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**Report Highlights:**

With the notable exception of Bt. cotton, biotech products are not allowed to be produced, imported, or marketed in Kenya. On October 30, 2024, Kenya's High Court is expected to make a ruling on the biotechnology case challenging the production and trade in genetically engineered (GE) agricultural products. The outcome of that ruling could change acceptance of GE products in country. Bt. corn and GE cassava have completed the required stages in the regulatory process, and are awaiting the court's decision to proceed to commercialization. The current Kenyan executive branch supports the use of genetic engineering technology to address food security and climate change challenges.

## **EXECUTIVE SUMMARY**

The Kenyan government lifted a 10-year ban on the importation and cultivation of genetically engineered (GE) and GE-derived products on October 3, 2022. However, this executive decision sparked six court cases, leading to an injunction on October 28, 2022, that prohibited the importation and cultivation of GE crops except for Bt. cotton. Note that, Bt.cotton had already been approved for cultivation, and commercialization. The High Court judge directed that the five cases in Kenyan courts be consolidated and heard in two independent courts based on their petitions; the High Court would address constitutional-based issues, and the Environment and Land Court would address environmental concerns. In October 2023, the Environmental and Land Court dismissed the environmental cases, ruling in favor of the release and planting of GE products. A constitutional injunction remains in force pending the determination of the remaining case, with an outcome expected by October 30, 2024. A new unrelated case was filed with the East African Court of Justice, which will be deferred until the decision of the Kenyan High Court.

Kenya has a well-defined approval process for GE products. For imports, shipments of GE products must apply to the National Biosafety Authority through the single window system. The system implemented by [KenTrade](#) allows submission of import documentation and approval from the relevant regulatory agencies. According to the biosafety authority, GE import applications will be approved if the reported GE traits are permitted in the country of origin. 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.

Research field trials for Bt. corn were completed in March 2021 at six national performance trials sites. A necessary follow-on report was submitted to the National Performance Trial Committee to recommend best varieties for release to the National Variety Release Committee. Commercialization of Bt. corn requires publication of approved varieties in the national gazette, which has not yet occurred. GE cassava has completed trials.

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 final 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 National Biosafety Authority approved 11 genome editing research applications under the Biosafety Act of 2009.

Kenya does not commercially produce food ingredients derived from microbial biotechnology. However, the country imports foods and ingredients derived from microbial biotechnology such as cheese and curd, enzymes, malt beer, wine, and other alcoholic beverages.

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## 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 of interest in Kenya.

**Table 1: GE Crops in Kenya**

<b>Crop</b>	<b>Trait</b>	<b>Developers</b>	<b>Stage of Development</b>	<b>Est Date of Release</b>
Corn	Insect resistance (MON 810)	KALRO <sup>1</sup> AATF/TELA Project <sup>2</sup> CIMMYT <sup>3</sup>	Trials were completed at six sites. The National Performance Trials Committee of Kenya Plant Health Inspectorate Service (KEPHIS) in June 2021 approved three insect-resistant Bt. maize varieties for release. The National Variety Release Committee will have the varieties listed in the official government records and released for to the market pending the outcome of the biotech court case.	2025
Corn	Stacked event with insect resistance (MON89034) and drought tolerance (MON87460) traits	KALRO AATF CIMMYT	Confined field trials completed at Kitale, and Kibos research sites. The researchers have applied to the biosafety authority for environmental release with additional data from Nigeria and South Africa. KALRO scientists positively assessed the stacked maize event's ability to withstand Fall Army Worm, an invasive pest which attacks corn and sorghum.	2025/2026

Cassava	Cassava Brown Streak Disease resistance; research ongoing in Kenya, Uganda, and Nigeria	KALRO DDPSC <sup>4</sup> IITA <sup>5</sup> NARO <sup>6</sup> ARCN <sup>7</sup> UON <sup>8</sup> ISAAA <sup>9</sup>	On June 15, 2021, the National Biosafety Authority approved limited release of disease-resistant GE cassava in Kenya. The trials were to be conducted at KALRO test sites. Second season harvesting will end in November 2024 at the seven field sites. The performance trials committee will evaluate eight lines and submit recommendations to the national varietal release committee for release.	2025/2026
Sorghum	Enhanced vitamin A levels, bioavailable zinc, and iron	KALRO AHBFI <sup>10</sup> Corteva Agriscience	Eighth confined field trials completed. Awaiting national performance trials, pending availability of funding.	TBD, pending funding availability
Potato	Late Blight resistance (3 R-gene LBR)	KALRO CIP <sup>11</sup> MSU <sup>12</sup>	Confined field trials completed in January 2024. Data generated used to write dossier for environmental release. National performance trials likely to start in April 2025.	2026

