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Report Highlights:

On October 3, 2022, Kenya's newly elected president, Dr. William Ruto, lifted the 10-year ban on importation and cultivation of genetically engineered (GE) agricultural products. This decision opens a path to importation of GE agricultural commodities and domestic production of GE crops in accordance with Kenya's existing regulatory structure. However on November 28, 2022, Kenya's Milimani High Court issued an order blocking implementation of the directive to lift the ban until December 15, 2022, as part of a legal challenge (Kenyan Peasants League vs State Law and Cabinet Secretary of Agriculture, Livestock and Fisheries). The GOK has appealed the court's decision, however at time of publication cultivation and import of GE products remain banned until December 15. Post will closely monitor and report on this development.

EXECUTIVE SUMMARY

During a Cabinet meeting on October 3, 2022, President Ruto lifted the 10-year ban on importation and open cultivation of genetically engineered (GE) and GE derived products. Since its issue on November 21, 2012, the Government of Kenya (GOK) banned the import and sale of all GE products, including processed and unprocessed goods, seeds, and food assistance commodities, citing a now-discredited study linking GE products to cancer. Removing the ban provides a way-forward for GE imports to enter Kenya and for GE crops to be cultivated domestically, however on November 28, 2022, Kenya's Milimani High Court issued an order blocking implementation of the directive to lift the ban until December 15, 2022, as part of a legal challenge (Kenyan Peasants League vs State Law and Cabinet Secretary of Agriculture, Livestock and Fisheries). The GOK has appealed the court's decision, however at time of publication cultivation and import of GE products remain banned until December 15. Post will closely monitor and report on this development

Kenya has a well-defined approval process for GE products. For imports, shipments of GE products must apply to the National Biosafety Authority (NBA) as part of their single-window entry process through KenTrade. According to NBA, GE import applications will be approved if the reported GE traits are permitted in the origin country. For cultivation, Kenya requires local field trials and environmental impact assessments. To date, insect-resistant bacillus thuringiensis (Bt.) cotton is the only product that has been commercialized in Kenya. On December 19, 2019, Kenya's Cabinet approved cultivation of Bt. cotton and allowed importation of Bt. cottonseeds. Since then, planting of Bt. cotton has continued, and Bt. cotton has entered Kenya's textile value chain. Cultivated area under Bt. cotton is currently estimated at 10,000 acres, and according to meetings with GOK, they target- to reach 40,000 acres over the next two years.

Bt. corn will likely be the first GE food crop to be commercially released and cultivated by Kenya farmers. Research field trials for Bt. corn were completed in March 2021 at six national performance trials (NPT) sites, and a necessary follow-on report was submitted to the National Performance Trial Committee (NPTC) to recommend best varieties for release to the National Variety Release Committee (NVRC).

Commercialization of Bt. corn requires publication of approved varieties in the national gazette, which has not yet occurred. According to the GOK, cultivation of Bt. corn is planned to start in demonstration farms in March 2023. In a press statement, Kenya Agricultural and Livestock Research Organization's (KALRO) Director General and its partner, African Agricultural Technology Foundation (AATF) said that they will avail 11 metric tons of Bt. corn seed to farmers.

Research trials for bio-fortified sorghum and virus-resistant sweet potato have been suspended due to a lack of funding, while trials for bacteria wilt-resistant banana discontinued because the trial site selected was not agronomically suitable. An application to commercialize GE Gypsophila cut flowers was rejected over concerns the European Union would ban Kenya floricultural exports.

In March 2022, Kenya published regulatory guidelines for genome-edited products. Under these guidelines, products derived through genome editing would not be subject to Kenya's GE approval process if the end product contains no foreign genetic material. If the genome-edited product has foreign material, then it must follow Kenya's full risk assessment and biosafety approval process. To date, Kenya's National Biosafety Authority (NBA) has approved 10 genome editing research applications

under the Biosafety Act of 2009.

Kenya's animal biotechnology research is still in its early stages of development. Research scientists at the International Livestock Research Institute (ILRI) are currently conducting research to develop trypanosome-resistant cattle and goats using various technologies including cloning, GE, and genome editing. Trypanosomiasis (also known as sleeping sickness) 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 to control African Swine Fever and disease diagnostic kits.

