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Pakistan

Agricultural Biotechnology Annual

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Report Highlights:
Pakistan continues to make significant progress towards implementing a full-fledged biotechnology and seed regulatory structure that is expected to facilitate the introduction of new seed technologies. The 2005 Federal Biosafety Rules, which approve applications to introduce new technologies, resumed operation in 2016 after a four-year hiatus and continued into 2017. New seed rules were introduced in 2016 that will facilitate private involvement in the sector, and rules are currently being drafted for an intellectual property regulation. Pakistan's participation in commercial biotechnology has been limited to two now-dated cotton events that were introduced informally a number of years ago. 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; The Seed Amendment Act of 2015; and the 2016 Plant Breeders Rights Act. As recently as two years ago, none of these regulations were operational, either due to uncertainty about their regulatory status or the

need for approval and rules implementation. It is possible that all three of these regulations will be operational in 2018, opening Pakistan to the official introduction of modern biotechnology, whether from the private or public sector, for the first time in its history.

Officials have approved or initiated the approval process for 190 technologies over the past two years. Cotton and corn are the major crops that are currently moving through the approval process. In addition, research on a variety of other crops is underway. Foreign and domestic private companies as well as public research institutions are conducting biotechnology research. Pakistan is a major importer of crops derived from biotechnology and is also an exporter of biotech cotton.

Section II. Author Defined:

PLANT AND ANIMAL BIOTECHNOLOGY

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

The pace of product development has accelerated as the federal government has resumed oversight of the biotechnology approval process. Following the decision to devolve many federal responsibilities to the provinces in 2010, it was unclear whether federal or provincial officials would regulate the sector, resulting in several years of limited progress in introducing new varieties and products. 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, which will introduce intellectual property protections in the sector for the first time has been approved by Parliament and implementation rules are being developed.

Table 1: DEVELOPMENT OF BIOTECH CROPS IN PAKISTAN

Crop	Trait	Status	Institute
	Diamondback moth resistance with Bt gene	Field trials	CEMB

Cotton	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
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
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 for maximum axillary branches to enhance yield	Experimental	AARI

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
CABB Centre of Agricultural Biochemistry and Biotechnology, University of Agriculture, Faisalabad
NIGAB National Institute for Genomics and Advanced Biotechnology, National Agriculture Research Centre, Islamabad

1. COMMERCIAL PRODUCTION

Biotech cotton is the only crop under commercial production in Pakistan. For biotech cotton, most of the approved seed varieties contain one of the two released events MON 531(Cry1Ac gene) and (Cry1Ab gene), both of which protect cotton from lepidopterans and were initially introduced on an informal basis a number of years ago. The Center of Excellence in Molecular Biology (CEMB) has developed three double gene transgenic cotton varieties that are being marketed commercially. In 2017, farmers planted 2.7 million hectares of biotech cotton (over 95 percent of total cotton area) using more than thirty seed varieties. GE events related to corn have been approved and are expected to be released for commercial production over the next 1-3 years.

2. EXPORTS

Pakistan exports small volumes of biotech cotton. Exports were valued at $30 million during cotton marketing year 2016/17. 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.

3. IMPORTS

In MY 2016/17, Pakistan imported around 1.9 million 480 lb bales of cotton (much of which was derived from biotech varieties) valued at approximately $700 million mostly from the United States, India, and Brazil. Pakistan is also an importer of soybeans, canola, soybean meal, distillers dried grains (DDG's), and soybean oil derived from biotech seeds from countries such as Brazil, the United States, Canada, and Argentina. Pakistan imported around 1.6 million metric tons of soybeans during marketing year 2016/17 valued at around $580 million.

4. FOOD AID

There are no known issues or restrictions affecting the importation of food aid produced from biotech crops. Pakistan has imported U.S. soybean oil under the Food for Progress development program.

5. TRADE BARRIERS

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

PART B: POLICY

a. REGULATORY FRAMEWORK

The federal biotechnology regulatory structure for approving new technologies was established 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 apex 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 National Biosafety Rules are consistent with the Cartagena Protocol of Biosafety which was ratified by Pakistan in 2009.

There are fifteen members of the NBC which includes 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 the 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), which 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 effectively 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 with some regularity. The most recent meeting was held in August of 2017. While new or existing challenges from the provinces may arise, for now, 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 has been keen to develop its own

approval process. This provincial objective accompanied by a court challenge, was a key reason for the inactivity of the NBC from 2012 to 2016. While there is still some uncertainty as to how provincial and federal objectives will be resolved, for now the federal government is moving ahead in close consultation with the provinces. Many in Pakistan believe that because Pakistan is signatory of the Cartagena Protocol, the responsibility should fall to the federal government.

b. APPROVALS

During 2016 and 2017, TAC and NBC approved 119 and 71 applications respectively for new events. While approved by the regulatory committees, a number of these approvals have not yet received the final license that would allow commercial introduction in the marketplace. In addition, 18 additional cases are pending before the committee. In some cases, despite NBC approvals, firms may decide to wait until the 2016 Plant Breeders Rights rules have been finalized to ensure that adequate intellectual property protection is in place.