**Notes:** <sup>1</sup>Kenya Agricultural and Livestock Research Organization; <sup>2</sup>African Agricultural Technology Foundation; <sup>3</sup>International Maize and Wheat Improvement Center; <sup>4</sup>Donald Danforth Plant Science Center; <sup>5</sup>International Institute of Tropical Agriculture; <sup>6</sup>National Agricultural Research Organization, Uganda; <sup>7</sup>Agricultural Research Council of Nigeria; <sup>8</sup>University of Nairobi; <sup>9</sup>International Service for the Acquisition of Agri-biotech Applications (ISAA Africenter); <sup>10</sup>Africa Harvest Biotechnology Foundation International; <sup>11</sup>International Potato Center (CIP); <sup>12</sup>Michigan 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: [Biosafety Clearing House](#)

#### • COMMERCIAL PRODUCTION

Bt. cotton was the first GE crop approved for cultivation in Kenya. Thirteen counties are farming Bt. cotton covering an estimated area of 22,620 hectares accounting for 69 percent of the total cotton cultivated area. The government of Kenya has set a target to increase overall cotton production from 29,000 bales of lint to 113,500 bales by 2025. Currently, there are six cotton gins operating in Makueni, Kitui, Tharaka Nthi, Baringo, Busia, and Meru counties.

- **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 could 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 for seeds and planting material, cereals and grains, and fresh fruits and vegetables, flowers, and ornamental plants.

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

- Application Form for Importation of GE Products found at: [here](#) at a fee of Kshs. 25,000 (~\$194).
- Import Declaration Form found at the Kenya Revenue Authority iCMS system. Depending on the product, other regulatory agencies will evaluate the application and fees may apply.

- **FOOD AID**

Kenya is a food aid recipient country. Prior to the GE import ban, the National Biosafety Authority approved imports of GE corn soy blend for humanitarian assistance through the World Food Program. Details of past GE food import approvals are available at: [Import Approvals](#)

- **TRADE BARRIERS**

All imported foods containing GE ingredients are subject to mandatory labeling. Violation of labeling provisions can result in a fine of up to \$230,000 and/or imprisonment up to ten years. For more details, visit: [Labeling Regulations](#).

## **PART B: POLICY**

- **REGULATORY FRAMEWORK**

Below is a table of common terms used in Kenya's biotechnology law 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

<b>Legal Term in English/Official Language</b>	<b>Legal Definition in English</b>
Genetically Modified Organism (GMO)	Any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques.
Modern Biotechnology	Includes the application of <ul style="list-style-type: none"> <li>(a) in-vitro nucleic acid techniques including the use of recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles;</li> <li>(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.</li> </ul>
Genome Editing (GE)	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 National Biosafety Authority, established by the Biosafety Act Two of 2009, is an agency within the Ministry of Agriculture, and Livestock Development. The National Biosafety Authority 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 National Biosafety Authority developed the following four GE implementing regulations:

- Contained Use Regulation, 2011
- Environmental Release Regulation, 2011
- Import, Export, and Transit Regulation, 2011
- 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.
- To establish effective tracking of GE products in the food supply chain and provide information to consumers.

The government of Kenya has developed an additional guideline on the handling, transport, packaging, and identification of GE products. Additional information on Kenya's regulations is available at the [National Biosafety Authority website](#).