Contents

EXECUTIVE SUMMARY
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CHAPTER1: PLANT BIOTECHNOLOGY		4
PART A: PRODUCTION AND TRADE	4	
PART B: POLICY	7	
PART C: MARKETING	13	
CHAPTER 2: ANIMAL BIOTECHNOLOGY		14
PART D: PRODUCTION AND TRADE	14	
PART E: POLICY	15	
PART F: MARKETING	16	
CHAPTER 3: MICROBIAL BIOTECHNOLOGY		16
PART G: PRODUCTION AND TRADE	16	
PART H: POLICY	17	
PART I: MARKETING	18	

CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

PRODUCT DEVELOPMENT

Kenya continues to build its GE research and development. The following table presents GE crops under development in Kenya currently commercialized or that may be commercialized in the next five years.

Crop	Trait	Developers	Stage of Development	Estimated
				Date of
				Commercial
				Release
Cotton	Insect resistance	KALRO ¹	10,000 acres of Bt. cotton are currently	Released in
	(African bollworm)		under cultivation in western, coastal,	2020
			eastern, and central regions of Kenya. The	
			GOK seeks to increase cultivated area to	
			40,000 acres by 2024.	
Corn	Insect resistance	KALRO	NPTs were completed at six sites: (Alupe;	2023
	(MON 810)	AATF/TELA	Kibos; Kakamega; Embu; Thika, and	
		Project ²	Mwea). The National Performance Trials	
		CIMMYT ³	Committee (NPTC) of KEPHIS in June	
			2021 approved three insect-resistant Bt	
			maize varieties for release. NVRC is yet to	
			Gazette the varieties for	

			commercialization.	
Corn	Stacked maize event	KALRO	Confined field trials (CFTs) have been	2023/2024, if
		AATF CIMMYT	completed in three seasons at two sites.	approved
	drought tolerance		KALRO scientists positively assessed the	
	(MON87460)		stacked maize event's ability to withstand	
			Fall Army Worm (FAW), an invasive pest	
	Stacked event with two insect resistance		which attacks corn and sorghum.	
	traits (MON810 and/or MON89034)		Plans are underway to conduct CFTs for MON 89034, which better withstands	
	and drought tolerance		FAW than MON810 and MON87460.	
	(MON87460)		KALRO's Bt. corn researchers have	
	(1,101(0,100)		submitted a dossier to the Institutional	
			Biosafety Committee (IBC) for review	
			before submission to the NBA.	
Cassava	Cassava Brown	KALRO	On June 15, 2021, the NBA approved	
	Streak Disease	$DDPSC^4$	environmental release of disease-resistant	2024/2025, if
	,,	IITA ⁵	GE cassava in Kenya. The crop will now	approved
		$NARO^6$	advance to complete NPTs before being	
	, , ,	ARCN ⁷	consideration for full commercial release.	
	Nigeria		NPTs are expected to start during the	
			October/November short-rains season if NEMA ⁹ approves the application.	
Sorghum Enhanced vitamin		KALRO	Eighth seasonal CFT is complete.	TBD, pending
	levels, bioavailable	AHBFI ⁸		funding
	zinc, and iron	Corteva Agriscience	funds.	availability
Potato	Late Blight resistance		First season CFT at KALRO, Muguga	2024/2025 if
	(3 R-gene LBR)	¹⁰ CIP ¹¹ MSU	Center is ongoing. Planting done in May 2022.	approved

Notes: ¹Kenya Agricultural and Livestock Research Organization; ²African Agricultural Technology Foundation; ³International Maize and Wheat Improvement Center; ⁴Donald Danforth Plant Science Center: ⁵International Institute of Tropical Agriculture; ⁶National Agricultural Research Organization, Uganda; ⁷Agricultural Research Council of Nigeria; ⁸Africa Harvest Biotechnology Foundation International; ⁹National Environment Management Authority; ¹⁰International Potato Center (CIP); ¹¹Michigan State University.

<u>Sources</u>: International Service for the Acquisition of Agri-biotech Applications (ISAAA) Report, 2022; FAS/Nairobi field visits, interviews, and meetings with key biotech stakeholders.

Additional information on approved GE projects is available at the Biosafety Clearing House Kenya: http://ke.biosafetyclearinghouse.net/.

