthetic spider venom gene	Experimental	NIBGE
	Salt tolerance with yeast, Arabidopsis Na+/H+ antiporter genes	Experimental	NIBGE
	Salt tolerance with ArDH chloroplast transformation (Biosafe GM)	Experimental	CABB
	Non-edible vaccine development against Bursal and Newcastle diseases of poultry	Experimental	CABB
Potato	Virus (PLRV, PLXV, PVY) resistance, Chitinase gene for fungal disease resistance	Experimental	NIBGE
	Insect-resistant transplastomic potato – chloroplast transformation	Experimental	CABB
	Fungal resistance using glucanase gene	Experimental	CABB
Peanut	Herbicide resistance, Tikka disease resistance	Experimental	NIGAB
Brassica	Glyphosate resistance, FAEI gene for reduced erucic acid and MAX1 gene	Experimental	AARI

	for maximum axillary branches to enhance yield		

CEMB Centre of Excellence in Molecular Biology, University of the Punjab, Lahore
NIBGE National Institute for Biotechnology and Genetic Engineering, Faisalabad
FCCU Forman Christian College University, Lahore
AARI Ayub Agriculture Research Institute, Faisalabad
NARC National Agriculture Research Center, Islamabad
CABB Centre of Agricultural Biochemistry and Biotechnology, University of Agriculture, Faisalabad
NIGAB National Institute for Genomics and Advanced Biotechnology, NARC, Islamabad

b. COMMERCIAL PRODUCTION

Biotech cotton is the only crop under commercial production in Pakistan. Most of the approved biotech cotton seed varieties contain one of the two released events – MON 531 (Cry1Ac gene) or (Cry1Ab gene) – both of which protect cotton from lepidopterans and were introduced a number of years ago. The Center of Excellence in Molecular Biology (CEMB) developed three double gene transgenic cotton varieties being marketed commercially. In 2018, farmers planted 2.7 million hectares of biotech cotton (over 95 percent of total cotton area) using more than 35 seed varieties. Pakistan approved GE events related to corn, and they are forecast for commercial sale in 2019 and onwards.

c. EXPORTS

Pakistan exports small volumes of biotech cotton. Exports reached $42 million during the cotton marketing year 2017/2018. Pakistan also exports cotton yarn, cotton fabric, and other items manufactured from both domestic and imported biotech cotton. The textile sector comprises a major share of Pakistan's economy and exports.

d. IMPORTS

In MY 2017/18, Pakistan imported around 2.9 million 480lb bales of cotton – much of which was derived from biotech varieties – valued at approximately $1.2 billion mostly from the United States, India, Brazil, and Egypt. Pakistan is also an importer of soybeans, canola, soybean meal, distillers dried grains (DDGs), and soybean oil derived from biotech grains from countries such as the United States, Brazil, Canada, and Argentina. Pakistan imported around 2.0 million metric tons of soybeans during marketing year 2017/18 valued at around $780 million.

e. FOOD AID

There are no known issues or restrictions affecting the importation of food aid produced from biotech crops. Pakistan imported U.S. soybean oil under the Food for Progress development program. In recent years, Pakistan has provided food aid to countries like Afghanistan and to some African countries.

f. TRADE BARRIERS

With the change in import requirements for agricultural commodities, the regulatory authorities in Pakistan are in the process of implementing more stringent measures to regulate trade. Officials explain they must comply with Pakistan's policies related to GE products under Pakistan's Biosafety Rules of 2005. The rules require Food, Feed, and Processing (FFP) approval, but the guidelines do not have SOPs in place which could hinder the importation of GE products (soybean seed, canola, DDGs, etc.)

into Pakistan. During October 2018, a delegation from the Department of Plant Protection and Quarantine, Ministry of National Food Security and Research (MNFSR) visited the United States to finalize the pest risk analysis (PRA) and quarantine requirements for imported soybeans, pulses and DDGs. The team also assessed the compliance of U.S. agricultural products with Pakistan's policies relating to GE products. During the final meeting in Washington, D.C., participants agreed that trade will continue uninterrupted pending Pakistan's completion of a PRA and any subsequent bilateral consultations. Pakistan must also complete the rules for the trade of FFP products.

At present, Pakistan has no labeling requirements in force for foods, seeds, fibers, oils, or feeds derived from biotech crops. Sources report that the government may be in the early stages of considering possible rules for labeling certain products.