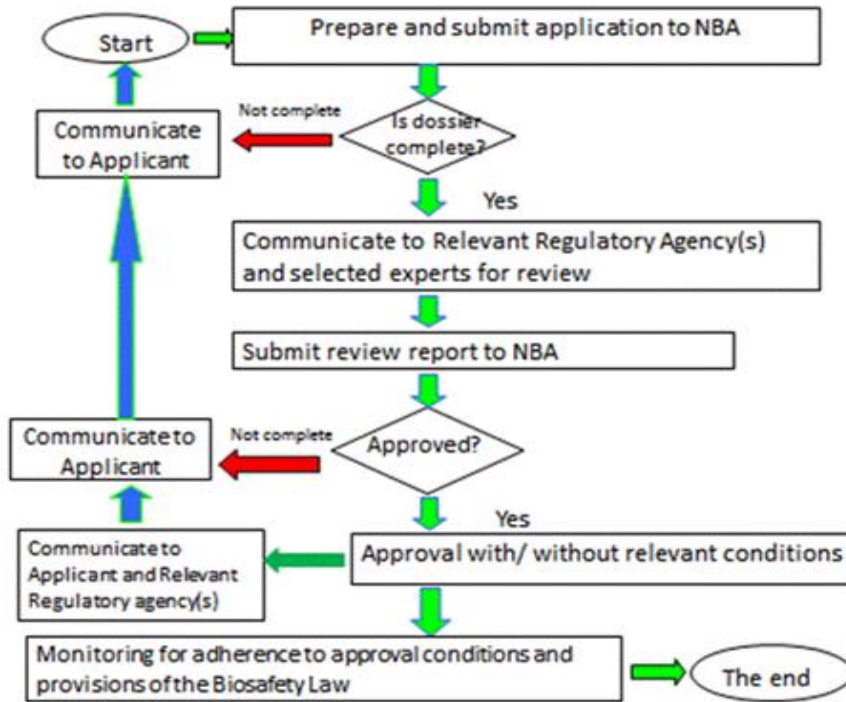
The National Biosafety Authority works closely with eight other regulatory agencies to achieve its mandate:

- The [Kenya Plant Health Inspectorate Service](#) (KEPHIS) under the Ministry of Agriculture, and Livestock oversees the introduction, testing and use of biotechnology plants and seeds.
- The [Department of Public Health](#), under the Ministry of Health, safeguards consumers' health through food safety and quality control, surveillance, prevention, and control of foodborne diseases.
- The [Kenya Bureau of Standards](#), (KEBS) under the Ministry of Trade, Investment and Industry develops food standards and rules regarding quality assurance, metrology 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 [Pest Control Products Board](#) (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 [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 [Kenya Industrial Property Institute](#) (KIPI), under the Ministry of Trade, Investment, and Industry administers intellectual property rights.
- The [Department of Veterinary Services \(DVS\)](#) 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.



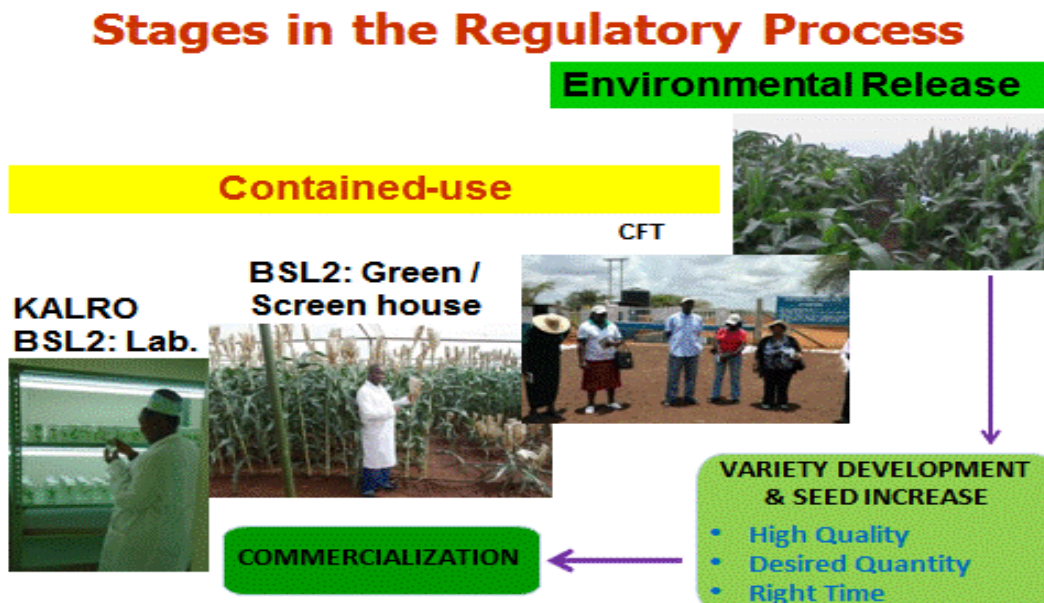
Figures 1-3 describes Kenya's approval and trial processes for GE crops.

