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Report Highlights:

Kenya's import ban on genetically engineered (GE) products continues to constrain commerce and trade of agricultural products, preventing local producers, consumers, and industry access to improved products. The Government of Kenya however supports the second planting of Bt. cotton for commercialization, scheduled for the October-November 2020 short rainy season in the eastern and central regions. Bt. Cotton is expected to help revive the national cotton, textile, and apparel sector, a priority under President Kenyatta's Big Four Agenda.

EXECUTIVE SUMMARY

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

Despite the import ban, the GOK continues to selectively support domestic development of GE products and allows importation of GE research materials. In December 2019, President Kenyatta approved the first commercial planting of Bt cotton, which took place in March 2020 in the western and coastal regions during the long rains season. Research trials for GE Gypsophila cut flower, insect resistant cotton, and GE cassava are complete, while that of bio-fortified sorghum, bacteria wilt resistant bananas, and virus resistant sweet potato are ongoing. An application to commercialize GE Gypsophila cut flowers was denied due to the fear that the European Union would ban Kenyan floricultural exports. National performance trials (NPTs) for insect resistant corn/Bt. corn began in 2020, after approval by the National Environment Management Authority (NEMA).

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

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

Kenya largely imports food ingredients derived from microbial biotechnology and has no known local production.

Table of Contents

EXECUTIVE SUMMARY	2
CHAPTER1: PLANT BIOTECHNOLOGY	
PART A: PRODUCTION AND TRADE	3
PART B: POLICY	ε
PART C: MARKETING	10
CHAPTER 2: ANIMAL BIOTECHNOLOGY	11
PART D: PRODUCTION AND TRADE	11
PART E: POLICY	12
PART F: MARKETING	13
CHAPTER 3: MICROBIAL BIOTECHNOLOGY	13

PART G: PRODUCTION AND TRADE	13
PART H: POLICY	14
PART I:	14

CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

• PRODUCT DEVELOPMENT

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

Crop	Trait	Developers	Stage of Development	Estimated Date of Commercial Release
Gypsophila Flower	Pink Coloration of Petals (The trait confers flower color stability)	¹ KALRO Imaginature Ltd., representing Danziger – "Dan" Flower Farm of Israel	Confined Field Trials (CFT) completed; No NPTs required for the plant.	Application for
Cotton	Insect Resistance (African bollworm)	KALRO Bayer Sciences	demonstration plots in five counties	2020/2021 (after NEMA issues the commercialization license)
Corn	Insect Resistance (MON 810)	¹ KALRO ² AATF CIMMYT	NEMA approved NPTs implementation at six sites (Alupe; Kibos; Kakamega; Embu; Thika, and Mwea)	2021/2022
	Stacked maize event for insect resistance (MON810) and drought tolerance (MON87460) Stack with two insect resistance traits (MON810 and/or MON89034) and drought tolerance (MON87460)	KALRO AATF CIMMYT		2022/2023
Cassava	Virus Resistance			

	Disease (CBSD); Research ongoing in	KALRO ⁴DDPSC ⁶ NARO ⁵ IITA ⁹ ARCN	CFT and NPT has been completed. KALRO has submitted an application to NBA for environmental release (open field cultivation) and placing on the market of disease resistant GE cassava in Kenya. The application is under review by NBA.	2021
	Cassava Brown Streak Virus (CBSV) and African Cassava Mosaic Virus (ACMV)	⁷ MMUST	CFT – First season has been completed	Unknown
Sorghum	levels, Bioavailable Zinc and Iron (Biofortification)	KALRO ⁸ AHBFI Pioneer Hi-Bred Kenya Ltd. (Corteva)	Eighth season CFT completed.	2022/2023
Sweet Potato	resistance to Sweet Potato	KALRO - Kakamega Center DDPSC	First season CFT completed	2022/2023
	Weevil Resistance through RNAi technology	ILRI	Contained use under laboratory and greenhouse trials ongoing at BecA-ILRI Hub, Nairobi	2022/2023
Banana	Banana bacterial Xanthomonas wilt (BXW) resistance	KALRO IITA	First season CFT completed at KALRO Research Station- Alupe	2022/2023

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; ⁷Masinde Muliro University of Science and Technology; ⁸Africa Harvest Biotechnology Foundation International; ⁹Agricultural Research Council of Nigeria

<u>Sources</u>: International Service for the Acquisition of Agri-biotech Applications (ISAAA), 2020; FAS/Nairobi field visits and meetings with key biotech stakeholders.

