



Required Report: Required - Public Distribution

Date: December 01, 2023 Report Number: KE2023-0007

Report Name: Agricultural Biotechnology Annual

Country: Kenya

Post: Nairobi

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Carol Kamau and Matthew Snyder

Approved By: Ryan Scott

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. Kenya's Cabinet cited the need to provide the agricultural sector with pest and drought-resistant crops and to adapt to climate change as motivating factors for lifting the ban. On October 28, 2022, Kenya's High Court blocked trade and production of GE products while the court considers a case challenging the removal of Kenya's 10-year ban on agricultural biotechnology. The High Court case is still ongoing. Importation and cultivation of GE products are currently halted due to the court case.

EXECUTIVE SUMMARY

On October 3, 2022, President Ruto lifted the 10-year ban on importation and open cultivation of GE and GE-derived products. The ban prohibited 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. Lifting the ban provides a way-forward for GE imports to enter Kenya and for GE crops to be cultivated domestically, subject to Kenya's approval process. However, removal of the ban has been halted due to a legal challenge.

On October 28, 2022, Kenya's High Court stopped the implementation of the Cabinet dispatch from the Executive Office of the President of Kenya that permitted the import and cultivation of GE crops and food into Kenya. This court order effectively blocks importation and cultivation of GE products until the case brought before the High Court is concluded. At time of publication, the High Court case is ongoing and trade and production of GE products are prohibited. The High Court case is one of several brought by plaintiffs seeking to block GE products. In 2023, six cases were brought against the decision to lift the ban. These cases have been reduced to two through merging and dismissals.

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 <u>KenTrade</u>. According to the 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 entered Kenya's textile value chain.

Sources note that Bt. corn will likely be the first GE food crop to be commercially released and cultivated by Kenya farmers once the court cases are finalized. Research field trials for Bt. corn were completed in March 2021 at six national performance trial (NPT) sites. 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.

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, the NBA has approved 10 genome editing research applications under the Biosafety Act of 2009.

Contents

EXECUTIVE SUMMARY

On October 3, 2022, President Ruto lifted the 10-year ban on importation and open cultivation of GE and GEderived products. The ban prohibited 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. Lifting the ban provides a way-forward for GE imports to enter Kenya and for GE crops to be cultivated domestically, subject to Kenya's approval process. However, removal of the ban has been halted due to a legal challenge.

CHAPTER 1: PLANT BIOTECHNOLOGY	4
PART A: PRODUCTION AND TRADE	4
PART B: POLICY	7
PART C: MARKETING1	5
CHAPTER 2: ANIMAL BIOTECHNOLOGY	16
PART D: PRODUCTION AND TRADE1	6
PART E: POLICY	8
PART F: MARKETING1	8

CHAPTER 3: MICROBIAL BIOTECHNOLOGY	19
PART G: PRODUCTION AND TRADE19	
PART H: POLICY	
PART I: MARKETING	

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

• RESEARCH AND PRODUCT DEVELOPMENT

Research and development of GE crops and/or plants remain unaffected by the ongoing biotech court cases. The following table presents GE crops that Kenya may commercialize in the next five years.

Crop	Trait	Developers	Stage of Development	Estimated
				Date of
				Commercial
				Release
Corn	Insect resistance	KALRO ¹	NPTs were completed at six sites: (Alupe;	2024
	(MON 810)	AATF/TELA	Kibos; Kakamega; Embu; Thika, and	

		Project ² CIMMYT ³	Mwea). The National Performance Trials Committee (NPTC) of KEPHIS in June 2021 approved three insect-resistant Bt. maize varieties for release. The NVRC has yet to gazette the varieties for commercialization.	
Corn	for insect resistance	KALRO AATF CIMMYT	Confined field trials (CFTs) have been completed in three seasons at two sites. KALRO scientists positively assessed the stacked maize event's ability to withstand Fall Army Worm (FAW), an invasive pest which attacks corn and sorghum. Plans are underway to conduct CFTs for MON 89034, which better withstands FAW than MON810 and MON87460. KALRO's Bt. corn researchers have submitted a dossier to the Institutional Biosafety Committee (IBC) for review before submission to the NBA.	2024
	Streak Disease (CBSD) resistance; research ongoing in Kenya, Uganda, and Nigeria	KALRO DDPSC ⁴ IITA ⁵ NARO ⁶ ARCN ⁷ UON ⁸ ISAAA ⁹	On June 15, 2021, the NBA approved environmental release of disease-resistant GE cassava in Kenya. The cassava is currently undergoing national performance trials (NPTs) at seven sites in eastern, western, and coastal Kenya.	
Sorghum	levels, bioavailable zinc, and iron	KALRO AHBFI ¹⁰ Corteva Agriscience		TBD, pending funding availability
Potato		KALRO CIP ¹¹ MSU ¹²	CFTs are ongoing at KALRO, Muguga Center. First planting was done in May 2022.	2024/2025

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; ⁸University of Nairobi; ⁹International Service for the Acquisition of Agri-biotech Applications (ISAA Africenter); ¹⁰Africa Harvest Biotechnology Foundation International; ¹¹International Potato Center (CIP); ¹²Michigan State University.