COMMERCIAL PRODUCTION

Bt. cotton is the first GE crop approved for production in Kenya. In public announcements and meetings, the GOK has stated that it plans to increase current cultivation from 10,000 acres to 40,000 acres by 2024. The GOK has set a target to increase overall cotton production from 29,000 bales of lint to 200,000 bales by 2022, however this goal has not yet been achieved.

The first planting of Bt. cotton occurred on March 9, 2020, at an Alupe University College farm in Busia County. Bt. cotton was then planted in five counties (Busia, Kisumu, Baringo, Kwale and Tana River) as demonstration plots for farmers during the March/April 2020 long rains season before full commercialization in the October/November 2020 short rain season. Positive results for Bt. cotton were observed in the 700 demonstration plots including high germination rates (95%), strong boll formation, resistance to African bollworm, and yields over 2.5 times greater than conventional cotton.

Bt. corn will likely be the second GE crop cultivated in Kenya and the first GE food staple. KALRO and AATF plan to import Bt. corn seed from South Africa for cultivation during the long rains season in March 2023.

EXPORTS

Kenya does not export GE crops or products that contain GE materials. An application for GE Gypsophila cut flowers would likely have resulted in exports, but this application was rejected over concerns that approval could cut off Kenya's access to the EU cut-flower market.

IMPORTS

With the removal of the ban, GE products can be imported into Kenya if the traits associated with the product are approved in the country of origin. However, as of time of publication, imports of GE products are suspended until December 15, 2022, due to a legal challenge to the decision to lift Kenya's ban on biotechnology. Post will closely monitor and report on this development. Given the GOK's plan to begin cultivation of Bt. corn in the spring of 2023, Bt. corn seed will likely be imported before the beginning of the long rains season in Kenya in March 2023, pending legal challenge.

Section 28 of Kenya's Biosafety Act of 2009 provides for expedited clearance of imported agricultural commodities subject to compliance with Kenya's import requirements. As an example, 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.

The NBA is responsible for the approval process to import shipments of GE products. Importers can request approval from NBA by completing the:

- Application form for importation of GE products found at: https://www.biosafetykenya.go.ke/index.php?option=com_content&view=article&id=29&Itemid=131 at a fee of Kshs. 25,000 (about \$208).
- Import Declaration Form (IDF) found at the Kenya Revenue Authority (KRA) iCMS system. Depending on the product, other regulatory agencies will evaluate the application and may

apply other fees.

FOOD AID

Kenya is a food aid recipient country. With the removal of the ban, GE food aid commodities are likely to be allowed access, pending legal challenge.

Prior to the GE import ban, the NBA approved imports of GE corn soy blend for humanitarian assistance through the World Food Program (WFP). Details of past GE food import approvals are available at: http://ke.biosafetyclearinghouse.net/importandtransit.shtml

F) TRADE BARRIERS

All foods containing GE ingredients are subject to mandatory labeling requirements. Violation of labeling provisions can result in a fine of up to \$230,000 and/or imprisonment up to 10 years.

PART B: POLICY

REGULATORY FRAMEWORK

The NBA, established by the Biosafety Act No.2 of 2009, is an agency within the Ministry of Agriculture and Livestock Development. The NBA is the main regulatory agency that oversees GE-related regulations and policies, and has general supervision and control over the transfer, handling, and use of GE products. Following the Biosafety Act of 2009, the 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.

These four regulations were issued to meet the following goals:

- To address potential adverse effects to human health and the environment associated with open cultivation of GE crops;
- To ensure safe movement of GE materials in and out of the country;
- To confirm research on GE products is done under appropriate experimental conditions; and
- To establish effective tracking of GE products in the food supply chain and provide information to consumers.

The GOK has developed an additional draft regulation on the handling, transport, packaging, and identification of GE products. Additional information on Kenya's regulations is available at the NBA website.