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

COMMERCIAL PRODUCTION

On March 9, 2020, the Ministry of Agriculture launched the first planting of Bt. cotton at Alupe University College farm in Busia County. Bt. cotton became the first genetically engineered (GE) crop to be commercially cultivated in Kenya.

Bt. cotton was planted in five counties (Busia, Kisumu, Baringo, Kwale and Tana River) as demonstration plots to train farmers during the March/April 2020 long rains season before full commercialization planned for the October/November 2020 short rain season. The planned area of cultivation will be 15,000 acres in Kenya's eastern and central regions.

Positive results for Bt. cotton have been observed in comparison to the conventional cotton for germination (95%), boll formation and resistance to the African bollworm from the 700 quarter acre demonstration plots.

EXPORTS

Kenya does not export GE crops or products that contain GE materials to the United States or any other country. GE Gypsophila cut flower was intended for export to the international market, including the United States, but NBA rejected the application for commercialization.

• IMPORTS

GOK banned importation of GE products (commodities, processed products, and seeds) on November 21, 2012. The Ministry of Health cited the widely discredited Séralini study, which claimed false links between GE corn and cancer in rats. Although the study was retracted, the GE import ban remains.

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

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

Kenya is a net food importer of agricultural commodities, mainly corn, wheat, rice, and edible oils, and other food products.

FOOD AID

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

Approved Genetically Modified Products for Imports and Transit

The GE import ban also affects food aid transshipments destined for other countries. Under advisement of the U.S government, food aid destined for inland east African countries, which would ordinarily enter through the Port of Mombasa, diverts to other ports. Sources note that such diversions cost the Port of Mombasa considerable revenue and jobs and are a barrier to economic growth. Likewise, GE food assistance (e.g., GE corn-soy blend products) that must move through the WFP hub in Mombasa are not allowed to pass through Kenya—even though they are welcomed by the recipient nation.

TRADE BARRIERS

In addition to the GE ban, mandatory labeling of GE foods effectively precludes importation of food with GE components. Violation of the mandatory labeling provisions imposes a fine of up to \$230,000 and/or imprisonment up to 10 years. The approval process for importation is also slow because of untenable pre-notification procedures.

PART B: POLICY

• REGULATORY FRAMEWORK

The NBA, established by the Biosafety Act No.2 of 2009, is under the Ministry of Education's State Department for University Education and Research. NBA is the main regulatory agency that oversees GE development in Kenya. It is responsible for regulations and policies, as well as general supervision and control over the transfer, handling, and use of GE products. Following the Biosafety Act 2009, NBA developed the following four GE implementing regulations:

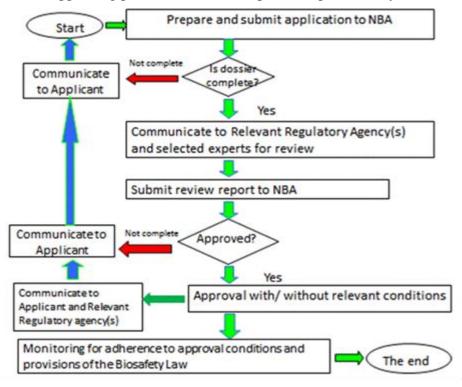
- Contained Use Regulation, 2011;
- Environmental Release Regulation, 2011;
- Import, Export, and Transit Regulation, 2011; and
- Labeling Regulation, 2012

