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2017 Kenya's Agricultural Biotechnology Report

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Report Highlights:
Genetically engineered (GE) Gypsophila will likely reach the market before Bt cotton and Bt corn, as GE Gypsophila is not subject to national performance trials (NPTs) stipulated in the Kenya Seeds and Plant Variety Act. In addition, the non-controversial nature of the GE plant in terms of food and environmental safety, favors its early release into the market.

Commercialization of Bt. cotton will follow later in 2018 when the NPTs are completed. On September 8, 2017, the Government of Kenya (GOK) approved the environmental release through open field trials for Bt. cotton, an effort to revive Kenya's cotton industry. If Kenya's plans move forward for cotton, this would be the first open field trials for a GE product.

Despite the progress on GE development, the import ban on GE products remains.

SECTION I. EXECUTIVE SUMMARY

On May 2, 2017, the Kenya Agricultural and Livestock Research Organization (KALRO) and Imaginature Ltd. (a subsidiary of Danziger, an Israeli company and patent owner of the gene) officially submitted to NBA an application to allow for environmental release and commercialization of GE-Gypsophila cut flower. Before submitting the application, KALRO and Imaginature Ltd. conducted and completed confined field trials for the GE Gypsophila in Naivasha, under the supervision of the National Biosafety Authority (NBA), and the Kenya Plant Health Inspectorate Service (KEPHIS) as per the Biosafety Act No. 2, 2009 and the relevant Biosafety regulations. According to the Biosafety Act 2009, NBA should take 90 to 150 days to approve or disapprove an application from the date of submission. GE Gypsophila's application has passed the 150 days as of now. Find additional information on the GE-Gypsophila at: GE-Gypsophila Cut-Flowers Brief

The GOK approved the initiation of environmental release through open field trials for Bt. cotton (MON 15985) and derived varieties through Kenya Gazette Notice No. 8846 dated September 8, 2017, an effort towards revival of Kenya's cotton industry. The government intends to put this variety into commercial use before the end of 2018. In addition, the GOK appointed a 13-member task force in mid-July 2017 to fast track the process. KEPHIS together with the task force identified and approved 10 sites for NPTs, the last experimental stage before commercialization. GOK will meet the NPTs costs, an expense normally taken by the technology developers, thus, a sign of commitment and political good will. NPTs will start in April-May 2018 across the 10 sites during the long rains season having missed the short rains window in 2017.

Plans are also underway for Bt. corn open field trials.

The GOK remains silent on the GE products import ban but supports domestic development of GE products, and allows importation of research material.

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SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

A) PRODUCT DEVELOPMENT

Kenya continues to build on the developed capacity for agricultural biotechnology research and development. The following table presents plant and GE crops under development in Kenya that may be commercialized the next five years.

Crop	**Trait**	**Developers**	**Stage of Development**	**Estimated Date of Commercial Release**
Gypsophila Flower	Pink Coloration of Petals/flower color stability	[1]KALRO Imaginature Ltd., *representing Danziger – "Dan" Flower Farm of Israel*	Confined Field Trials (CFT) completed; No NPTs required for the plant. NBA reviewing the application for environmental release/open cultivation, and thereafter commercialization	2018
Cotton	Insect Resistance (*bollworms*)	KALRO Monsanto	Environmental Impact Assessment (EIA) ongoing at the 10 sites identified for National Performance Trials (NPTs), followed by NPTs across the 10 sites during the long rains season, April-May 2018. NPTs at three sites will be under irrigation.	First cultivation planned for April – May 2018
Corn	Drought Tolerance/Water Efficient Maize for Africa (WEMA) -- MON 87460	KALRO [2]AATF [3]CIMMYT	CFT completed at the 6th season;	2018/2019
	WEMA Insect Resistance (MON 810)	[1]KALRO [2]AATF CIMMYT	Awaiting NEMA's approval to conduct NPTs at six sites identified.	2018/2019
	Stacked maize event for insect resistance (MON810) and drought tolerance (MON87460)	KALRO AATF CIMMYT	First season CFT completed.	2019/2020
Cassava	Virus Resistance			
	Cassava Mosaic Disease (CMD)	KALRO [4]DDPSC	CFT – second season completed	2020/2021