Sources: International Service for the Acquisition of Agri-biotech Applications (ISAAA) Report, 2023;

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: <u>http://ke.biosafetyclearinghouse.net/</u>.

• COMMERCIAL PRODUCTION

Bt. cotton is the first GE crop approved for cultivation in Kenya. In public announcements and meetings, the Government of Kenya (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 113,500 bales by 2025.

The first planting of Bt. cotton occurred on March 9, 2020, at the 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.

• 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, due to a legal challenge to the decision to lift Kenya's 2012 ban on GE products, GE imports and cultivation of GE products are currently not permitted.

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. 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: <u>https://www.biosafetykenya.go.ke/index.php?option=com_content&view=article&id=29&Itemi</u> <u>d=131</u> 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. 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: <u>http://ke.biosafetyclearinghouse.net/importandtransit.shtml.</u>

• 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. For more details, visit: <u>https://www.biosafetykenya.go.ke/images/conferencetwotwo/Biosafety%20Labeling-Regulations-2012.pdf</u>.

PART B: POLICY

• **REGULATORY FRAMEWORK**

Below is a table of common terms used in Kenya's biotechnology laws and regulations. These terms are referenced in the following laws and regulations:

- Biosafety Act, No. 2 of 2009;
- Contained Use Regulation, 2011;
- Environmental Release Regulation, 2011;
- Import, Export, and Transit Regulation, 2011;
- Labeling Regulation, 2012.

Legal Term in English/Official	Legal Definition in English	
Language		
Genetically Modified Organism	Any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques.	

Madam Dist 1 1	Tu des the small of C
Modern Biotechnology	 Includes the application of (a) in-vitro nucleic acid techniques including the use of recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; (b) fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive, and recombination barriers and which are not techniques used in traditional breeding and selection.
Genome Editing	Targeted methods to introduce new traits in organisms using various techniques which induce breaks in DNA that can be repaired by endogenous mechanisms and lead to a range of changes at a targeted locus within the gene. This may be achieved by deleting, replacing, editing the organism's DNA or inserting a DNA sequence.
Biosafety	The avoidance of risk to human health and safety and the conservation of the environment as a result of the use of genetically modified organisms.
Contained Use	Any activity undertaken within a facility, installation, or other physical structure which involves genetically modified organisms that are controlled by specific measures.
Environment	Includes the physical factors of the surroundings of human beings, including land, water, atmosphere, soil, vegetation, climate, sound, odor, aesthetics, fish, and wildlife.
Placing in the Market	Making a genetically modified organism available for sale.
Authority	Usually refers to the National Biosafety Authority established under Section 5 of the Biosafety Act.

Regulatory Agency	A regulatory agency as set out in the First Schedule of the Biosafety Act, or such other agency as the Cabinet Secretary of Agriculture and Livestock Development may, by order in the gazette, determine.
Applicant	An individual submitting an application pursuant to the provisions of the Biosafety Act.

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 and animal 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 <u>NBA</u> website.

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

- The <u>Kenya Plant Health Inspectorate Service</u> (KEPHIS) under the Ministry of Agriculture, and Livestock 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 <u>National Environment Management Authority</u> (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 regulates

the import, export, manufacture, distribution, and use of products used for the control of pests;

- The <u>Kenya Wildlife Service</u> (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 protects against the spread of animal diseases and pests to safeguard human health, improve animal welfare, and increase livestock productivity.

The following figures describe Kenya's approval and trial processes for GE crops.