**Figure 1: Kenya's Approval Process for GE Crops**



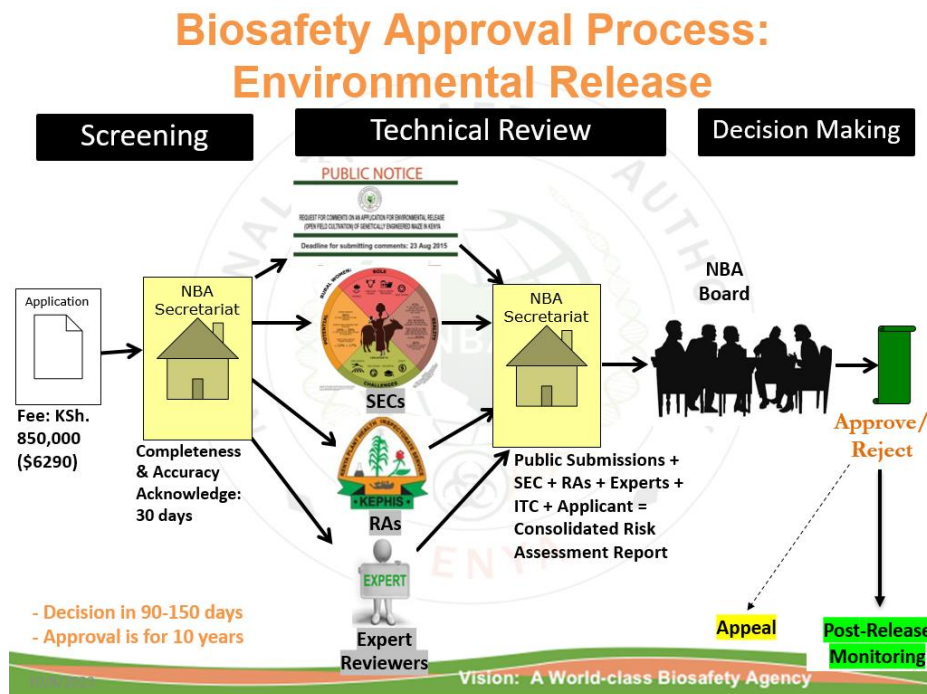
Source: National Biosafety Authority

**Figure 2: Kenya's Research Trials Procedure for GE Crops**



Source: National Biosafety Authority

**Figure 3: Kenya’s Procedure for GE Environmental Release**



Source: National Biosafety Authority

\*Regulatory Agencies; Social Economic Considerations; Institutional Technical Committee

**• APPROVALS/AUTHORIZATIONS**

Kenya approved Bt. Cotton, which is 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 pending conclusion of the biotech court case. GE cassava research trials are completed and awaiting varietal release.

**• STACKED OR PYRAMIDED EVENT APPROVALS**

Stacked corn event testing for insect resistance and drought tolerance is ongoing. The National Biosafety Authority conducts risk assessments for each trait individually to approve a stacked product.

**• FIELD TESTING**

Kenya has conducted confined field trials for six GE crops (corn, cassava, sorghum, banana, sweet potato, Irish potato), and two GE plants (cotton and Gysophila cut flower). Only Bt.cotton has been approved for commercialization. For security reasons, only KALRO research centers are used as trial sites, for both confined field trials and national performance trials. These trials are usually conducted on plots measuring between one half and one quarter of an acre depending on the crop. Additionally, the National Environmental Management Authority conducts an environmental impact assessment on trial sites before national performance trials commence and performs an environmental social impact assessment before commercialization.