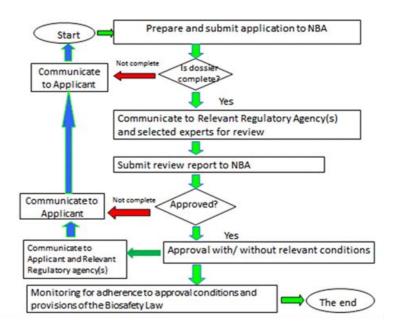
The NBA works closely with eight other regulatory agencies to achieve its mandate:

• The Kenya Plant Health Inspectorate Service (KEPHIS) under the Ministry of Agriculture

- and Livestock Development oversees the introduction, testing and use of biotechnology plants and seeds;
- The <u>Department of Public Health</u>, under the Ministry of Health, safeguards consumers' health through food safety and quality control, surveillance, prevention, and control of foodborne diseases;
- The <u>Kenya Bureau of Standards</u>, (KEBS) under the Ministry of Trade, Investment and Industry develops food standards and rules regarding quality assurance and testing;
- The 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 NPTs for GE crops;
- The <u>Pest Control Products Board</u> (PCPB), under the Ministry of Agriculture and Livestock Development regulates the import, export, manufacture, distribution, and use of products used for the control of pests;
- The Kenya Wildlife Service (KWS), under the Ministry of Tourism, Wildlife, and Heritage undertakes and coordinates 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 tourism-generating biodiversity;
- The <u>Kenya Industrial Property Institute</u> (KIPI), under the Ministry of Trade, Investment, and Industry administers intellectual property rights; and,
- The <u>Department of Veterinary Services (DVS)</u> under the Ministry of Agriculture and Livestock Development protects against the spread of animal diseases and pests to safeguard human health, improve animal welfare, and increase livestock productivity.

The following figure describes Kenya's approval and trial processes for GE crops.

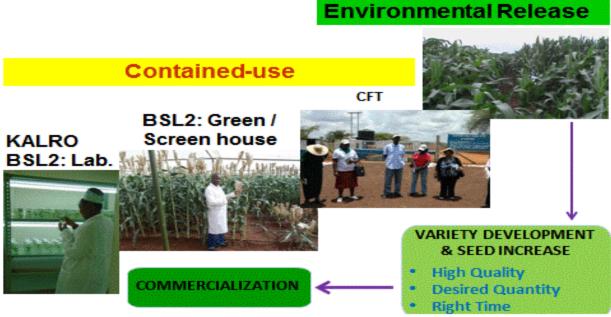
Figure 1: Kenya Approval Process for GE Crops



Source: NBA

Figure 2: Kenya Trial Procedure for GE Crops

Stages in the Regulatory Process



Source: NBA

APPROVALS

The following table shows decisions made by the NBA on GE applications since 2010. Currently only two applications have been approved for open cultivation (Bt. cotton and GE cassava).

Status Lab/Greenhouse	Confined Field	Import and	Limited open
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	Trials (Contained use)	Trials (CFT)	Transit	cultivation/environmental release (NPT)
Approved	35	14	28	2
Withdrawn	0	0	2	0
Rejected	0	0	0	1
Pending	2	0	0	1
Total	37	14	30	4

Source: NBA

STACKED OR PYRAMIDED EVENT APPROVALS

Stacked corn event testing for insect resistance and drought tolerance is ongoing. In addition, confined field trials (CFTs) for biofortified sorghum for enhanced levels of multiple vitamins are complete but this product is unable to proceed to NPTs due to a lack of funds. The NBA conducts risk assessments for each trait individually to approve a stacked product.

• FIELD TESTING

Kenya has conducted CFTs for sorghum, sweet potato, and banana, and has completed national performance trials (NPTs) for corn. For security reasons, only KALRO test centers are used as trial sites (for both CFTs and NPTs). These sites are usually less than one-acre. In addition, NEMA conducts an environmental impact assessment (EIA) on trial sites before NPTs commence and an environmental social impact assessment before commercialization.

KEPHIS, NBA, and KALRO have developed NPT guidelines on GE crop processes in Kenya, which address control of gene flow and the number and size of confined field trials.

KALRO has 16 research institutes spread across different agroecological zones, providing an ample supply of field test sites in different environments.