PART B: POLICY

a. REGULATORY FRAMEWORK

Pakistan established the federal biotechnology regulatory structure for approving new technologies in 2005 and created a three-tiered system under the provisions of the Environmental Protection Act of 1997. Under this Act, Pakistan created the National Biosafety Rules (NBR) and established the National Biosafety Committee (NBC) as the body responsible for review and approval of laboratory procedures, monitoring of field trials, regulation of trade, and facilitation of the commercialization of biotech crops and products. The NBC is governed by the 2005 National Biosafety Guidelines and is housed within Pakistan's Environmental Protection Agency (EPA) in the Ministry of Climate Change. The NBR are consistent with the Cartagena Protocol of Biosafety which was ratified by Pakistan in 2009.

There are fifteen members of the NBC, which include representatives from the Ministries of National Food Security and Research, Health, Education, Science and Technology, Commerce, Planning and Development, and Textiles. Other members include the Pakistan Agricultural Research Council, the Pakistan Atomic Energy Commission, and representatives from provinces and territories.
In addition to the apex NBC, the NBR created two additional bodies that provide technical support to the review and approval process:

i) The Technical Advisory Committee (TAC) is responsible for examining applications for new biotech crops and organisms and makes recommendations to the NBC on technical matters related to laboratory manipulation, field work, and the commercialization of the organisms. The TAC is chaired by Director General of the EPA and the participants includes member from provinces, as well as from Azad Jammu and Kashmir and Gilgit Baltistan.

ii) The Institutional Biosafety Committee (IBC) is responsible for undertaking risk assessment, implementing safeguards, and monitoring and inspecting all regulated research and product development that has been authorized by the NBC. The IBC's findings are forwarded to the TAC for review and to formulate recommendations to the NBC.

While the NBC was inactive from 2012 to 2016, due to uncertainty over whether the provinces or the federal government was responsible for regulatory oversight following devolution, the NBC resumed functions under the EPA in 2016 and continues to meet. While new or existing challenges from the provinces may arise, the system is working, and private and public sector companies and organization

are submitting applications for approval. Concerns over the availability of approved cotton seed varieties have been a major impetus in reigniting the operations of the NBC.

The Province of Punjab, Pakistan's leading agricultural producer, aims to develop its own approval process. A court challenge to this provincial objective was a key reason for the inactivity of the NBC from 2012 to 2016. While uncertainty remains as to how provincial and federal objectives will be resolved, the federal government is moving ahead in close consultation with the provinces. Sources report that because Pakistan is signatory to the Cartagena Protocol, the responsibility should fall to the federal government. This view is supported by stakeholders and the inherent functions of federal government. The newly elected federal government in place since August 2018 is expected to support federal oversight over the biotech regulatory system.

b. APPROVALS

Since 2016, the TAC and NBC held regular meetings and approved a number of applications for new events. While approved by the regulatory committees, the authorities did not approve the licenses for these events that would allow commercial introduction in the marketplace.

Following are the details of approvals for commercialization granted by the NBC:

Approvals for Commercialization			
S. No	**Institute**	**Crop**	**Trait**
1	CEMB NIBGE NARC	Cotton	More than 40 cases of Bt cotton approved
2	Cotton Research Institute (CRI) Faisalabad	Cotton	Bt cotton variety FH- Lalazar, MNH- 988, BH-184
3	Auriga, Lahore	Cotton	Bt cotton Variety Sayban -202
4	Monsanto Pakistan	Maize	Roundup Ready corn® (NK603 Genuity VT Double Pro (MON89034XNK603)
5	Pioneer Pakistan	Maize	Maize 1507xNK603; MON 810xNK603

Pakistan's Biosafety Rules of 2005 provide a time line for the approval process. Once officials receive an application, a final decision shall be made and communicated to the applicant within:

- 60 days for work bearing low risk and work bearing considerable level of risk for lab work, green house and field testing,
- 90 days for experimental release, or
  120 days for commercialization.

c. STACKED OR PYRAMIDED EVENT APPROVALS

When introducing a new technology, Pakistan's Biosafety Rules 2005 treat single or multiple gene transformations as a single separate event. For example, a seed with multiple biotech genes would be treated as a single event in the approval process. Pakistan recently approved a Plant Breeders' Rights Act, and Intellectual Property Rights (IPR) regulatory officials suggest that each new genetic trait will

be protected separately. NBC approved three single and stacked events for maize and one staked event for cotton. Details for commercial approval and field trial are as follows:

Genes	Approval Stage	Company
cp4epsps	Commercial	Monsanto
cry2Ab2 & cry1A.105 and cp4epsps	Commercial	Monsanto
cry1F, cry1Ab and cp4epsps	Commercial	Pioneer
Cry1Ac + Cry2Ab + Glyphosate	Commercial	CEMB

Field Trials

Maize	Insect Resistance	Field trials	CEMB, NIGAB
	cry1F, cry1Ab and cp4epsps	Field trials	Pioneer
	cry1Ab x mESPSPS	Field trials	Syngenta
	mESPSPS	Field trials	Syngenta

d. **FIELD TESTING**

Pakistani biotech institutes are actively engaged in conducting field trials. Following are the details of approvals for field trials granted by the NBC meetings held during 2018:

Approvals for Field Trials			
S. No	**Institute**	**Crop**	**Trial**
1	NIBGE	Wheat	Increased salinity and heat tolerance
2	NIBGE	Cotton	Abiotic stress tolerance, insect resistance (IR-NIBGE+8)
3	NIBGE	Cotton	NIAB Bt-1 +NIAB Bt2
4	CEMB	Cotton	CEMB Klean Cotton
5	CEMB	Cotton	CEMB-77, CEMB-88
6	CEMB	Potato	By transmission of Multiple genes
7	AARI	Cotton	Bt cotton variety 181
8	AARI	Cotton	Synthetic Bt gene Cry 1Ac & Cry 2Ab
9	FCCU	Wheat	Bio fortified wheat for increased bioavailability of iron and zinc
10	FCCU	Wheat	Increased phosphorus use efficiency
11	CRI Faisalabad	Cotton	Bt cotton CIM 600 &616; Cyto-177

12	CRI Faisalabad	Cotton	Bt cotton Variety Eagle1-6
13	CABB, UAF	Wheat	Salinity and drought tolerance
14	CABB, UAF	Sugarcane	Herbicide tolerance and borer-resistance

e. INNOVATIVE BIOTECHNOLOGIES

A few academic institutions and research centers have been working on gene editing (CRISPR-R). While limited in use, a few scientists are pursuing research, primarily in plants.

f. COEXISTENCE

At present, the Government of Pakistan has not formulated a policy on coexistence between biotech and non-biotech crops.

g. LABELING

Pakistan has no labeling requirements for foods, seeds, fibers, oils, or feeds that are derived from biotech crops. Sources indicate that the government may be considering rules for labeling certain products.

h. MONITORING AND TESTING

The Pakistan Government is in the process of changing the import requirements and at the initial stage of monitoring GE products. A proposal would require that any imported GE products have an import permit and certificate from the NBC. The mechanisms for monitoring and testing are outlined in the 2005 Biosafety Guidelines but lack any format or SOPs for the import of FFP. Pakistan must design regulations for the trade of FFP products. The NBC and its two supporting technical committees are responsible for overseeing all lab work, field trials, and approval of the commercial release of biotech crops.

i. LOW LEVEL PRESENCE (LLP) POLICY

Pakistan has not considered a LLP policy. Timely technical assistance could assist local governments in developing their understanding and guidelines to support the need for increased GE grain imports in the country.

j. ADDITIONAL REGULATORY REQUIREMENTS

Once a biotech seed is approved by the NBC, the applicant must register the product with the Federal Seed Certification and Registration Department (FSC&RD) of the Ministry of National Food Security and Research before it can be commercialized in line with the requirements of Seed Rules 2016.

k. INTELLECTUAL PROPERTY RIGHTS (IPR)

The Plant Breeders' Rights Act and subsequent rules will establish Pakistan's first-ever intellectual property protection for seeds and plant varieties and attract investment in agriculture field. Enforcement of the Act and subsequent rules falls under MNFSR. The Federal Seed Certification and Registration Department (FSC&RD) of MNFSR developed PBR Rules in 2018 and are now in process of establishing the Registry to enforce these regulations.

l. CARTAGENA PROTOCOL RATIFICATION

Pakistan ratified the Cartagena Protocol on Biosafety on March 2, 2009, and the NBR provides a

framework for the trans-boundary movement, transit, handling, and use of living modified organisms.

m. INTERNATIONAL TREATIES and FORUMS

Pakistan is a member of the International Plant Protection Convention (IPPC) and the Codex Alimentarius (Codex) and actively participates in discussions on biotechnology.

n. RELATED ISSUES

Pakistan's biotechnology sector is dependent on three key regulations: the 2005 Biosafety Rules, Seed Amendment Act of 2015, and 2016 Plant Breeders Rights Act. None of these regulations are fully operational, either due to uncertainty about their regulatory status or the need for approval and rule implementation. However, these regulations will be operational in 2019 and onwards, opening Pakistan to the official introduction of biotechnology whether from the private or public sector. The prior introduction of now dated cotton events was the result of informal adoption of these technologies. While Pakistan eventually recognized these events officially, the regulatory structure that is moving towards final approval will allow the official introduction of new technologies.