Details of approvals for commercialization granted by the NBC meetings held during 2016 and 2017 are as follows:

Approvals for Commercialization			
S. No	**Institute**	**Crop**	**Trait**
1	CEMB NIBGE NARC	Cotton	40 cases of Bt. Cotton were 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 Biosafety Rules of 2005 provide a time line for the approval process. It maintains that in response to an application submitted, 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
- 120 days for commercialization

c. STACKED OR PYRAMIDED EVENT APPROVAL

For the purpose of introducing new technology, the Pakistan 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. While the draft Plant Breeders' Rights Act has not yet been approved, preliminary discussion with IPR regulatory officials suggest that each

new genetic trait will be protected separately. NBC in its meetings held during 2016 and 2017 approved three stacked events for corn and one staked event for cotton. Details follow:

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

d. FIELD TESTING

Pakistani biotech institutes are actively engaged in conducting field trials. Details of approvals for field trials granted by the National Biosafety Committee (NBC) meetings held during 2016 and 2017 are as follows:

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

The gene editing tool (CRISPR-R) has been introduced in research labs by a few academic institutions and research centers. While its use is limited, 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
There are no labeling requirements for foods, seeds, fibers, oils, or feeds that are derived from biotech crops. Reports suggest that the government may be in the early stages of considering possible rules for labeling certain products.

h. MONITORING AND TESTING
While not currently functioning, the mechanisms for monitoring and testing are outlined in the 2005 Biosafety Guidelines, the National Biosafety Committee 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 low-level presence policy.

j. ADDITIONAL REGULATORY REQUIREMENTS
Once a biotech seed is approved by the National Biosafety Committee, it must be registered with the Federal Seed Certification and Registration Department (FSC&RD) of the Ministry of National Food Security and Research before it can be commercialized. Currently, a number of new events are pending before the FSC&RD.

k. INTELLECTUAL PROPERTY RIGHTS (IPR)
The Plant Breeders' Rights Act, which will establish Pakistan's first-ever intellectual property protection for seeds, was approved by Parliament and implementing rules are currently in the review process. Enforcement of the Act will fall to the Ministry of Food Security and Research. The Federal Seed Certification and Registration Department (FSC&RD) is in the process of developing a registry for biotech crops that will keep track of approved technologies.

l. CARTAGENA PROTOCOL RATIFICATION
Pakistan ratified the Cartagena Protocol on Biosafety on March 2, 2009, and the National Biosafety Rules provide a framework for the trans-boundary movement, transit, handling, and use of living modified organisms.

m. INTERNATIONAL TREATIES/FORA
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, the Seed Amendment Act of 2015, and the 2016 Plant Breeders Rights Act. As recently as two years ago, none of these regulations were operational, either due to uncertainty about their regulatory status or the need for approval and rules implementation. It is possible that all three of these regulations will be operational in 2018, opening Pakistan to the official introduction of modern biotechnology, whether from the private or public sector, for the first time in its history. Note that the prior introduction of now-dated cotton events was the result of the informal adoption and spread of those technologies. While

those events were eventually recognized officially, the regulatory structure that is currently moving towards final approval will allow the official introduction of new technologies.

PART C: MARKETING

a) MARKET ACCEPTANCE
Pakistan's agricultural community is generally supportive of the expanded utilization of biotechnology. Consumer acceptance is more mixed, but the production and consumption of biotech crops is generally accepted. However, consumer sentiment has not really been tested given the lack of progress in regulating 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. Biotech cotton accounts for nearly 95 percent of cotton production in Pakistan.

b) **PUBLIC/ PRIVATE OPINIONS**
See "Market Acceptance" above.

c) 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.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE
No production or trade of animal biotechnologies or cloning is happening in Pakistan.

a. PRODUCT DEVELOPMENT:
There are recent developments to develop Recombinant Animal Vaccines for New castle disease for poultry industry in NIBGE and CABB Faisalabad and NIGAB Islamabad.

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 its 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 or their products and NBC will likely be charged with the responsibility of reviewing any new product application.

b. INNOVATIVE BIOTECHNOLOGIES:

None

c. LABELING AND TRACEABILITY:

There is no labeling policy at this time. (See Plant Section)

d. INTELLECTUAL PROPERTY RIGHTS (IPR):

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

e. INTERNATIONAL TREATIES/FORA:

While Pakistan is a WTO member and participates in fora related to the WTO and its 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.

f. RELATED ISSUES:

None

PART F: MARKETING

a. PUBLIC/PRIVATE OPINIONS:

General awareness appears to be very limited.

b. MARKET ACCEPTANCE/STUDIES:

FAS Islamabad is not aware of any studies.