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Pakistan

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Report Highlights:

Pakistan is making progress towards approving and implementing the regulations that will modernize its seed and biotechnology regulatory systems. The Plant Breeders' Rights Act is expected to receive final executive approval soon; the Act would provide intellectual property protection for biotech seeds for the first time ever. Similarly, regulators are working to finalize the implementing rule of the 2015 Seed Act that would encourage private sector investment in the industry. The status of the final piece of the regulatory puzzle is still somewhat uncertain as federal and provincial regulators work to determine the lines of regulatory oversight in the approval process. Meanwhile, 95 percent of Pakistani cotton is biotech and Pakistan imports biotech soybeans, canola, and cotton; foreign and domestic firms are eager to introduce new technologies as soon as the regulatory structure is in place.

Section I. Executive Summary:

Farmers in Pakistan plant 95 percent of their cotton area with biotech cottonseeds and cottonseed oil is the country's largest domestically produced vegetable oil. Pakistan imports significant quantities of biotech crops like cotton, canola, and soybeans to support its textile industry and meet food and feed requirements. At present, there are no labelling requirements for the import of biotech commodities and their derived products. Pakistan's federal regulatory structure for approving new biotechnologies was established in 2005, and functioned until the passage of the 18th Amendment to the constitution that devolved a number of federal powers to the provinces. Since then federal and provincial regulatory bodies have lacked clarity as to which is responsible for approving new biotech crops. In early 2016, in response to a potential shortfall in licensed biotech cottonseeds prior to the start of harvest, the federal approval process was re-started and 119 pending cases were approved including a number of new events ready for commercialization. Unfortunately, following the flurry of activity earlier this year, a number of events have yet to receive the necessary licenses to begin commercial production. The Plant Breeders' Rights Act has been passed by the National Assembly (lower house), the Senate (upper house) and is now with the President of Pakistan for final approval. It is expected to be promulgated soon and, if approved, will introduce intellectual property protections for the first time. Pakistan ratified the Cartagena Protocol on Biosafety on March 2, 2009, and is a member of the International Plant Protection Convention (IPPC) and the Codex Alimentarius (Codex) and actively participates in discussions on biotechnology. 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. No production or trade of animal biotechnologies or cloning is happening in Pakistan.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

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CHAPTER 1: PLANT BIOTECHNOLOGY

a) PRODUCT DEVELOPMENT:

Foreign and domestic firms and public sector researchers are working to develop and introduce new biotech crops in Pakistan. However, the uncertain regulatory environment has impeded progress thus far. The Government of Pakistan is making progress towards approving and implementing the regulations that will help to encourage investment in the seed sector.

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)		
	AVP1-H+ for salt and drought tolerance	Field trials	CEMB & NIBGE
	Cry1Ac and Cry2Ab	Field trials	NIBGE
	Cry1Ac + Cry2Ab and Glyphosate	Field trials	CEMB
		Field trials	CEMB
Wheat	Rust, drought and salt tolerance	Experimental/ Field Trial	NIBGE
	Bio-fortified Wheat for increased Iron and Zinc bioavailability	Field Trial	FCCU/AARI
	Rust resistance markers	experimental	ABRI, 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	Field trials	CEMB, NIGAB
	cp4epsps	Field trials	Monsanto
	cry2Ab2 & cry1A.105 and cp4epsps	Field trials	
	cry1F, cry1Ab and cp4epsps	Field trials	Monsanto

	cry1Ab x mESPPSPS	Field trials	Pioneer Syngenta
Sugarcane	Insect resistance with Cry gene	Experimental	NIBGE
	Chloroplast Transformation	Experimental	CEMB
	Drought tolerance	Experimental	AARI
Chickpeas	Insect resistance (Bt gene)	Experimental	CEMB
Tobacco	Insect(Helicoverpaarmigera and Heliiothesisvericens) resistance with a novel synthetic spider venom gene	Experimental	NIBGE
	Salt Tolerance with Yeast, Arabidopsis Na ⁺ /H ⁺ antiporter genes	Experimental	NIBGE, CABB
	Salt Tolerance with ArDH Chloroplast transformation (Biosafe GM)	Experimental	CABB
Potato	Virus (PLRV, PLXV, PVY)resistance, Chitinase gene for fungal disease resistance	Experimental	NIBGE
Groundnut	Herbicide resistance, Tikka disease resistance	Experimental	NIGAB