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

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

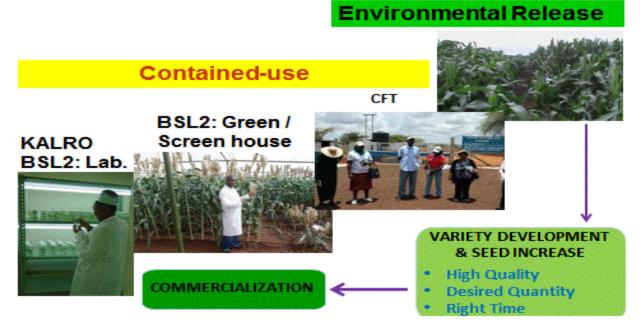
- <u>Kenya Plant Health Inspectorate Service</u> (KEPHIS) under the Ministry of Agriculture, Livestock, Fisheries and Cooperatives, oversees the introduction, testing and use of biotechnology plants and seeds:
- <u>Department of Public Health</u>, under the Ministry of Health, safeguards consumers' health through food safety and quality control, surveillance, prevention and control of foodborne diseases;
- <u>Kenya Bureau of Standards</u>, (KEBS) under the Ministry of Industrialization, Trade and Enterprise Development develops food standards, quality assurance, and testing;
- <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 national performance trials (NPTs) on GE crops and plants;
- Pest Control Products Board (PCPB) (website down), under the Ministry of Agriculture, Livestock, Fisheries and Cooperatives regulates the import, export, manufacture, distribution, and use of products used for the control of pests;
- <u>Kenya Wildlife Service</u> (KWS), under the Ministry of Tourism and Wildlife undertakes and coordinates biodiversity research and monitoring through its Biodiversity Research and Monitoring Division. This Division provides scientific information that is used in the conservation and management of Kenya's invaluable biodiversity;
- <u>Kenya Industrial Property Institute</u> (KIPI), under the Ministry of Industrialization, Trade, and Enterprise Development administers intellectual property rights; and,
- <u>Department of Veterinary Services (DVS)</u> under the Ministry of Agriculture, Livestock, Fisheries and Cooperatives, protects and controls spread of animal diseases and pests to safeguard human health, improve animal welfare, and increase livestock productivity through production of high-quality livestock and livestock products.

The process for approving production of GE crops developed in Kenya:



Source: NBA

Stages in the Regulatory Process



Source: NBA

• APPROVALS

Status	Lab/Greenhouse Trials (Contained use)	Confined Field Trials (CFT)	Import and Transit	Limited open cultivation/environmental release (NPT)
Approved	32	14	28	2
Withdrawn	0	0	2	0
Rejected	0	0	0	1
Pending	1	0	0	1
Total	33	14	30	4

Source: NBA

Kenya registered Bt. cotton for commercial cultivation, and GE cassava application for open field cultivation/environmental release is under review. The government, through NEMA approved NPTs for Bt. corn but rejected commercialization of GE Gypsophila cut flower.

Prior to the GE products import ban, NBA approved imported GE corn-soy blend for humanitarian assistance through WFP. Since the import ban came into effect in November 2012, no GE food has come through WFP either for Kenya or on transit to the neighboring countries. WFP has limited its food aid to non-GE commodities.

• STACKED OR PYRAMIDED EVENT APPROVALS

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

FIELD TESTING

Kenya allowed CFTs for, sorghum, sweet potato, banana, and NPTs for corn. For security reasons, ease of control, and management, KALRO centers exclusively provide trial sites (for both CFT and NPT) that are normally on less than one-acre plots. In addition, NEMA conducts an environmental impact assessment (EIA) before the NPTs start, and before commercialization.

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

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

• INNOVATIVE BIOTECHNOLOGIES

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

Interest has emerged in Synthetic Biology (SB) to find practical synthetic biology solutions in animal and human health, industry, and environment. Kenyan and United Kingdom's researchers and

policymakers held a third workshop in June 26-27, 2019 at Imperial College, London. The workshop considered development of synthetic biology research and applications in the context of East Africa, specifically in Kenya.