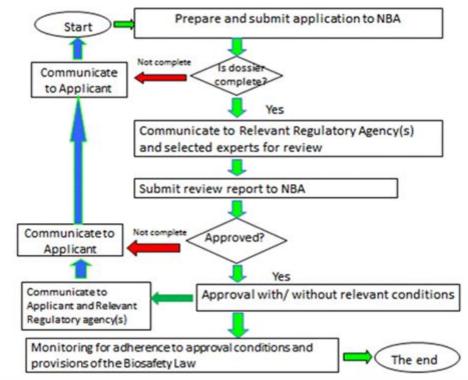
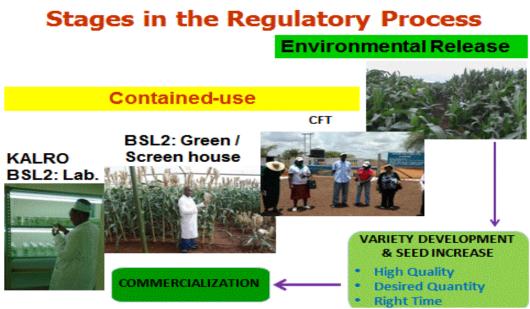


Figure 1: Kenya Approval Process for GE Crops

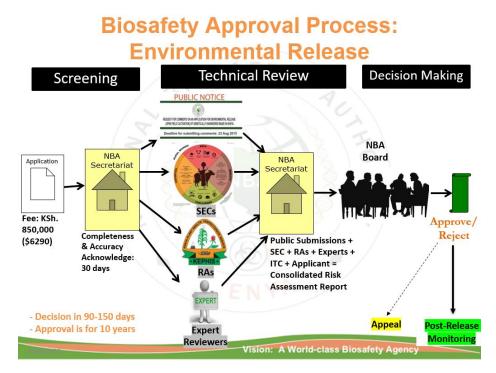
Source: NBA

Figure 2: Kenya Trial Procedure for GE Crops



Source: NBA

Figure 3: Kenya Procedure for GE Environmental Release



Source: NBA

*Regulatory Agencies (RA); Social Economic Considerations (SEC); Institutional Technical Committee (ITC)

• APPROVALS/AUTHORIZATIONS

Kenya approved Bt. cotton (cotton resistant to the African bollworm) for cultivation and use in 2020. Bt. maize research trials are complete and awaiting final approval for use in Kenya subject to the conclusion of ongoing biotech court cases.

GE cassava is approved for open field trials and environmental release. GE cassava is currently undergoing NPTs at seven sites in eastern, western, and coastal regions.

• STACKED OR PYRAMIDED EVENT APPROVALS

Stacked corn event testing for insect resistance and drought tolerance is ongoing. 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 NPTs are ongoing for cassava. For security reasons, only KALRO test centers are used as trial sites (for both CFTs and NPTs). These trials are usually conducted at a plot smaller than one acre. Additionally, NEMA conducts an environmental impact assessment (EIA) on trial sites before NPTs commence and performs 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.

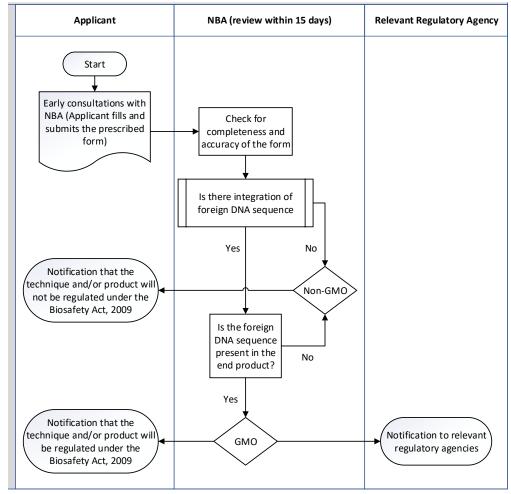
• INNOVATIVE BIOTECHNOLOGIES

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. The guidelines align with Africa Union's (AU) genome editing guideline document. Details on the Kenyan 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.

Figure 4: Flowchart for Early Genome Editing Consultation



Source: NBA

NBA has received two genome editing applications to conduct trials:

- 1. Gene-edited corn lines with increased tolerance to Maize Lethal Necrosis (MLN) in Kenya 2022;
- 2. *Kosakonia sacchari* and *Klebsiella variicola* bacteria species with enhanced nitrogen fixing capabilities 2022.

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

- Genome-edited yams for resistance to yam mosaic virus and Anthracnose disease as well as enhanced Vitamin A, approved in January 2018;
- Banana edited for resistance against nanoviruses, caulimoviruses and aphids, approved in June 2015;
- 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 \$110,650 (Ksh 12 million) to the National Council for Science, Technology, and Innovation (NACOSTI) 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 partner institutions for this project.

• COEXISTENCE

The NBA has drafted policy guidance on coexistence between GE and conventional crops.

• 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 GE 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 in the market, 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. The draft policy sets the LLP threshold level at 1 percent (0.01); meaning that any product with GE traces over 1 percent by weight is treated as a GE product and must be labeled as such. The converse is true. Any product with GE traces of less than 1 percent is allowed into the Kenya market and treated as a non-GE product. Kenya has a zero-tolerance policy for adventitious presence.

