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Report Highlights:

The first planting of Bt. Cotton for commercialization in Kenya is planned for the start of the long rains season, which is expected in March or April 2020. Bt. Cotton is expected to help revive the nation's cotton and textile sector, which is a priority under the President's Big Four Agenda and, specifically, the Manufacturing and Food Security pillars. The import ban on genetically engineered (GE) products remains, denying many Kenyan producers and industry access to the best available science, limiting genetic engineering technology adoption and acceptance, and severely and unduly restricting commerce, trade, and regional food assistance.

SECTION I. EXECUTIVE SUMMARY

On November 21, 2012, the Government of Kenya (GOK) banned imports of GE products, including processed and unprocessed goods, seeds, and food assistance commodities. The Ministry of Health prompted the move over unfounded – and since debunked and discredited - food safety concerns. As the demand for feed inputs rises, the ban is especially hampering potential U.S. exports of feed ingredients including soy, feed corn, and other products.

Despite the import ban, the GOK continues to support domestic development of GE products and allows importation of GE research materials. Research trials for GE Gypsophila cut flower and insect resistant cotton are complete, while that of bio fortified sorghum, bacteria wilt resistant bananas, and virus resistant sweet potato are ongoing. An application to commercialize GE Gypsophila cut flowers was denied due to the fear that the EU would ban Kenyan exports. The virus resistant cassava research is at the stage of environmental release request.

Insect resistant corn/Bt. corn awaits National Environment Management Authority's approval for environmental release. Efforts are underway to open the process.

Kenya's animal biotechnology research is at early stages of development. Research scientists at the International Livestock Research Institute (ILRI) are conducting research to develop trypanosome resistant cattle and goats using various technologies that include cloning, GE, and genome editing. Trypanosomiasis is one of the most significant constraints to cattle production in Africa, directly affecting livestock productivity. Other related animal biotechnology research includes development of vaccines and diagnostic kits.

The National Biosafety Authority (NBA) has developed guidelines on the contained use of GE animals, a draft regulation on animal biotechnology, as well as a draft regulation on genome edited organisms.

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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 the capacity for GE research and development. The following table presents GE crops under development in Kenya that may commercialize in the next five years.

Crop	Trait	Developers	Stage of Development	Estimated Date of Commercial Release
Gypsophila Flower	Pink Coloration of Petals (The trait confers flower color stability)	[1]KALRO Imaginature Ltd., representing Danziger – "Dan" Flower Farm of Israel	CFT completed; No NPTs required for the plant. NBA did not approve the application for commercialization.	Uncertain due to concerns over the effect on the European market if approved.
Cotton	Insect Resistance (African bollworm)	KALRO Bayer Sciences	Two seasons of National Performance Trials, (NPTs) completed.	First cultivation planned for March/April 2020
Corn	Drought Tolerance/Water Efficient Maize for Africa (WEMA) -- MON 87460	KALRO [2]AATF [3]CIMMYT	Six seasons of CFTs completed. Project dropped to pave way for the other two trials with superior technologies – MON810 and the stacked event, MON810 and MON 87460.	Not Applicable
	WEMA Insect Resistance (MON 810)	[1]KALRO [2]AATF CIMMYT	Awaiting NEMA's approval to conduct NPTs at six sites (Alupe; Kibos; Kakamega; Embu; Thika, and Mwea)	2021/2022
	Stacked maize event for insect resistance (MON810) and drought tolerance (MON87460)	KALRO AATF CIMMYT	Two seasons completed at two sites. KALRO scientists observed the stacked maize event trials to withstand the Fall Army Worm (FAW), a devastating, invasive pest mainly attacking maize and sorghum, key staple foods.	2022
Cassava	Virus Resistance			