Possible areas of research identified using synthetic biology include development of biosensors for use in agriculture (plant diseases); human health (cholera); and environment sectors. The Kenyan government, through the National Research Fund (NRF), has awarded the National Council for Science, Technology and Innovation (NACOSTI) \$110,650 (Kshs. 12 million) to initiate the SB research. In addition, NACOSTI will review the legal framework to ensure that policy sufficiently covers SB.

COEXISTENCE

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

LABELING

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

• MONITORING AND TESTING

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

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

• LOW LEVEL PRESENCE (LLP) POLICY

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

ADDITIONAL REGULATORY REQUIREMENTS

Kenya's Ministry of Health advocates for precautionary use of GE products and despite established science and international norms has proposed additional testing to evaluate safety of GE foods for human consumption. These include acute and subacute toxicity testing; chronic toxicity; and long-term and epidemiological surveillance. The committee wants all GE products to pass preliminary, independently verified, 90-day animal feeding tests that will qualify the GE producer for issuance of a

Class A permit from the Food Safety and Quality Control Unit of the Ministry of Health. The permit should be for a limited period and not exceed two years.

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

• CARTAGENA PROTOCOL RATIFICATION

Kenya was the first country to sign the Cartagena Protocol on Biosafety (CPB) on January 29, 2000. Kenya ratified the Protocol in 2002 and it entered into force on September 11, 2003. The international regulatory agreement requires countries to address environmental safety and human health by ensuring safe handling, transport, and use of GE products. NBA is Kenya's focal point of the CPB and shares data with the Biosafety Clearing House, a mechanism set up by CPB to facilitate information exchange on GE product development and to assist member countries in complying with their obligations under the protocol. More details on the protocol can be found at: Cartagena Protocol on Biosafety Kenya adopted the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the CPB on October 15, 2010. It gives Kenya flexibility to implement legislative, administrative or judicial rules and procedures relevant to liability and redress.

• INTERNATIONAL TREATIES/FORUMS

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

RELATED ISSUES

Not applicable.

PART C: MARKETING

PUBLIC/PRIVATE OPINIONS

Debate on biotech crops and bioengineered foods in Kenya remains contentious, political, emotional, and sensational, and may not always be based on science. Some non-governmental organizations engage in well-funded fear mongering targeting Kenyan consumers with negative, baseless messaging, while Kenyan agricultural research scientists, farmers, university professors and students, seed companies, and other pro-biotech non-governmental organizations continue to provide science-based messaging.

• MARKET ACCEPTANCE/STUDIES

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

Of the 3,529 respondents,

- 76 percent supported GM product imports;
- 71 percent knew about GM products presence in Kenya;
- 50 percent were aware of the Biosafety regulations; and
- 93 percent had knowledge of "GMOs" consumption in the world.
- Seven out of every 10 Kenyans thought "GMOs" are safe for human consumption;
- Eight out of every 10 Kenyans knowingly consume "GMOs";
- Nine out of every 10 Kenyans support the technology in all its applications;
- 14 percent of those opposed to the technology cited mistrust for government regulatory ability, and 37 percent lack of awareness on safety and regulations.

CHAPTER 2: ANIMAL BIOTECHNOLOGY PART D: PRODUCTION AND TRADE

• PRODUCT DEVELOPMENT

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

Product/Animal	Trait	Developers	Stage of Development
Rift Valley Fever Vaccine	Evaluate ChAdOxl-GnGc vaccine in confined field trial to assess its safety, and immunogenicity among sheep, goats, cattle, and	International Livestock Research	CFT approved on November 25, 2016; Kapiti Ranch, Machakos is the location of the trial.
Recombinant Viral Vaccine	dromedary camels in Kenya. To control infections caused by Mycoplasma mycoides cluster.	ILRI	Contained Use/Laboratory Stage
Disease Diagnostic test kits	Example: latex agglutination test kit for CCPP (CAPRITESTR)	ILRI	Awaiting commercial release
Cattle	Resistance to Trypanosomes	ILRI; KALRO; and Institute of Primate Research (IPR)	Pre-CFT

Source: NBA

ILRI research scientists plan to develop disease-resistant cattle for Africa using technologies such as cloning, GE, and genome editing. The aim is to reduce cattle disease incidences across the continent, and to improve livelihoods for African farmers through increased cattle productivity.