• ADDITIONAL REGULATORY REQUIREMENTS

- Any person who undertakes any "GMO-related" activity without the approval of the NBA commits an offence as provided for by the Biosafety Act, 2009; Section 52.
- The Biosafety Act gives the NBA powers to halt and resume GE-related activities.
- Existing civil judicial mechanisms are able to offer redress for damage to affected persons on a

case-by-case basis.

• 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 for 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: https://bch.cbd.int/protocol/.

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 biannual 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), Codex Alimentarius (Codex), the 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.

In February 2023, Alliance for Science conducted a quantitative study of "GMO" media articles published in the Kenyan media between October 2022 and January 2023. They found that 40% (151 out of 376 articles) contained unchallenged negative misinformation about "GMOs". Only 3% of articles contained "pro – GMO" misinformation. More details from this study are available at https://allianceforscience.org/wp-content/uploads/2023/02/GMO-misinformation-in-the-Kenyan-media-1.pdf.

• MARKET ACCEPTANCE/STUDIES

On November 3rd and 4th, 2022, GeoPoll, a remote mobile research company, conducted a rapid survey to assess Kenyans awareness and perceptions on "GMO" foods after the government lifted the 2012 import ban. The sample size was 708, composed of random users between ages 18 and 60. Since the survey was randomly distributed, the results are slightly skewed towards younger, male respondents according to GeoPoll. According to the survey:

- 86 percent of the respondents are aware of "GMOs" compared to 65 percent of respondents in a similar study conducted in 2014;
- 91 percent of the 86 percent were aware of the government' decision to lift the ban;
- 51 percent agreed with the government's decision to approve "GMOs"; 35 percent disagreed; and 16 percent neither agreed nor disagreed with the government;
- 51 percent believed that "GMOs" are unsafe for human consumption;
- 60 percent believed that there is not enough information on "GMOs"; 30 percent believed that there is; and 10 percent were unsure.

Find more details of the report at:

https://www.geopoll.com/blog/gmo-foods-kenya-report/#About_this_GeoPoll_survey.

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
	1,0,,	Livestock Research	CFT approved on November 25, 2016. Research trials are ongoing.
Recombinant Viral Vaccine	Vaccine against <i>Mycoplasma mycoides</i> cluster.	ILRI	Contained use/laboratory stage
Disease Diagnostic Test Kits	Diagnostic tests for several diseases, for example a latex agglutination test kit for CCPP (CAPRITESTR)	ILRI	Research ongoing pending availability of funds
Cattle	Resistance to Trypanosomes	and Institute of	Research has stalled for the last two years due to lack of funds. Researchers plan to restart the project using a new cow.

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 improve livelihoods for African farmers through increased cattle productivity.

Trypanosomiasis is a zoonotic disease (also known as Nagana) in cattle and sleeping sickness in humans. It has a widespread impact on human health and livestock production across Africa. ILRI scientists estimate its impact exceeds \$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</u> <u>Biotechnology</u>.

• COMMERCIAL PRODUCTION

No animal biotechnology products have been approved for commercial production.

• EXPORTS

Kenya does not export animal biotechnology products.

• IMPORTS

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 an 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.

• 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 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.

• 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 flavoring, colorings, additives, and food preparations.¹ The following chart shows the import value of traditionaluse products that may contain microbial derived products in calendar year 2022, totaling \$231 million. The United States supplied 3.3 percent of these products. Other major suppliers include India (17.4 percent), the United Kingdom (10.4 percent), France (9.5 percent), and South Africa (8.6 percent).

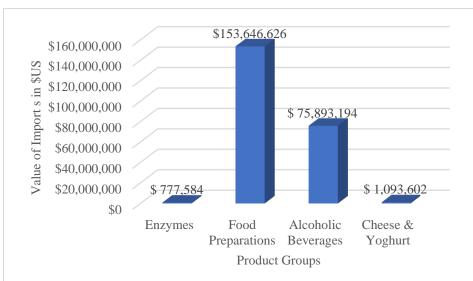


Figure 5: Kenya Imports That May Contain Microbial-Derived Products (CY 2022, \$US Millions).

¹ Food preparations includes baking inputs, mixes and doughs, flavorings, vegetable saps and extracts, protein concentrates, thickeners, and other processed food ingredients.

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. Microbial biotech-derived foods are subject to general regulations applicable to all food products such as food safety and labeling requirements which are implemented through KEBS and the Department of Health through the Certificate of Conformity (CoC).

• APPROVALS

None.

• LABELING AND TRACEABILITY

None.

• MONITORING AND TESTING

See Part A on imports.

ADDITIONAL REGULATORY REQUIREMENTS

None.

• 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