		[5]IITA		
	Cassava Brown Streak Disease (CBSD)	KALRO DDPSC IITA	CFT – first season completed	2020/2021
	Bio fortified Cassava (VIRCA Plus)	KALRO DDPSC [6]NARO IITA	One CFT season completed	2020/2021
	Cassava Brown Streak Virus (CBSV) and African Cassava Mosaic Virus (ACMV)	[7]MMUST	CFT – First season completed	2020/2021
Sorghum	Enhanced pro-Vitamin A levels, Bioavailable Zinc and Iron	KALRO [8]AHBFI Pioneer Hi-Bred Kenya Ltd. a DuPont Business	CFT – Seventh season completed	2018/2019
Sweet Potato	Virus Resistance: siRNA resistance to Sweet Potato virus Disease	KALRO DDPSC	CFT – First CFT season completed	2020
	Weevil Resistance through RNAi technology	ILRI	Contained use under laboratory and greenhouse trials ongoing at BecA-ILRI Hub, Nairobi	2020/2021
Banana	Banana bacterial – *Xanthomonas Wilt* (BXW) resistance	KALRO IITA	CFT – First season ongoing at KALRO Research Station- Alupe	2020

Notes: [1]Kenya Agricultural and Livestock Research Organization; [2]African Agricultural Technology Foundation; [3]International Maize and Wheat Improvement Center; [4]Donald Danforth Plant Science Center: [5]International Institute of Tropical Agriculture; [6]National Agricultural Research Organization, Uganda; [7]Masinde Muliro University of Science and Technology; [8]Africa Harvest Biotechnology Foundation International
Sources: International Service for the Acquisition of Agri-biotech Applications (ISAAA), 2016; FAS/Nairobi field visits/meetings with key biotech stakeholders

Find additional information on approved GE projects at: Biosafety Clearing House Kenya

B) COMMERCIAL PRODUCTION

Kenya does not commercially produce GE crops or GE seeds. However, commercialization of GE Gypsophila cut flower will likely happen on/about late 2017/early 2018, followed by Bt. cotton later in 2018.

C) EXPORTS

Kenya does not export GE crops or products that contain GE materials to the United States or any other country. Commercialization of GM-Gypsophila will be an addition to Kenya's assortment of cut flowers exports in the international market including the United States.

D) IMPORTS

The Government of Kenya banned importation of GE products (crops, processed products, and

seeds) on November 21, 2012. Ministry of Health prompted the move. The following link provides a report on the ban: Kenya Bans Imports of Genetically Modified Foods

NBA is responsible for the approval process of import shipments of GE products. The authoritative legislation, Kenya's Biosafety Act of 2009, stipulates that the approval process should take 90-150 days. In addition, the Kenya Plant Health Inspectorate Service (KEPHIS) requires imported GE plant products to have:

- A declaration from the country of origin that states the import's GE status, and
- A phytosanitary certificate.

Kenya is a net food importer of agricultural commodities mainly corn, wheat, rice, and edible oils. No GE foods and related products have entered into the Kenyan market to date since the effect of the import ban.

E) FOOD AID

Kenya is a food aid recipient country. Some food aid commodities, like corn-soy blend, are GE products. Prior to the GE import ban, NBA approved imported GE corn-soy blend for humanitarian assistance through the World Food Program (WFP). Since the GE products import ban came into effect, no humanitarian assistance containing GE products has accessed Kenya. Find details of past GE food imports approvals at: Approved Genetically Modified Products for Imports and Transit

The GE import ban also affects food aid shipments destined for other countries. Under advisement of the U.S government, food aid destined for inland east African countries, which would ordinarily enter through the Port of Mombasa are diverted to other ports.

F) TRADE BARRIERS

In addition to the GE ban, mandatory labeling of GE foods effectively precludes importation of food with GE components. Violation of the mandatory labeling provisions imposes a fine up to $230,000 and/or imprisonment up to ten years. The approval process for importation is also slow because of untenable pre-notification procedures.