Trypanosomiasis, a zoonotic disease also known as Nagana in cattle and sleeping sickness in humans, has widespread impact on both human health and livestock production across Africa. ILRI scientists

estimate its impact to exceed \$1 billion in losses annually to the African economy, reportedly affecting more than 70 percent of the reared cattle. The prevalence of trypanosomiasis effectively limits animal agriculture across Sub-Saharan Africa, depriving many communities of high-quality protein sources and draft animals.

The ILRI scientists have developed a cloned Boran calf named "Tumaini" in the first phase of the project. In the second phase of the project, the ILRI scientists will develop a genome-edited, trypanosome-resistant Boran cow ("Mzima") with a gene for a different form of a common protein (Apolipoprotein) that promises to confer immunity to trypanosomes.

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

COMMERCIAL PRODUCTION

Not Applicable

EXPORTS

Not Applicable

IMPORTS

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

• TRADE BARRIERS

The same GE import ban applies to products of animal biotechnology.

PART E: POLICY

• REGULATORY FRAMEWORK

NBA's regulatory mandate covers both plants and livestock. NBA is currently working on specific animal biotechnology regulations. Animal science researchers use NBA's protocols/guidelines on experiments under contained use, and 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. NBA has developed genome-editing guidelines for further discussion with stakeholders once finalized.

• LABELING AND TRACEABILITY

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

• INTELLECTUAL PROPERTY RIGHTS

Same as plant biotechnology

• INTERNATIONAL TREATIES/FORUMS

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

RELATED ISSUES

Not Applicable

PART F: MARKETING

PUBLIC/PRIVATE OPINIONS

Generally, the Kenyan food processors are aware of food ingredients produced through microbial biotechnology, and their inclusion in imported products. Most likely, the Kenyan consumer is unaware.

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.

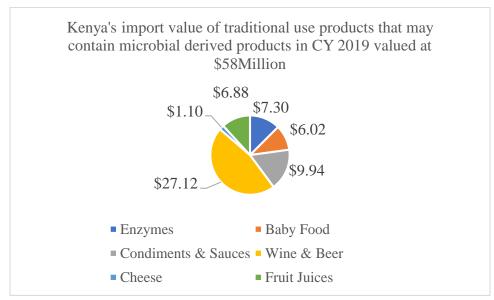
However, NACOSTI together with researchers at Imperial College, London are soliciting for funding to establish a Synthetic Biology Bio-Foundry lab in Kenya. The facility will be used to produce industrial products such as primers, enzymes, and reagents.

• EXPORTS:

Kenya does not export either GE microbes or any products that contain microbial biotech-derived food ingredients such as protease, lactase, steviol glycosides, asparaginase, etc., to the United States or any other 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 2019:



Source: Trade Data Monitor

• TRADE BARRIERS:

Currently, there is no known trade barrier that negatively affects 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 Department of Health regulates the food ingredients through the Certificate of Conformity (CoC) just like other imported food products.

- **APPROVALS:** None
- LABELING AND TRACEABILITY: None

MONITORING AND TESTING:

See Part A: Section D on Imports

If an unapproved product arrives in the country, entry is denied.

- ADDITIONAL REGULATORY REQUIREMENTS: None
- INTELLECTUAL PROPERTY RIGHTS (IPR): Unknown/No information available
- **RELATED ISSUES:** None

PART I:

- **PUBLIC/PRIVATE OPINIONS:** No information available/Unknown
- MARKET ACCEPTANCE/STUDIES: No information available/Unknown

Attachments:

No Attachments