The National Biosafety Authority, KEPHIS, and KALRO developed national performance trials 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 semi-autonomous research institutes spread across different agroecological zones in the country, providing an ample supply of field test sites in the different environments.

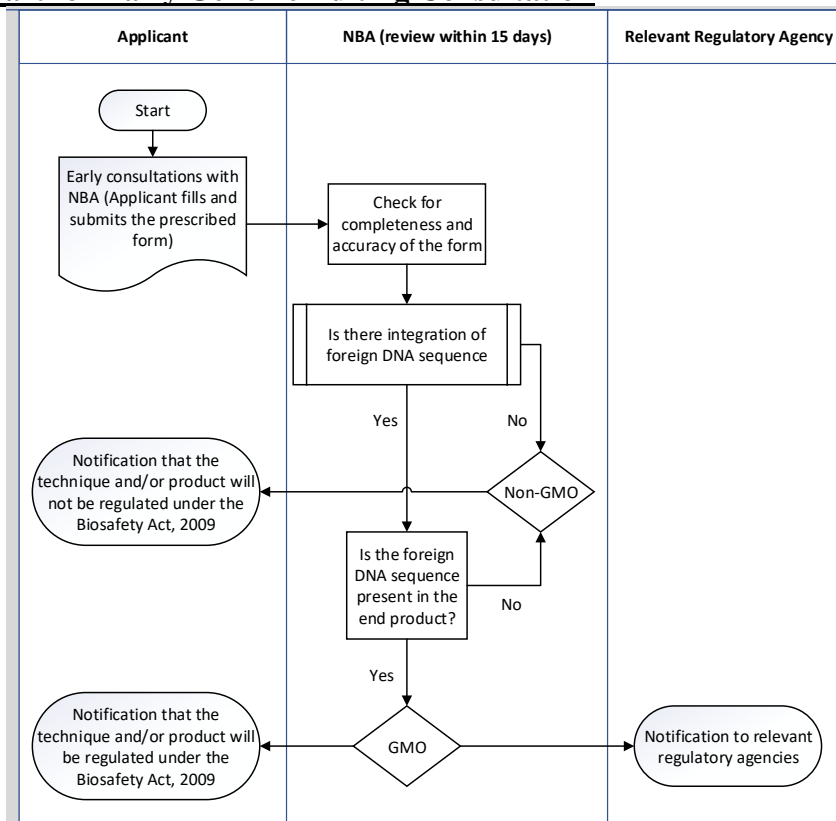
• **INNOVATIVE BIOTECHNOLOGIES**

Genome Editing

Kenya’s local and international research institutions, including local universities, KALRO, International Livestock Research Institute, International Institute of Tropical Agriculture, and the International Center for Wheat and Maize Improvement are testing genome editing and RNA interference techniques at laboratory level to proof concept. The National Biosafety Authority 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 genome editing guideline document. Details on the Kenyan guidelines can be found at: [Genome Editing Guidelines](#).

Under the National Biosafety Authority’s guidelines, only genome-edited products with foreign DNA sequences in the final product that must go through Kenya’s full approval process under the Biosafety Act of 2009.

**Figure 4: Flowchart for Early Genome Editing Consultation**



Source: National Biosafety Authority

The National Biosafety Authority as approved 11 genome editing applications at research level using the Biosafety Act 2009.

The Authority approved two genome editing applications to conduct trials in 2022:

1. Two gene-edited corn lines with increased tolerance to Maize Lethal Necrosis.
2. *Kosakonia sacchari* and *Klebsiella variicola* bacteria species with enhanced nitrogen fixing capabilities for cereals, but the research project has since stalled due to lack of funds.

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

- Genome-editing of yams or 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 and nutritional enhancement (increase of beta-carotenoid) – approved in August 2021.
- Banana for fungal (*Fusarium wilt and Black sigatoka*) and bacterial resistance (*Banana Xanthomonas Wilt*) – approved in April 2021.
- Potato for potato virus Y resistance- approved in February 2022.
- Sorghum genotypes, with or without Lr34 resistance genes, to anthracnose (*colletotricum sublineolium*) disease under natural and controlled conditions – Approved February 2020.