	VIRCA Plus Project Biofortified Cassava resistant to Cassava Mosaic Disease (CMD) and Cassava Brown Streak Disease (CBSD); Research ongoing in Kenya, Uganda, and Nigeria	KALRO [4]DDPSC [6]NARO [5]IITA [9]ARCN	CFTs completed Regulatory trials for safety data collection ongoing	The developers to submit regulatory dossier to NBA end of 2019 for environmental release request. 2021/2022
	Cassava Brown Streak Virus (CBSV) and African Cassava Mosaic Virus (ACMV)	[7]MMUST	CFT – First season has been completed ACMV remained a challenge; MMUST re-adapting the research to address the issue.	Unknown
Sorghum	Enhanced pro-Vitamin A levels, Bioavailable Zinc and Iron	KALRO [8]AHBFI Pioneer Hi-Bred Kenya Ltd. (Corteva)	Seventh season CFT completed.	2020/2021
Sweet Potato	Virus Resistance: siRNA resistance to Sweet Potato virus Disease	KALRO - Kakamega Center DDPSC	First season CFT completed	2021/2022
	Weevil Resistance through RNAi technology	ILRI	Contained use under laboratory and greenhouse trials ongoing at BecA-ILRI Hub, Nairobi	2021/2022
Banana	Banana bacterial Xanthomonas wilt (BXW) resistance	KALRO IITA	First season CFT completed at KALRO Research Station-Alupe	2021/2022

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; [9]Agricultural Research Council of Nigeria
Sources: International Service for the Acquisition of Agri-biotech Applications (ISAAA), 2017; FAS/Nairobi field visits and 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 Bt. cotton will likely happen in early 2020.

C) EXPORTS

Kenya does not export GE crops or products that contain GE materials to the United States or any other country. GE Gypsophila was intended for export to the international market, including the United States, but it is not approved.

D) IMPORTS

GOK banned importation of GE products (commodities, processed products, and seeds) on November 21, 2012. The Ministry of Health cited Séralini – a debunked work of propaganda disguised as science that claimed false links between GE corn and cancer. The GE ban remains.

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.

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, diverts to other ports. Such diversions cost the Port of Mombasa considerable revenue and jobs and are a barrier to economic growth.

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 of 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

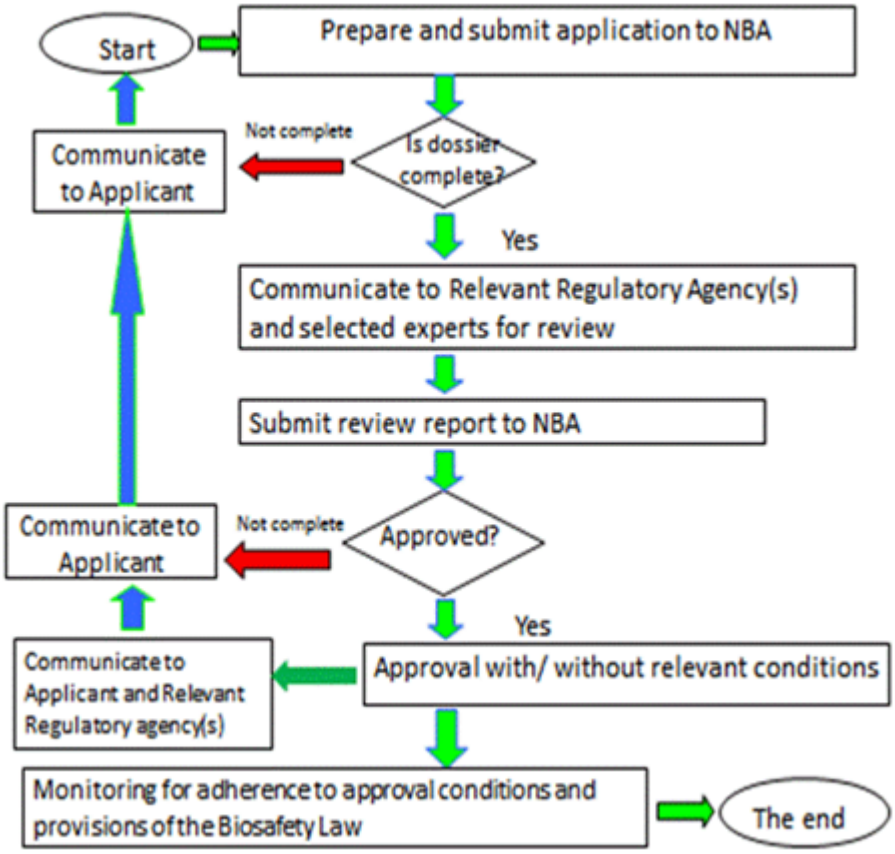
In addition, in draft stage is the Packaging, Transport, and Identification regulation. Find additional information at the National Biosafety Authority website.