PART B: POLICY

A) REGULATORY FRAMEWORK

The NBA, established by the Biosafety Act No.2 of 2009, is under the Ministry of Agriculture, Livestock and Fisheries administratively, but under the Ministry of Education, Science and Technology legally. NBA is the main regulatory agency that oversees GE development in Kenya. It is responsible for regulations and policies, as well as general supervision and control over the transfer, handling, and use of GE products. Following the Biosafety Act 2009, NBA developed the following four GE implementing regulations:

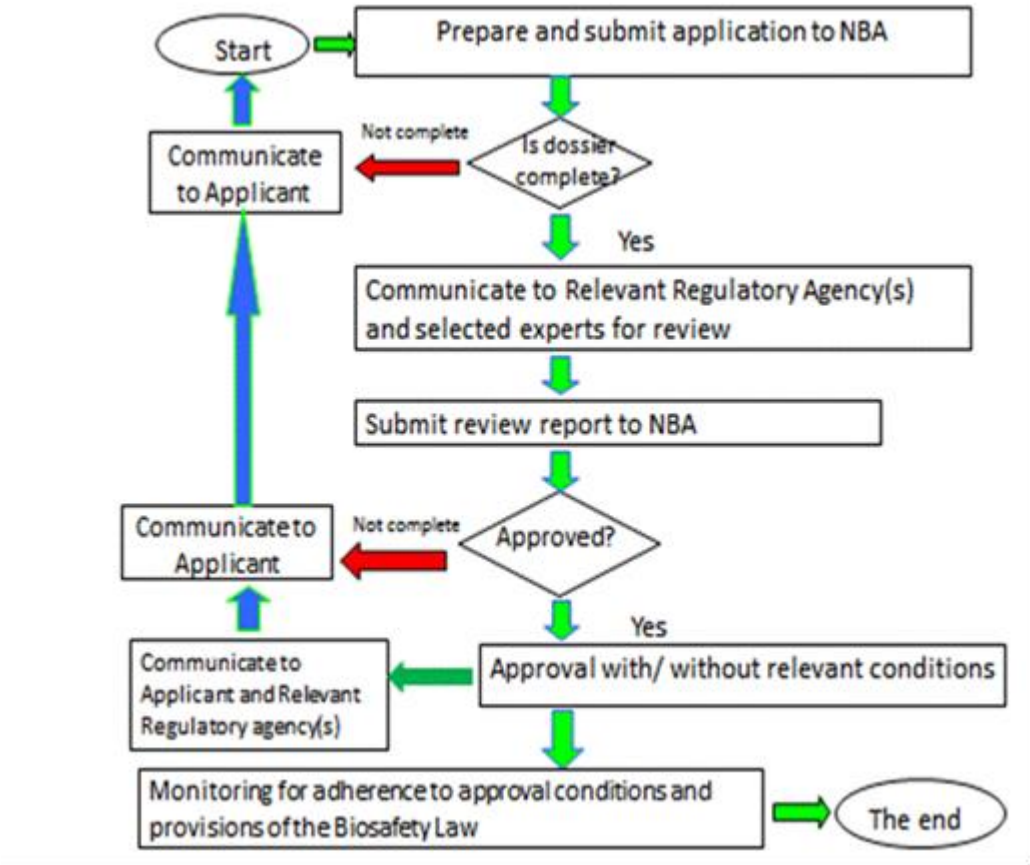
- Contained Use Regulation, 2011;
- Environmental Release Regulation, 2011;