### Synthetic Biology

Kenyan researchers have expressed interest in synthetic biology to find new techniques to improve animal and human health, the agricultural industry, and the environment. Amidst the Covid 19 pandemic, a team of research scientists, developed low-cost diagnostic tools and biosensors for rapid detection of crop and human pathogens, the first-ever project on synthetic biology in the country.

The research project used the technology to detect cassava brown streak disease, and cholera through a government research grant. Innovations through synthetic biology will be useful in addressing challenges in food security, climate change, and health care. In addition, the technology provides a venue to design vaccines.

#### • **COEXISTENCE**

The NBA has a draft policy on coexistence between GE and conventional crops that is yet to be finalized.

#### • **LABELING AND TRACEABILITY**

The government of Kenya requires mandatory labeling of foods and feed containing at least one percent GE content by weight. No labeling is required if the GE content is less than one percent of the total weight and the product has been approved by the National Biosafety Authority as safe.

#### • **MONITORING AND TESTING**

The National Biosafety Authority is responsible for approving imports of GE products, while

KEPHIS, Kenya Bureau of Standards 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, KEBS may test imported commodities on an ad-hoc basis.

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

- **LOW LEVEL PRESENCE (LLP) POLICY**

The National Biosafety Authority has a policy on managing low-level presence of GE traits not approved in Kenya for grain and seed imports. The policy sets the low-level threshold level at one percent (0.01); meaning that any product with GE traces over one 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 one 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 biosafety authority commits an offence as provided for by the Biosafety Act, 2009; Section 52.
- The Biosafety Act gives the National Biosafety Authority powers to halt and to resume GE-related activities.
- Existing civil judicial mechanisms can offer redress for damage to affected persons on a case-by-case basis.

- **INTELLECTUAL PROPERTY RIGHTS (IPR)**

The Kenya Industrial Property Institute 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 during the 5<sup>th</sup> 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 National Biosafety Authority 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: [Biosafety Clearing House](#).

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.

- **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, 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, Bt.cotton 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 percent (151 out of 376 articles) contained unchallenged negative misinformation about “GMOs”. Only three percent of articles contained “pro – GMO” misinformation. More details from this study are available at [Alliance for Science GMOs Media Articles Study](#)

- **MARKET ACCEPTANCE/STUDIES**

In a research article published in January 2024 on “Public Perception of Genetically Modified Organisms and the Implementation of Biosafety Measures in Kenya”, 57 percent of the respondents indicated that “GMOs” and derived foods are a solution to food security in Africa, including Kenya. Fifty two percent of the respondents believe that introduction of the “GMO” technology is beneficial, while 55 percent of the respondents believe that “GMO” foods are safe. Over 90 percent of the respondents indicated that the technology has a low threat on the environment, human, and animal health. However, public awareness of “GMO” foods is still low, and there are contentious issues on socioeconomic effects, particularly those related to trade. Find the full research article at [Public Perceptions of Genetically Modified Organisms Research Article](#) .

On November 3<sup>rd</sup> and 4<sup>th</sup>, 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: [GeoPoll GMOs Market Survey](#).



## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

### **PART D: PRODUCTION AND TRADE**

#### **• PRODUCT DEVELOPMENT**

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

<b>Product/Animal</b>	<b>Trait</b>	<b>Developers</b>	<b>Stage of Development</b>
Rift Valley Fever Vaccine	ChAdOx1-GnGc vaccine against Rift Valley Fever for sheep, goats, cattle, and dromedary camels.	International Livestock Research Institute (ILRI)	Confined field trials 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 Contagious caprine pleuropneumonia.	ILRI	Research ongoing pending availability of funds.
Cattle	Resistance to Trypanosomes	ILRI; KALRO; and Institute of Primate Research (IPR)	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

Research scientists at the International Livestock Research Institute 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 or sleeping sickness in humans. It has a widespread impact on human health and livestock production across Africa. International Livestock Research Institute scientists estimate its impact exceeds \$1 billion in losses annually to the African continent, reportedly affecting more than 70 percent of 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 International Livestock Research Institute scientists developed a cloned Boran calf named “Tumaini” as a first step towards producing trypanosomiasis-resistant cattle. In the second phase of



the project, the 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 the Institute of Primate Research. The National Biosafety Authority regulates the application of biotechnology in livestock. Find more information on their approved livestock projects at [Approved Contained Use Research Activities including Livestock Biotechnology](#).