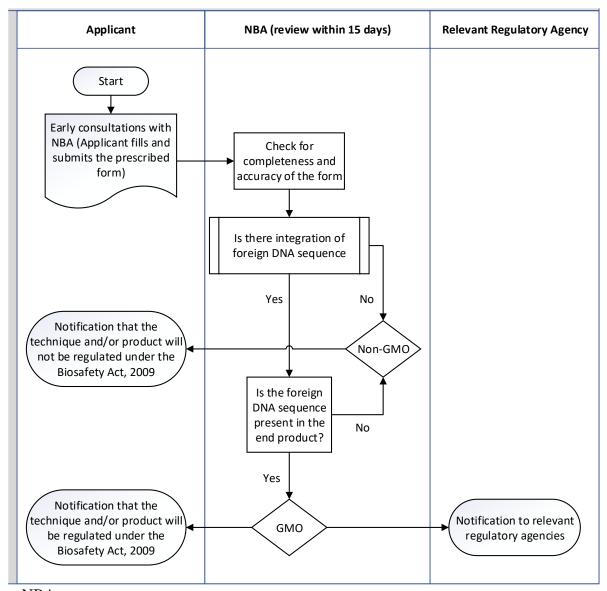
• INNOVATIVE BIOTECHNOLOGIES

Genome Editing

Kenya's local and international research institutions (including local universities, KALRO, ILRI, IITA, and CIMMYT) are testing genome editing and RNA interference techniques at the laboratory level as a proof of concept. The NBA has published genome editing guidelines to inform applicants and reviewers how to submit applications for consideration of projects for research, trials, and commercial release of genome-edited products. Details on the guidelines can be found at:

https://www.biosafetykenya.go.ke/images/GENOME-EDITING-GUIDELINES-FINAL-VERSION-25th-Feb-2022-03.pdf. Under the NBA's guidelines, only genome-edited products with foreign DNA sequences in the final end product must go through Kenya's full approval process under the Biosafety Act of 2009.

Flowchart for Early Genome Editing Consultation



Source: NBA

Kenya has approved laboratory research for the following seven plant-based applications:

- Banana edited for resistance against nanoviruses, caulimoviruses and aphids, approved in June 2015;
- Genome-edited yams for resistance to yam mosaic virus and Anthracnose disease as well as enhanced Vitamin A, approved in January 2018;
- Grass pea edited for nutritional and other agronomic practices, approved in November 2019;
- Genome-edited sorghum for striga weed resistance, approved in October 2020;
- Cassava with an induced early flowering trait by ILRI/IITA and nutritional enhancement;
- Banana for fungal and bacterial resistance; and
- Potato for potato virus Y resistance.

Synthetic Biology

Kenyan researchers have expressed interest in synthetic biology (SB) to find new techniques to improve animal and human health, the agricultural industry, and the environment. In June 2019, policymakers and researchers from Kenya and the United Kingdom held a workshop at Imperial College, London. The workshop considered development of SB research and applications in the context of East Africa, specifically Kenya.

Kenya's first foray into SB is a research project using the technology to detect cassava brown streak disease and cholera. The project aims to develop biosensors and diagnostic kits for these two diseases. The GOK, through the National Research Fund (NRF), has awarded the National Council for Science, Technology, and Innovation (NACOSTI) \$110,650 (Kshs. 12 million) to initiate this research. To facilitate this technology, NACOSTI is reviewing Kenya's existing legal framework to assess if it sufficiently covers SB products. ISAAA-AfriCenter, Kenyatta University, University of Nairobi, and NACOSTI are partnering institutions for this project.

COEXISTENCE

The NBA has drafted policy guidance on coexistence between GE and conventional crops that awaits stakeholder consultation.

LABELING

The GOK requires mandatory labeling of foods and feed containing at least 1 percent GE content by weight. No labeling is required if the GE content is less than 1 percent of the total weight and the product has been approved by the NBA as safe.

MONITORING AND TESTING

The NBA is responsible for approving imports of GE products, while KEPHIS, KEBS, and Port Health Services (under the Department of Public Health) monitor and test agricultural commodities and food product imports at ports of entry for compliance to Kenya's standards and requirements. Multiple public and private institutions in Kenya currently have the capacity to test for GE content, mainly using protein ELISA and PCR methods. While there is currently no formal monitoring regime to test imports, Kenya may test imported commodities on an ad-hoc basis.

Additionally, the NBA inspects facilities that conduct GE research to ensure compliance to the Biosafety Law of 2009 and relevant regulations.

• LOW LEVEL PRESENCE (LLP) POLICY

The NBA has a draft policy on managing low-level presence of GE traits not approved in Kenya for grain and seed imports that is still under stakeholder review. The draft policy sets the LLP threshold level at 1 percent (0.01); meaning that any product, with GE traces of more than 1 percent is treated as a GE product and is not allowed in Kenya's market. The converse is true. Any product with GE traces of less than 1 percent is allowed into the Kenyan market and treated as a non-GE product. Kenya has a zero-tolerance policy for adventitious presence.