- Import, Export, and Transit Regulation, 2011; and
- Labeling Regulation, 2012

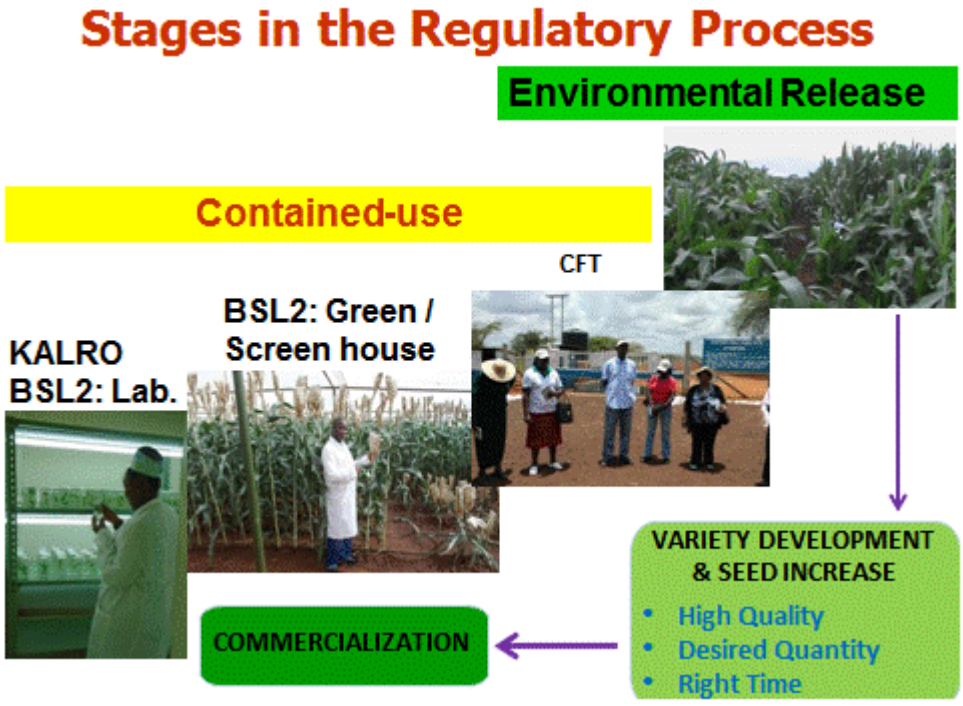
Also in draft stage is the Packaging, Transport, and Identification regulation.
NBA works together with eight other regulatory agencies that have different roles in regulating GE products:

- Kenya Plant Health Inspectorate Service (KEPHIS)under the Ministry of Agriculture, Livestock and Fisheries, oversees the introduction, testing and use of biotechnology plants and seeds;
- Department of Public Health, under the Ministry of Health, safeguards consumers' health through food safety and quality control, surveillance, prevention and control of food borne diseases. The Agriculture committee has recommended the establishment of a Food Safety and Control Unit to evaluate food safety of GE foods for human consumption, and to issue import permits for GE foods;
- Kenya Bureau of Standards, (KEBS) under the Ministry of Industrialization and Enterprise Development, develops food standards, quality assurance, and testing; https://www.kebs.org/index.php?opt=standards&view=biosafety
- National Environment Management Authority (NEMA), under the Ministry of Environment, Water, and Natural Resources, oversees environmental questions and conducts environmental impact assessments. NEMA issues licenses that permit national performance trials (NPTs) on GE crops and plants.
- Pest Control Products Board, (PCPB), under the Ministry of Agriculture, Livestock and Fisheries, regulates pesticide use;
- Kenya Wildlife Service (KWS), under the Ministry of Environment and Natural Resources, handles biodiversity and biotechnology related matters in wildlife and forestry;
- Kenya Industrial Property Institute (KIPI), under the Ministry of Industrialization and Enterprise Development, handles intellectual property issues; and,
- Department of Veterinary Services (DVS), under the Ministry of Agriculture, Livestock and Fisheries, protects and controls spread of animal diseases and pests to safeguard human health, improve animal welfare, and increase livestock productivity through production of high quality livestock and livestock products.

The following figure shows the process for approving production of GE crops developed in Kenya.


Start
Prepare and submit application to NBA
Is dossier complete?
Not complete
Communicate to Applicant
Yes
Communicate to Relevant Regulatory Agency(s) and selected experts for review
Submit review report to NBA
Approved?
Not complete
Communicate to Applicant
Yes
Approval with/ without relevant conditions
Communicate to Applicant and Relevant Regulatory agency(s)
Monitoring for adherence to approval conditions and provisions of the Biosafety Law
The end

Source: NBA


Stages in the Regulatory Process
Environmental Release
Contained-use
CFT
BSL2: Green / Screen house
KALRO BSL2: Lab.
VARIETY DEVELOPMENT & SEED INCREASE
• High Quality
• Desired Quantity
• Right Time
COMMERCIALIZATION

Source: NBA

B) APPROVALS

Kenya is yet to register GE plants or crops for cultivation, import. Since the import ban came into effect in Nov. 2012, no GE food has come through WFP either for Kenya or on transit to the neighboring countries. WFP has limited its food aid to non-GM commodities.