- **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 bovine fibroblasts, blastocysts, sperm, and possibly transgenic live animals.

- **TRADE BARRIERS**

Not applicable.

## **PART E: POLICY**

- **REGULATORY FRAMEWORK**

The National Biosafety Authority’s regulatory mandate covers both plants and livestock. The agency is currently preparing regulations specific to animal biotechnology. Animal science researchers use the biosafety authority’s protocols/guidelines on experiments under contained use and field trials.

- **INNOVATIVE BIOTECHNOLOGIES**

The International Livestock Research Institute plans to develop a Trypanosome-resistant cow using CRISPR-Cas9 genome editing technology. The transgenic trait used will be subject to the National Biosafety Authority’s regulations. The NBA’s published genome-editing guidelines include research in animal biotechnology.

In addition, the National Biosafety Authority approved research trials for:

- An African Swine fever vaccine using recombinant antigens of the African Swine fever vaccine, and mutated African Swine fever vaccine viruses (approved in March 2014, renewed in March 2021).
- Development of Trypanosome-resistant goats using genome editing (approved in October 2019).
- Gene edited surrogate host chickens for trials on biobanking and recovery of indigenous chicken breeds (approved in May 2022).

- **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. 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<sup>1</sup>. The following table shows the import value of traditional-use products that may contain microbial derived products in calendar year 2023, totaling \$276 million. The major suppliers of these products , France (35 percent), Rwanda (10 percent) and India (8 percent).

**Figure 5: Kenya Imports with Potentila Microbial-Derived Products (CY 2023, USD Million)**

Description	Annual Series (Value: USD)					
	2018	2019	2020	2021	2022	2023
<b>Microbial biotech group</b>	<b>138,766,984</b>	<b>115,759,702</b>	<b>158,444,126</b>	<b>167,711,466</b>	<b>190,758,243</b>	<b>275,665,050</b>
Food preparations nesoi	47,740,442	49,284,379	93,341,061	86,074,140	98,688,978	174,460,049
Food preparations for infant use, put up for retail sale, nesoi	4,098,618	4,891,149	10,751,829	15,594,653	24,532,973	31,386,493
Wine of fresh grapes, including fortified wines; grape must (having an alcoholic strength by volume exceeding 0.5% vol.) nesoi	23,239,111	20,919,376	17,707,161	21,371,888	22,474,276	23,965,418
Sauces and preparations therefor; mixed condiments and mixed seasonings; mustard flour and meal and prepared mustard	7,543,009	8,464,034	8,226,096	9,551,427	10,122,529	11,649,820
Bread, pastry, cakes, biscuits and other bakers' wares; communion wafers, empty capsules for medicine etc., sealing wafers, rice paper etc.	6,491,721	7,074,894	7,095,983	7,818,100	7,984,582	8,889,873
Enzymes; prepared enzymes nesoi	8,969,642	7,285,895	6,651,321	8,998,750	8,708,395	8,538,610
Beer made from malt	8,477,842	6,221,110	5,928,856	6,619,953	6,323,567	7,423,290

<sup>1</sup> Food preparations include baking inputs, mixes and doughs, flavorings, vegetable saps and extracts, protein concentrates, thickeners, and other processed food ingredients.

Fruit juices not fortified w vit or minls (incl grape must) & vegetable juices, unfermentd & nt containing add spirit, whet or nt containing added sweeteng	6,305,713	6,883,121	4,067,789	6,464,487	7,155,678	5,121,655
Prepared foods from swelling or roasting cereals or products; cereals (exc corn), in grain form flakes or worked grain prepared n.e.s.o.i	25,039,816	3,619,716	3,697,462	4,405,870	3,674,726	3,294,278
Cheese and curd	861,072	1,116,029	976,567	812,199	1,092,540	935,565

**Data Source:** Trade Data Monitor, LLC

- **TRADE BARRIERS**

Currently, there are no known trade barriers that negatively affect U.S. exports of microbial biotech-derived 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.

- **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