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
ABRI Agricultural Biotechnology Research Institute, Faisalabad
CABB Center of Agricultural Biochemistry and Biotechnology

b) 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, both of which protect cotton from lepidopterans. The CEMB has developed three double gene

transgenic cotton varieties that are being marketed commercially. In 2016, farmers planted 2.3 million hectares of biotech cotton (over 95 percent of total cotton area) using more than thirty five seed varieties (including one hybrid). While some corn events have been approved, firms have not received the licenses they need to begin production and sales.

c) EXPORTS:

Pakistan exports significant volumes of biotech cotton to Indonesia, Thailand, Taiwan, and India. Exports were valued at \$52 million during cotton marketing year 2015/16. 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 2015, Pakistan imported around 3.0 million 480 lb bales of biotech cotton valued at approximately \$1.0 billion mostly from India, Brazil, and the United States. Pakistan is also a major importer of canola and soybean oil derived from biotech seeds in countries such as Canada, Australia, Brazil, the United States, and Argentina. Pakistan imported over a million tons of soybeans during marketing year 2015/16 valued at around \$355 million. The bulk of the soybeans was sourced from the United States, Brazil, and Argentina and is presumed to be biotech.

e) FOOD AID:

There are no known issues or restrictions affecting the importation of food aid produced from biotech crops. Soybean oil was the main food aid provided under Food For Progress during the past and upcoming programs in Pakistan.

f) TRADE BARRIERS:

There are no labeling requirements for foods, seeds, fibers, oils, or feeds derived from biotech crops. However, there is a possibility that regulators will seek to develop a system at some point in the future.

PART B: POLICY:

a) REGULATORY FRAMEWORK

Pakistan's federal biotechnology regulatory system has faced challenges since the passage of the 18th Amendment to the Constitution which "devolved" many federal roles and responsibilities to the provinces in 2010. At the time, it was not clear if oversight of the seed and biotechnology sector would fall to the federal or provincial governments and the federal system continued to operate until 2012. However, the role of the federal government was challenged in 2012 when the Government of Punjab announced its plans to approve several new biotechnology products, mainly the approval considerations of biotech cotton seed varieties. Between 2012 and early 2016, Pakistan's federal biosafety regulatory structure effectively ceased to function as the courts reviewed the lines authority between provincial and

federal governments. There was a 2014 meeting of the approval committees, but new approvals were not validated given the uncertainty over federal vs. provincial oversight. In early 2016, the National Biosafety Committee (NBC) met on a temporary basis to approve new events and facilitate the licensing of cottonseeds prior to the onset of cotton planting (see the “Approvals” section for more detail).

The federal regulatory structure 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 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 in the Ministry of Climate Change. The NBR is 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 work, field work, and the commercialization of the organisms.
- 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.

The federal government has prepared a Biosafety Law that would re-establish federal oversight of the approval process by effectively re-implementing the review process that functioned through 2012 and functioned briefly during early 2016 to ensure that there was an adequate supply of cottonseeds. At this stage it is not clear if or when the federal regulatory system will resume, whether on a temporary or final basis. There is a pending court challenge in Punjab. However, federal regulators believe that the rationale for federal oversight stems from Pakistan’s status as a signatory to the Cartagena Protocol on Biosafety. The Protocol outlines certain requirements that are best implemented and regulated at the federal level rather than at the provincial level. If approved for introduction in the Parliament or for approval via a Federal decree, the Biosafety Act would re-establish federal oversight of the biotechnology sector; thereby, eliminating the need for the provinces to develop independent regulatory structures.

The lack of certainty within the regulatory system has prevented both foreign, domestic, and government organizations from introducing new technologies that would boost yields and improve the livelihoods of farmers.

b) APPROVALS

In early 2016, in an effort to ensure that there was a sufficient supply of approved biotech cottonseeds (licenses for number of varieties had lapsed) in the market, the Ministry of Climate Change conducted meetings of TAC and NBC. As noted above, this was the first time that events have been approved since 2012, a total of 119 cases were reviewed and decided in these meetings. The cases decided in 2014 were also revalidated. Details follow:

- 35 cases of commercialization of Bt cotton varieties were decided; out of which thirty three (33) varieties of Bt cotton having the single gene i.e. Cry1Ac (MON531 event) and three varieties having double genes i.e. Cry1Ac + Cry2Ab (CEMB-2 event) were approved.
- Five cases of commercialization of biotech corn were approved.
- 60 cases for exempt status for imports and field trials of biotech corn hybrids, cotton, and wheat were decided.
- Nineteen (19) cases of laboratory genetic manipulation work of various crops i. e., maize, cotton, wheat, potato, groundnuts, peas, brassica and sugarcane were decided

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, 30 additional cases have been presented to the committees for approval, but the committees have not met since early 2016.

