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Report Highlights:

Although biotechnology laws (i.e., Pakistan Biosafety Rules of 2005, Seed Amendment Act 2015 and Plant Breeders Rights Act 2018, etc.) exist in Pakistan, the rules and administrative processes to implement the legislation have yet to be established. National regulatory bodies are in different stages of promulgating rules and administrative procedures, which need to be synchronized for Pakistan's legal system governing agricultural biotechnology to operate effectively.

EXECUTIVE SUMMARY

Pakistan's biotechnology sector is dependent on three key regulations, the Biosafety Rules of 2005, Seed Amendment Act of 2015, and the Plant Breeders Rights Act 2018. Until recently, none of these laws were in full effect, either due to uncertainty about their regulatory status or the need for parliamentary approval and rule implementation. While Pakistan has approved the use and cultivation of GE (genetically engineered) cotton, the commercialization of GE hybrid corn in 2019 was suspended due to a self-imposed moratorium by the National Biosafety Committee (NBC). Research on a variety of other crops is underway, but their fate is uncertain. The lack of a timeline and transparency has left critical regulatory bodies to be managed on an ad-hoc basis and without much coordination. Only public research institutions are conducting biotechnology research on crops such as wheat, corn, rice, sugarcane, potato, and tomato while domestic private seed companies are restricted to cotton. The Biosafety Rules of 2005 require biotech-derived products used for food, feed, and processing (FFP) to be approved by the National Biosafety Committee (NBC). To date, the NBC has yet to promulgate rules or establish administrative protocols that would enable companies to legally register their GE products for FFP purposes.

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PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT

Pakistan's pace of approving biotech derived products slowed in 2018/19 primarily due to ambiguity regarding GE rules and regulations. The Ministry of National Food Security and Research (MNFSR) and the Ministry of Climate Change (MOCC) are the two main ministries involved in the approval and regulation of GE products. The MNFSR is the ministry responsible for approving the cultivation of GE plants and issuing import permits for GE products while the Ministry of Climate Change's National Biosafety Committee (NBC) is the body responsible for reviewing and approving laboratory procedures, monitoring of field trials, regulation of trade, and facilitation of the commercialization of GE crops and products. Regulatory approval for the cultivation and commercialization of GE cotton has been in place since 2010. Recently, the MNFSR halted the approval and commercialization of GE hybrid corn as it ruled that corn directly falls under the food value chain. The NBC subsequently issued a unilateral moratorium on the GE corn approval process. Research and development on a variety of biotech crops is ongoing in various public research institutes and a few in collaboration with foreign and domestic firms.

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	
	Cry1Ac + Cry2Ab and Glyphosate	Field trials	CEMB/NIBGE + 4 Domestic Seed Companies
	Fiber improvement	Experimental	CEMB/NIBGE+ 4 Domestic Seed Companies 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 IIUI IBGE, Peshawar

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, IBGE
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 IBGE

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

IBGE Institute of Biotechnology and Genetic Engineering, Ag. Univ. Peshawar

IIUI International Islamic University, Islamabad

b. COMMERCIAL PRODUCTION

Biotech cotton is the only biotech 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 few years ago. The Center of Excellence in Molecular Biology (CEMB) developed three double gene transgenic

cotton varieties being marketed commercially. In 2019, farmers planted 2.5 million hectares of biotech cotton (over 95 percent of total cotton area) using more than 30 seed varieties. The NBC issued a unilateral moratorium on the GE corn approval process in 2019.

c. EXPORTS

Pakistan exports small volumes of biotech cotton. Exports reached $29 million during the cotton marketing year 2018/19. Pakistan also exports cotton yarn, cotton fabric, and other items derived from both domestic and imported biotech cotton. The textile sector comprises a major share of Pakistan's economy and exports. During 2018-19, Pakistan's textile exports totaled $13 billion, which were 58 percent of total Pakistan's overall exports.