NBA and eight other regulatory agencies are tasked in regulating GE products:

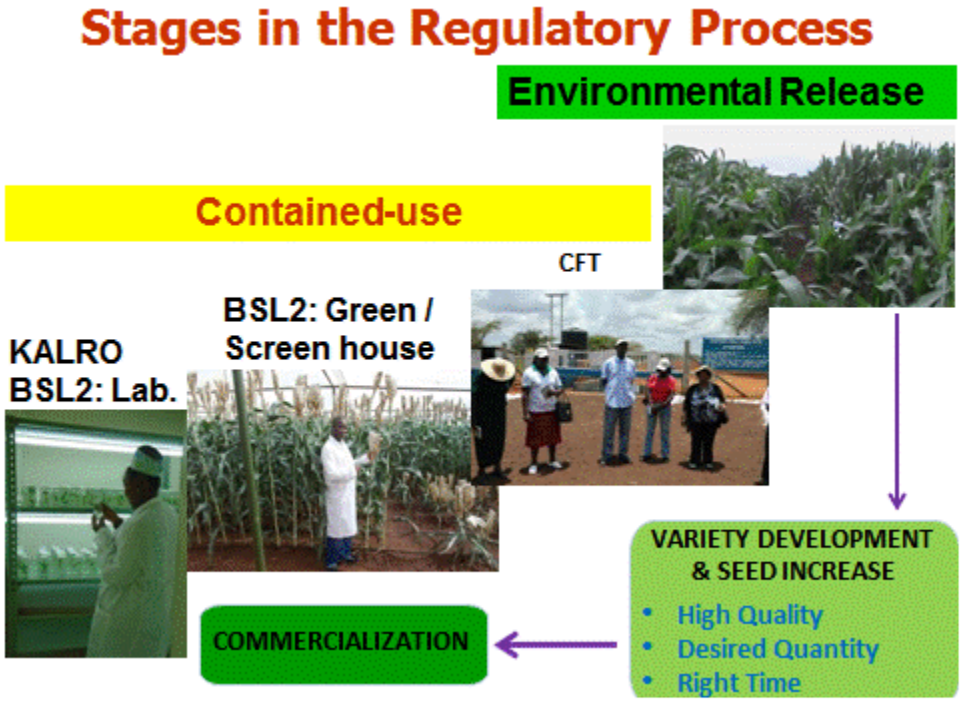
- Kenya Plant Health Inspectorate Service (KEPHIS) under the Ministry of Agriculture, Livestock, Fisheries and Irrigation, oversees the introduction, testing and use of biotechnology plants and seeds
- Department of Public Health, under the Ministry of Health, safeguards consumers' health through food safety and quality control, surveillance, prevention and control of food borne diseases;
- Kenya Bureau of Standards, (KEBS) under the Ministry of Industry, Trade and Cooperatives develops food standards, quality assurance, and testing;
- National Environment Management Authority (NEMA), under the Ministry of Environment and Forestry oversees environmental safety issues 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, Fisheries and Irrigation regulates the import, export, manufacture, distribution, and use of products used for the control of pests;
- Kenya Wildlife Service (KWS), under the Ministry of Tourism and Wildlife undertakes and coordinates biodiversity research and monitoring through its Biodiversity Research and Monitoring Division. This Division provides scientific information that is used in the conservation and management of Kenya's invaluable biodiversity;
- Kenya Industrial Property Institute (KIPI), under the Ministry of Industry, Trade, and Cooperatives administers intellectual property rights; and,
- Department of Veterinary Services (DVS), under the Ministry of Agriculture, Livestock, Fisheries and Irrigation, 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 process for approving production of GE crops developed in Kenya:



Source: NBA



Source: NBA

B) APPROVALS

Kenya has not registered GE plants or crops for cultivation or export. But, with the progress with Bt. cotton, Bt. corn, and virus resistant cassava, Kenya will likely have GE crops and a plant under cultivation soon. The NBA has also granted approvals for contained use and for confined field trials (CFTs).

Prior to the GE import ban, NBA approved imported GE corn-soy blend for humanitarian assistance through the World Food Program (WFP). Since the import ban came into effect in November 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-GE commodities.

C) STACKED OR PYRAMIDED EVENT APPROVALS

Stacked corn event testing for insect resistance and drought tolerance is ongoing. In addition, CFTs for biofortified 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 Gypsophila flower, corn, cassava, sorghum, sweet potato, banana, and NPTs for cotton. 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 environmental impact assessment (EIA) before the NPTs start, and before commercialization.

KEPHIS, NBA, KALRO, AATF, and the Program for Biosafety Systems (PBS) have developed NPT guidelines to guide the NPT process on GE crops in Kenya. The guidelines address

measures to control gene flow, the number and size of confined field trials, and related issues.

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

E) INNOVATIVE BIOTECHNOLOGIES

Kenya's local and international institutions (universities, KALRO, ILRI, IITA, and CIMMYT) are testing genome editing, and RNA interference (RNAi, switching on and off gene expression) at the laboratory level for proof of concept. NBA has drafted guidelines on genome editing and approved three applications for research under contained used for developing mosaic resistant yams; virus (Nano and Caulimo) resistant banana; and a vaccine to control the African Swine Fever virus. Three more pending applications include developing a Trypanosome resistant goat, modification of grass pea for nutrition and agronomic traits, and developing a striga resistant sorghum.

Interest has emerged in Synthetic Biology to find practical synthetic biology solutions in animal and human health, industry, and environment. Kenyan and United Kingdom's researchers and policy held a third workshop in June 26-27, 2019 at Imperial College, London. The workshop considered development of synthetic biology research and applications in the context of East Africa and specifically, Kenya.

Possible areas of research identified from the workshop include development of biosensors for use in agriculture, health, and environment sectors. Synthetic biology will also 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

GOK 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.

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 product imports at ports of entry for compliance to the set standards and requirements. The Kenyan government continues to develop personnel and testing facilities for monitoring agricultural products for GE content.

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

I) LOW LEVEL PRESENCE (LLP) POLICY

NBA has drafted a low-level presence and adventitious presence policy guidance that awaits further consultation with stakeholders. In response to poor 2017 harvests following

localized drought conditions, on June 21, 2017, the CEO of the National Biosafety Authority (NBA) issued a statement on a "Revised Procedure for importing 99.1 percent Genetically Modified–Free Maize Grains," allowing up to 0.9 percent low level presence of GE maize during a duty-free emergency importation period from June 1 to July 31, 2017. For countries like the United States with commercialized GE maize, the NBA was to sample and carry out conformity assessment tests at the cost to the applicant of KSH 30,000 ($291), and if found to have greater than 0.9 percent biotechnology content, the maize would not be cleared for use as food or feed.