Detail of approvals for commercialization granted by the NBC meetings held during February, March, and April 2016 follow:

Approvals for Commercialization			
S.No	Institute	Crop	Trait
1	CEMB NIBGE NARC	Cotton	Bt. cotton, 22 pending cases approved
2	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

While not currently functioning, the Pakistan Biosafety Rules of 2005 provides a timeline 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 corn, the NBC approved the following stacked events in its meetings held in early 2016:

Genes	Approval Stage	Company
cp4epsps	Commercial	Monsanto
cry2Ab2 & cry1A.105 and cp4epsps	Commercial	Monsanto
cry1F, cry1Ab and cp4epsps	Commercial	Pioneer

d) FIELD TESTING

Pakistani biotech institutes are actively engaged in conducting field trials. Details of approvals for field trials granted by the NBC meetings held during the month of February, March and April 2016 follow:

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

e) INNOVATIVE BIOTECHNOLOGIES

The National Biosafety Committee allowed field testing of stacked gene (Cry 1Ac and Cry 2Ab) in cotton developed by the CEMB Lahore. Six stacked gene products are reportedly awaiting approval.

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. However, there is a possibility that regulators will seek to develop a system at some point in the

future.

h) MONITORING AND TESTING

While not currently functioning, the mechanisms for monitoring and testing are outlined in the 2005 Biosafety Guidelines, 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 low-level presence policy.

j) ADDITIONAL REGULATORY REQUIREMENTS

Once a biotech seed is approved by the NBC, 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.

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

Currently, there is no IPR protection system in place which has hindered investment in the seed sector and the introduction of the latest products that biotechnology sector has to offer. However, the Plant Breeders' Rights Act has been approved by National Assembly (lower house), the Senate and is now with the President of Pakistan for final approval. It is expected that the Act will receive approval soon, thereby providing plant IPR protection in Pakistan for the first time ever. Enforcement of the Act was recently shifted to the Ministry of Food Security and Research, the equivalent of Pakistan's Ministry of Agriculture.

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

On July 23, 2015, Pakistan's President approved the amendments to the 1976 Seed Act, subsequently The Seed Amendment Act 2015, was promulgated on 29th July 2015. The amendments have been awaiting approval for a number of years and passage is considered an important step to facilitating the growth of the seed sector. Key provisions include:

- The amendments would bring the private sector under the purview of the Seed Act. Currently, the Act makes little mention of the private sector, leaving private companies, which have formed under other regulatory statutes (the 1984 companies act for example), largely unregulated.
- Anyone seeking to participate in the seed industry would need to have a seed processing plant or work as a registered seed dealer.
- Selling seed without proper registration and selling misbranded seed would be subject to jail time or a fine.
- Biotech seeds may not contain the “terminator gene,” a gene that prohibits the replanting of a crop, but is not deployed in commercial crop crops.
- Biotech seed must have approval from the NBC stating that the seeds will not have an adverse effect on the environment, human, animal, or plant life and health.

The amendments to the Seed Act are likely to have several important effects, including increased access by farmers to regulated and high quality seeds, increased financial and technological investments by large seed companies in research and development, punitive measures and enhanced fines have been instituted to deter the illegal and substandard sale of seed in the market. This should result in higher levels of agricultural production and the creation of new jobs in the agricultural sector. The Ministry of Food Security & Research is in the process of finalizing the rules that will implement the Seed Act.

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.

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:

None

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 Government of Pakistan’s 2005 Biosafety Rules would likely be the basis for any regulation of genetically engineered animals or their products, and the NBC would likely be charged with reviewing any new product application.

b) INNOVATIVE BIOTECHNOLOGIES:

None

c) LABELING AND TRACEABILITY:

There is no labeling policy at this time.

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 ACCEPTENCE/STUDIES:

FAS Islamabad is not aware of any studies.