However, with the progress made in GE Gypsophila, Bt cotton, and Bt corn to move from confined field trials to open field trials, Kenya will in the near future have GE crops and a plant under cultivation.

C) STACKED OR PYRAMIDED EVENT APPROVALS

Stack trait corn event testing for insect resistance and drought tolerance is ongoing. In addition, CFTs for bio fortified sorghum and cassava involve more than one trait. NBA conducts risk assessment for each trait individually (per event) in order to approve a stacked product.

D) FIELD TESTING

Kenya has allowed CFTs for GE corn, cotton, cassava, sorghum, sweet potato, banana, and Gypsophila flower. For security reasons, ease of control and management, KALRO centers exclusively provide trial sites (for both CFT and NPT) that are normally on less than one-acre plots. In addition, NEMA must conduct an EIA before the NPTs start.

KEPHIS, NBA, KALRO, and CIMMYT have developed NPT guidelines to guide the NPT process. The guidelines address measures to control gene flow, number and size of confined field trials, and related issues.

KALRO has 16 research institutes spread across different agro ecological zones of Kenya.

E) INNOVATIVE BIOTECHNOLOGIES

Kenya's local institutions (the universities and KALRO) are testing genome editing, and RNAi (switching on and off gene expression) at the laboratory level for proof of concept. Generally, Kenya views genome editing as another genetic modification technique, and therefore, part of the regulatory process for GE products.

Interest has emerged in Synthetic Biology to find practical synthetic biology solutions in animal and human health, industry, and environment. On March 15-17, 2017, Kenya held the first ever workshop on Synthetic Biology in collaboration with the United Kingdom's Engineering and Physical Sciences Research Council (EPSRC) to create awareness on the technology. Possible areas of research identified from the workshop include development of biosensors for use in agriculture, health, and environment sectors. Synthetic biology can also be used to develop industrial products used in research laboratories such as primers.

F) COEXISTENCE

NBA has drafted policy guidance on coexistence between GE and conventional crops that awaits discussion with stakeholders.

G) LABELING

The Kenyan government requires mandatory labeling of foods and feed containing at least one percent, by weight, of GE content. No labeling is required if the GE content is less than one percent of the total weight and the product has been approved by NBA as safe. Find details on the labeling regulations at: Labeling Regulations 2012 and 2012 Kenya Agricultural Biotechnology Report

H) MONITORING AND TESTING

NBA is responsible for approving imports of GE products, while KEPHIS, KEBS, and Port Health (Department of Public Health) monitor and test agricultural commodities and food products imports at ports of entry for compliance to the set standards and requirements. However, the Kenyan government has limited personnel and testing facilities for evaluating agricultural products for GE content.

In addition, NBA inspects facilities that conduct GE research to ensure compliance to the Biosafety law and approved conditions.

I) LOW LEVEL PRESENCE (LLP) POLICY

NBA has drafted a low-level presence and adventitious presence policy guidance that awaits consultation with stakeholders.

J) ADDITIONAL REGULATORY REQUIREMENTS

Kenya's National Assembly Agriculture committee has proposed additional testing to evaluate safety of GE foods for human consumption. These include acute and sub-acute toxicity testing; chronic toxicity; and long-term and epidemiological surveillance. The committee wants all GE products to pass preliminary, independently varied, 90-day animal feeding tests that will qualify the GE producer for issuance of a Class A permit from the Food Safety and Quality Control Unit of the Ministry of Health. The permit should be for a limited period not exceeding two years.

K) INTELLECTUAL PROPERTY RIGHTS (IPR)

The Kenya Industrial Property Institute (KIPI) is the government institution that administers and protects intellectual property issues that may pertain to genetic engineering, including patents, trademarks, utility models, industrial designs, and technovations.

Kenya is a signatory to the Trade Related Intellectual Property Rights (TRIPS) being a member of the World Trade Organization (WTO). The Seeds and Plant Varieties Act (Plant Breeders Rights), and related regulations offer patent owners protection.