d. IMPORTS

In MY 2018/19, Pakistan imported around 2.7 million 480lb bales of cotton – much of which were derived from biotech varieties mostly from the United States, 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 2.3 million metric tons of soybeans during marketing year 2018/19 valued at around $590 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 provided food aid to countries like Afghanistan and African countries.

f. TRADE BARRIERS

Pakistan authorities are in the process of implementing more stringent measures to regulate trade claiming that they must comply with policies related to GE products, particularly those used for FFP. While the Biosafety Rules of 2005 stipulates that approval is required for biotech derived products that will be used for FFP purposes, the government has yet to promulgate any rules or administrative processes that explain how to obtain the necessary authorizations. The lack of clear rules, guidelines, and procedures are stymying the importation of GE products (soybean seed, canola, sunflower seed, DDGS, etc.) into Pakistan.

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 apex body responsible for the review and approval of laboratory procedures, monitoring field trials, regulating trade, and facilitating 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 (MOCC). 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 include member from the provinces.

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.

b. APPROVALS

The TAC and NBC hold regular meetings and have previously approved several GE applications mainly involving cotton events. Applications for corn events have been put on hold as the MNFSR opposed the use of GE corn directly in food value chain.

The following are details of approved commercialized event 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	Bayer Pakistan	Maize	Roundup Ready corn® (NK603 Genuity VT Double Pro (MON89034XNK603)
5	Corteva Pakistan	Maize	Maize 1507xNK603; MON 810xNK603

Pakistan's Biosafety Rules of 2005 provide a timeline 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 of 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. Although Pakistan recently approved a Plant Breeders' Rights Act, and Intellectual Property Rights (IPR) Act, regulatory officials suggest that each new genetic trait will be protected separately. In addition, while the NBC has approved three single and stacked events for maize, their commercial approval has been put on hold by regulatory authorities as they assert maize should not be directly used in the food value chain.

Details for commercial approval and field trial are as follows:

Genes	**Approval Stage**	**Company**
cp4epsps	Commercial	Bayer
cry2Ab2 & cry1A.105 and cp4epsps	Commercial	Bayer

cry1F, cry1Ab and cp4epsps	Commercial	Corteva
Cry1Ac + Cry2Ab + Glyphosate	Commercial	CEMB

Field Trials

	Insect Resistance	Field trials	CEMB, NIGAB
Maize	cry1F, cry1Ab and cp4epsps	Field trials	Corteva
	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.

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 AND TRACEABILITY

Pakistan has no labeling requirements for bulk imports of 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 from the Department of Plant Protection (DPP) and certification from the NBC. The mechanisms for monitoring and testing are outlined in the 2005 Biosafety Guidelines, but currently, there is no clear and transparent process to register GE events. Pakistan must design regulations for the trade of FFP

products. The NBC is 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 into 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. 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 is now in the 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 implementation rules.

PART C: MARKETING

a. PUBLIC/PRIVATE OPINIONS

The MNFSR, Climate Change, Health, Education, Science and Technology, Commerce, Planning and Development, Textiles and agricultural community is generally supportive of the expanded utilization of

GE technology. Lack of GE certification and FFP approval process is creating uncertainty in the trade of biotech products. This ambiguity is also making foreign entities reluctant to invest in Pakistan due to the lack of legal protections. 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 introduction of 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 unaware 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, cloning or trade of animals derived from biotechnology is occurring in Pakistan. Experiments for cloning mice embryos is in progress, but there are no commercial applications yet. In vitro embryo production and transfer in humans is practiced on a limited scale. Production technology is researched for animals in some institutes.

Recent developments for Recombinant Animal Vaccines for Newcastle disease in Pakistan's poultry industry at 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 a 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 of 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

The approval process has not yet started on a commercial scale as no production or trade of animal biotechnologies or cloning is taking place 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 unaware of any existing IPR provisions for animal biotechnology.

f. INTERNATIONAL TREATIES AND FORUMS

While Pakistan is a World Trade Organization (WTO) member, it 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 unaware 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 unaware 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.

Attachments:

No Attachments