• INTELLECTUAL PROPERTY RIGHTS (IPR)

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) agreement as a member of the World Trade Organization (WTO). The Seeds and Plant Varieties Act (Plant Breeders Rights) and related regulations offer protection to patent owners.

• CARTAGENA PROTOCOL RATIFICATION

Kenya was the first country to sign the Cartagena Protocol on Biosafety (CPB) during the 5th Conference of Parties at UNEP headquarters, Nairobi in May 2000. Kenya ratified the Protocol in 2002 and it entered into force on September 11, 2003. The Cartagena Protocol requires countries to protect environmental safety and human health by ensuring safe handling, transport, and use of GE products. The NBA is Kenya's focal point of the Cartagena Protocol and shares data with the Biosafety Clearing House, a mechanism set up by the Cartagena Protocol to facilitate information exchange on GE product development and to assist member countries in complying with their obligations. 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 Cartagena Protocol on October 15, 2010. The protocol gives Kenya additional flexibility under the Cartagena Protocol to implement legislative, administrative, or judicial rules and procedures relevant to liability and redress issues.

Kenya actively participates and sends a delegation to the Cartagena Protocol bi-annual Conference of Parties serving as the Meeting of Parties (COP-MOP).

• 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 Cartagena Protocol. 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.

• RELATED ISSUES

Not applicable.

PART C: MARKETING

PUBLIC/PRIVATE OPINIONS

Debate on biotech crops and bioengineered foods in Kenya remains contentious, political, emotional, and occasionally sensational. Some non-governmental organizations engage in well-funded advertising targeting Kenyan consumers with negative messaging that often lacks a scientific basis. On the other hand, Kenyan agricultural research scientists, farmers, university professors, seed companies, and other pro-biotech non-governmental organizations continue to provide science-based messaging.

• MARKET ACCEPTANCE/STUDIES

A 2015 survey carried out by the Kenya University Biotechnology Consortium (KUBICO) titled

"Architecture of GMO acceptance in Kenya" indicated that a majority of Kenyans favors "GMO" products and technology. Urban respondents were more receptive to the use of "GMOs" and favorability towards "GMOS" had no correlation with level of education. 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 "GMO" consumption in the world.
- Seven out of every 10 Kenyans thought "GMOs" are safe for human consumption;
- Nine out of every 10 Kenyans support the technology in all its applications;
- 14 percent of those opposed to the technology cited concerns regarding the ability of the GOK to regulate "GMOs."

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

• PRODUCT DEVELOPMENT

Kenya scientists at the International Livestock Research Institute (ILRI) have conducted research to develop trypanosome-resistant cattle and goats, vaccines against animal diseases, and diagnostic test kits.

Product/Animal	Trait	Developers	Stage of
			Development
Rift Valley Fever	ChAdOxl-GnGc vaccine	International	CFT approved on
Vaccine	against Rift Valley Fever	Livestock	November 25, 2016.
	for sheep, goats, cattle,	Research	
	and dromedary camels.	Institute (ILRI)	
Recombinant Viral	Vaccine against	ILRI	Contained
Vaccine	Mycoplasma mycoides		use/laboratory stage
	cluster.		
Disease Diagnostic test	Diagnostic tests for		Research ongoing
kits	several diseases, for		pending availability
	example a latex		of funds
	agglutination test kit for		
	CCPP (CAPRITESTR)		
Cattle	Resistance to	ILRI; KALRO;	Pre-CFT
	Trypanosomes	and Institute of	
		Primate Research	
		(IPR)	

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 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 a widespread impact on human health and livestock production across Africa. ILRI scientists estimate its impact to exceed \$1 billion in losses annually to the African continent, reportedly affecting more than 70 percent of 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.

ILRI scientists have developed a cloned Boran calf named "Tumaini" as a first step towards producing trypanosomiasis-resistant cattle. In the second phase of the project, ILRI scientists plan to develop a trypanosome resistant Boran cow ("Mzima") with a gene that produces a protein that may confer immunity to trypanosomes (Apolipoprotein) using genome editing technology.

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

COMMERCIAL PRODUCTION

No animal biotechnology products have been approved for commercial production.

EXPORTS

Kenya does not export animal biotechnology products.

IMPORTS

In order to produce a trypanosome-resistant cow, Kenya will need to import transgenic products such as cow fibroblasts, blastocysts, sperm, and possibly transgenic live animals.