L) CARTAGENA PROTOCOL RATIFICATION

Kenya was the first country to sign the Cartagena Protocol on Biosafety (CPB) on January 29, 2000. Kenya ratified the Protocol in 2002 and it entered into force on September 11, 2003. The international regulatory agreement requires countries to address environmental safety and human health by ensuring safe handling, transport, and use of GE products. NBA is Kenya's focal point of the CPB and shares data with the Biosafety Clearing House, a mechanism set by CPB to facilitate information exchange on GE product development and to assist member countries in

complying with their obligations under the protocol.

Kenya adopted the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the CPB on October 15, 2010. It gives Kenya flexibility to implement legislative, administrative or judicial rules and procedures relevant to liability and redress.

M) INTERNATIONAL TREATIES/FORUMS

Kenya is a member of several international organizations that deal with plant protection and plant health, including the International Plant Protection Convention (IPPC), the Codex Alimentarius (Codex), and the aforementioned CPB. Generally, these international frameworks seek to protect the environment and human health without unduly hindering international trade, aim to be transparent and in harmony with international trade regulations, and are science-based.

N) RELATED ISSUES

Not applicable.

PART C: MARKETING

A) PUBLIC/PRIVATE OPINIONS

Debate on biotech crops and bioengineered foods remains contentious and political. Some non-governmental organizations have exposed Kenyan consumers to negative messaging, while Kenyan agricultural research scientists, farmers, university professors and students, seed companies, and other pro-biotech non-governmental organizations continue to provide positive messaging.

B) MARKET ACCEPTANCE/STUDIES

Studies conducted by the CIMMYT, KALRO, and Kansas State University over five years revealed that Kenyan consumers are generally not aware of bioengineered foods. Processors and retailers showed a higher level of awareness, especially with regard to GE foods.

Survey Group	**Number Surveyed**	**Awareness (%)**	
		Biotechnology	**GE Crops**
Urban consumers in Nairobi	612	46	38
Rural consumers in Western Kenya	121	16	13
Eastern Kenyans	400	63	31
Gatekeepers at milling companies	32	67	87
Supermarkets Managers	40	83	79

Source: CIMMYT

Surveys and studies conducted in Kenya reveal that, although many respondents have heard about genetic engineering in agriculture, most are not informed about the science. Studies also indicate that most Kenyans wish to learn more about GE, regardless of their current perceptions.

A 2011 study, conducted by Hannington Odame and Elijah Muange and sponsored by the UK's Department for International Development (DFID), asked Kenyan farmers and agro-dealers about their awareness and perceptions of GE seeds. The study was conducted in high-

rainfall Uasin Gishu and low-rainfall Machakos. Among the results, summarized in the table below, they found that about 60 percent of respondents would buy GE seeds but wanted more information. More details are available in the report Agro-Dealers and the Political Economy of Agricultural Biotechnology in Kenya

Aspect of GE Seeds	Agree (%)			Don't Know (%)		
	Uasin Gishu	Machakos	Avg.	Uasin Gishu	Machakos	Avg.
Alleviate food shortage	78.0	81.5	79.4	12.2	11.1	11.8
More Nutritious	12.2	38.5	22.4	34.1	34.6	34.3
More Yield	63.4	77.8	69.1	19.5	18.5	19.1
Tolerate drought better	43.9	70.4	54.4	34.1	22.2	29.4
Resist pest better	42.5	63.0	50.7	27.2	29.6	28.4
Resist herbicide better	19.5	48.1	30.9	39.0	40.7	39.7
Contaminate local varieties	51.2	42.3	47.8	17.1	30.8	22.4
Dangerous to human health	50.0	40.7	46.3	30.0	29.6	29.9
Injurious to non-target organisms	42.5	36.0	40.0	40.0	32.0	36.9
More expensive	53.7	75.0	61.5	17.1	20.8	18.5
Require more expertise to trade	63.2	58.3	61.3	21.1	12.5	17.7
Would trade in GM seeds	48.8	75.0	57.4	26.8	25.0	26.2

Another study, conducted by Simon Chege Kimenju of the University of Nairobi and Hugo De Groote of CIMMYT, indicated that approximately 70 percent of Nairobi consumers would pay the same price for GE or non-GE corn meal. More details are available in the report Consumers' Willingness to Pay for Genetically Modified foods in Kenya.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

A) PRODUCT DEVELOPMENT

Research scientists based at the International Livestock Research Institute (ILRI) headquarters in Nairobi, Kenya have designed research to develop vaccines, disease diagnostic test kits, and trypanosomiasis-resistant cattle. The ultimate goal is to improve on livestock health, and consequently, their productivity.