J) ADDITIONAL REGULATORY REQUIREMENTS

Kenya's Ministry of Health advocates for precautionary use of GE products, and – despite established science and international norms – has proposed additional testing to evaluate safety of GE foods for human consumption. These include acute and subacute toxicity testing; chronic toxicity; and long-term and epidemiological surveillance. The committee wants all GE products to pass preliminary, independently verified, 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) NTELLECTUAL PROPERTY RIGHTS (IPR)

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

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 up by CPB to facilitate information exchange on GE product development and to assist member countries in complying with their obligations under the protocol. More details on the protocol can be found at: Cartagena Protocol on Biosafety

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), World Trade Organization (WTO), and the 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, political, emotional, sensational, and not based on science. Some non-governmental organizations engage in well-funded fear mongering – targeting Kenyan consumers with negative, baseless messaging, while Kenyan agricultural research scientists, farmers, university professors and students, seed companies, and other pro-biotech non-governmental organizations continue to provide science-based messaging.

MARKET ACCEPTANCE/STUDIES
A 2015 survey carried out by Kenya University Biotechnology Consortium (KUBICO) titled "Architecture of GMO acceptance in Kenya" indicated that a majority of Kenyans favors "GMO" products and technology. The urban population was more receptive to the use of "GMOs" and that acceptance had no correlation with level of education.

- Seven out of every 10 Kenyans thought "GMOs" are safe for human consumption;
- Eight out of every 10 Kenyans knowingly consume "GMOs";
- Nine out of every 10 Kenyans support the technology in all its applications;
- 14 percent of those opposed to the technology cited mistrust for government regulatory ability, and 37 percent lack of awareness on safety and regulations.

Of the 3,529 respondents,

- 76 percent supported GM product imports;
- 71 percent knew about GM products presence in Kenya;
- 50 percent were aware of the Biosafety regulations; and
- 93 percent had knowledge of "GMOs" consumption in the world.

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 trypanosome-resistant cattle. The 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 mycoides cluster.	ILRI	Contained Use/Laboratory Stage
Disease Diagnostic test kits	Example: latex agglutination test kit for CCPP (CAPRITESTR)	ILRI	Awaiting commercial release
Cattle	Resistance to Trypanosomes	ILRI; KALRO; and Institute of Primate Research (IPR)	Pre-CFT

Source: NBA

ILRI research scientists plan to develop disease-resistant cattle for Africa using technologies such as cloning, GE, and genome editing. The aim is to reduce cattle disease incidences across the continent, and to improve livelihoods for African farmers through increased cattle 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 exceed $1 billion in losses annually to the African economy, reportedly affecting more than 70 percent of the reared cattle. The prevalence of trypanosomiasis effectively limits animal agriculture across Sub-Saharan Africa, depriving many communities of high-quality protein sources and draft animals.

The ILRI scientists have 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 genome-edited, trypanosome-resistant Boran cow ("Mzima") with a gene for a different form of a common protein (Apolipoprotein) that promises to confer immunity to trypanosomes.

The key institutions involved in livestock biotechnology research and development include ILRI, KALRO, and IPR. NBA regulates the 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 biotech import ban 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 trypanosome resistant cow.

E) TRADE BARRIERS
The same GE import ban applies to products of animal biotechnology.

PART E: POLICY

A) REGULATORY FRAMEWORK
NBA's regulatory mandate covers both plants and livestock. NBA is currently working on specific animal biotechnology regulations. Animal science researchers use NBA's protocols/guidelines on experiments under contained use, and confined field trials.

B) INNOVATIVE BIOTECHNOLOGIES
ILRI plans to develop a Trypanosome-resistant cow using CRISPR-Cas9 genome editing technology. The transgenic trait used will be subject to NBA regulations. NBA has developed genome-editing guidelines for further discussion with stakeholders once finalized.

C) LABELING AND TRACEABILITY
No information available for now. However, labeling and traceability requirements will likely be the same as for plants when GE animal products become available in the market.

D) INTELLECTUAL PROPERTY RIGHTS (IPR)
Same as plant biotechnology

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/No information available

B) MARKET ACCEPTANCE/STUDIES

Not Applicable

Attachments:

No Attachments