PART C: MARKETING

a. PUBLIC/PRIVATE OPINIONS

Government of Pakistan's ministries like MNFSR, Climate Change, Health, Education, Science and Technology, Commerce, Planning and Development, Textiles and the agricultural community are generally supportive of the expanded utilization of biotechnology. Consumer acceptance is more mixed, but the production and consumption of biotech crops is generally accepted. Consumers are generally unaware of amendments in regulations, given the slow pace of development and introducing new biotech crops and products. Pakistan is both a producer (cottonseed oil) and importer (oilseeds, meals, and oils) of biotech crops and products.

b. MARKET ACCEPTANCE/ STUDIES

FAS Islamabad is not aware of any marketing studies except two PhD theses on Bt cotton in Pakistan at the Universities of Melbourne and Guelph. One focused on the evolution of Bt cotton and the national seed system in the country, and the other studied the adoption of Bt cotton with respect to poverty alleviation in rural areas of Southern Punjab and upper Sindh. Pakistan is an importer/ user of GE soybeans, canola, soybean meal, DDGs, soybean oil and cotton sourced from various countries. The rules required for FFP approval are under discussion with the concerned authorities.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

No production or trade of animal biotechnologies or cloning is happening in Pakistan. Experiments for cloning mice embryos is in progress but no commercial application yet. In vitro embryo production and transfer in humans is practiced on a limited scale. Production technology is researched for animals in some institutes.

There are recent developments to develop Recombinant Animal Vaccines for Newcastle disease for poultry industry in the National Institute for Biotechnology and Genetic Engineering (NIBGE) and Centre of Agricultural Biochemistry and Biotechnology (CABB), University of Agriculture, Faisalabad and National Institute for Genomics and Advanced Biotechnology (NIGAB), NARC, Islamabad. A limited number of cattle embryos are produced in the embryo transfer center of military dairy farm but are mainly used at the center. CEMB developed some interferon product, but Drug Regulatory Authority of Pakistan (DRAP) did not register it because no efficacy and safety studies were provided.

b. COMMERCIAL PRODUCTION

None.

c. EXPORTS

None.

d. IMPORTS

None.

e. TRADE BARRIERS

Given the absence of a regulatory framework, FAS Islamabad believes that imports of animal biotechnology and related products would likely be restricted. Imports must first receive a "No Objection Certificate" from the relevant ministry, and officials would likely raise concerns if the products were significantly unique or substantially different from conventional animals or their products.

PART E: POLICY

a. REGULATORY FRAMEWORK

The Biosafety Rules 2005 mentions organisms (animal, plants, insects, fungi, and microbes), and there are separate chapters on animals and plants in the Biosafety Guidelines. These rules would be the basis for any regulation of genetically engineered animals, livestock clones or their products, and the NBC will likely be charged with the responsibility of reviewing any new product applications.

b. APPROVALS

Approval process has not yet started on commercial scale as no production or trade of animal biotechnologies or cloning is happening in the country. Only in vitro experiments are in process in some institutes.

c. INNOVATIVE BIOTECHNOLOGIES

None.

d. **LABELING AND TRACEABILITY**

There is no labeling policy at this time.

e. **INTELLECTUAL PROPERTY RIGHTS (IPR)**

FAS Islamabad is not aware of any existing IPR provisions for animal biotechnology.

f. **INTERNATIONAL TREATIES and FORUMS**

While Pakistan is a World Trade Organization (WTO) member, participates in fora related to the WTO, and refers to reference bodies such as the World Organization for Animal Health and Codex Alimentarius, FAS Islamabad is not aware of participation in discussions related to animal biotechnology.

g. **RELATED ISSUES**

None.

PART F: MARKETING

a. **PUBLIC/PRIVATE OPINIONS**

General awareness is limited.

b. **MARKET ACCEPTANCE/STUDIES**

FAS Islamabad is not aware of any studies related to the market acceptance of GE animals and livestock clones. There is no production or sale of GE animals in the country.