Product/Animal	Trait	Developers	Stage of Development
Rift Valley Fever Vaccine	Evaluate ChAdOxl-GnGc vaccine in confined field trial to assess its safety, and immunogenicity among sheep, goats, cattle, and dromedary camels in Kenya.	International Livestock Research Institute (ILRI)	CFT approved on November 25, 2016; Kapiti Ranch, Machakos is the location of the trial.
Recombinant Viral Vaccine	To control infections caused by Mycoplasma	ILRI	Contained Use/Laboratory Stage

	mycoides cluster.		
Disease Diagnostic test kits	Example: latex agglutination test kit for CCPP (CAPRITESTR)	ILRI	Awaiting commercial release
Cattle	Resistance to Trypanosomiasis	ILRI;KALRO; and Institute of Primate Research (IPR)	Pre-CFT

Source: NBA

ILRI research scientists plan to develop disease-resistant cattle for Africa using state of the art technologies including cloning and gene editing. Reducing disease incidence in cattle could increase across the continent. It also has the potential to improve livelihoods for African farmers through increased agricultural productivity.

Trypanosomiasis, a zoonotic disease also known as Nagana in cattle and sleeping sickness in humans, has widespread impact on both human health and livestock production across Africa. ILRI scientists estimate its impact to be over $1 billion in losses annually to the African economy, reportedly affecting over 70 percent of the reared cattle. The prevalence of trypanosomiasis effectively limits the extent of animal agriculture across Sub-Saharan Africa, depriving many communities of high quality protein sources and draft animals. The ILRI scientists have successfully developed a cloned Boran calf named "Tumaini" in the first phase of the project. In the second phase of the project, the ILRI scientists will develop a new cloned Boran cow with a gene for a different form of a common protein (Apolipoprotein) that promises to confer immunity to trypanosomiasis.

The key institutions involved in livestock biotechnology research and development include; ILRI, KALRO, and IPR. NBA regulates application of biotechnology in livestock. Find more information on NBA-approved livestock projects at Approved Contained Use Research Activities including Livestock Biotechnology

B) COMMERCIAL PRODUCTION

Not Applicable

C) EXPORTS

Not Applicable

D) IMPORTS

The ban on biotech imports affects both plant and animal products but excludes research materials. Kenya will need to import transgenic products such as cow fibroblasts, blastocysts, sperm, and possibly transgenic live animals to facilitate development of the trypanosomiasis resistant cow.

E) TRADE BARRIERS

Not Applicable

PART E: POLICY

A) REGULATORY FRAMEWORK
NBA's regulatory mandate covers both plants and livestock, but specific animal biotechnology regulations are yet to be published. Animal science researchers use NBA's protocols/guidelines on experiments under contained use, and confined field trials.

B) INNOVATIVE BIOTECHNOLOGIES
Trypanosome resistant cattle are being developed by ILRI using CRISPR/Cas9 gene editing technology. It is not yet clear how the NBA will regulate animal products developed with gene editing.

C) LABELING AND TRACEABILITY
Not Applicable

D) INTELLECTUAL PROPERTY RIGHTS (IPR)
The Kenya Industrial Property Institute (KIPI) is the government institution that administers and protects intellectual property issues that may pertain to genetic engineering, including patents, trademarks, utility models, industrial designs, and technovations.

Kenya is a signatory to the Trade Related Intellectual Property Rights (TRIPS) being a member of the World Trade Organization (WTO). The Seeds and Plant Varieties Act (Plant Breeders Rights), and related regulations protect the patent owners.

E) INTERNATIONAL TREATIES/FORUMS
Kenya has not taken a position on animal biotechnologies in international forums despite being a member of Codex and the World Organization for Animal Health (OIE). Research on animal biotechnologies is in its early stages of development.

F) RELATED ISSUES
Not Applicable

PART F: MARKETING

A) PUBLIC/PRIVATE OPINIONS
Unknown/Not Applicable

B) MARKET ACCEPTANCE/STUDIES
Not Applicable