• TRADE BARRIERS

Not applicable.

PART E: POLICY

REGULATORY FRAMEWORK

The NBA's regulatory mandate covers both plants and livestock. The NBA is currently preparing regulations specific to animal biotechnology. Animal science researchers use the NBA's protocols/guidelines on experiments under contained use and CFTs.

• 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. The NBA's published genome-editing guidelines include research in animal biotechnology.

In addition, the NBA approved research trials for African Swine fever vaccine and development of Trypanosome-resistant goats using genome editing in 2018 and 2019, respectively.

• LABELING AND TRACEABILITY

No specific requirements for animal biotechnology products currently exist. The same labeling and traceability requirements for biotech plant products will likely apply when GE animal products become available in the market.

• INTELLECTUAL PROPERTY RIGHTS (IPR)

Animal biotechnology products are subject to the same IPR protections as plant biotechnology products.

• INTERNATIONAL TREATIES/FORUMS

To date, Kenya has not taken a position on animal biotechnologies in international forums such as Codex Alimentarius and the World Organization for Animal Health (OIE). Kenya research on animal biotechnologies remains at an early stage of development.

RELATED ISSUES

Not Applicable

PART F: MARKETING

PUBLIC/PRIVATE OPINIONS

No information is currently available.

• MARKET ACCEPTANCE/STUDIES

No information available

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

• COMMERCIAL PRODUCTION

Kenya does not commercially produce food ingredients derived from microbial biotechnology.

However, NACOSTI together with researchers at Imperial College, London is soliciting funding to establish a Synthetic Biology Bio-Foundry lab in Kenya. The facility would be used to produce industrial products such as primers, enzymes, and reagents.

EXPORTS

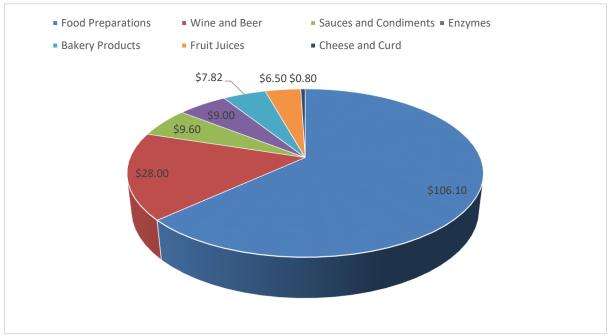
Kenya does not export GE microbes or any products that contain microbial biotech-derived food ingredients such as protease, lactase, steviol glycosides, or asparaginase to any country.

IMPORTS

Kenya imports microbial biotech-derived food ingredients such as enzymes, vitamins, food flavors, colorings, additives, and food preparations. The following chart shows the import value of traditional use products that may contain microbial derived products in calendar year 2021, totaling \$168 million. The United States supplied 3.36 percent of the total microbial products imported in 2021. Other major

suppliers include France(11.97 percent), South Africa (11.47 percent), Ireland (6.99 percent), India (6.77 percent), and the rest of the world 59.44 percent

Figure 3: Kenya Imports That May Contain Microbial-Derived Products (CY 2021, \$US Millions).



Source: Trade Data Monitor, LLC

• TRADE BARRIERS

Currently, there are no known trade barriers that negatively affect U.S. exports of microbial biotechderived food ingredients or processed food products containing microbial biotech-derived food products.

PART H: POLICY

REGULATORY FRAMEWORK

No specific regulation exists for microbial biotech derived food ingredients, which are largely imported. Local production is non-existent. KEBS and/or the Department of Health regulate microbial biotech-derived food ingredients through the Certificate of Conformity (CoC) which applies to all imported food products.

APPROVALS

None.

• LABELING AND TRACEABILITY

None.

MONITORING AND TESTING

See Part A on imports.

•	ADDITIONAL REGULATORY REQUIREMENTS	3
Non	· ·	

• INTELLECTUAL PROPERTY RIGHTS (IPR)

No information available.

• RELATED ISSUES

None.

PART I: MARKETING

• PUBLIC/PRIVATE OPINIONS

Generally, Kenya food processors are aware of food ingredients produced through microbial biotechnology and their inclusion in imported products.

• MARKET ACCEPTANCE/STUDIES

No information available.

Attachments:

No Attachments