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2016 Kenya's Agricultural Biotechnology Report

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REPORT HIGHLIGHTS:

Kenya’s progress in agricultural biotechnology has suffered a setback after the National Assembly’s Agriculture committee recommended that a new food safety law on genetically engineered (GE) products be put in place, before the 2012 import ban is lifted.

The Agriculture committee’s move follows an earlier decision by Kenya’s National Environment Management Authority (NEMA) to retract the open field trials license for Bt corn.

SECTION I. EXECUTIVE SUMMARY:

On December 1, 2016, Kenya's National Assembly Agriculture committee recommended that the import ban on GE products be upheld until a new legislation on food safety of GE foods for human consumption is developed. The committee proposed that the Ministry of Health establishes a Food Safety and Control Unit to evaluate GE foods, and to issue import permits, a role entrusted to the Kenya's National Biosafety Authority (NBA).

NEMA had previously retracted its license for Bt corn open field trials despite prior approval by NBA, thus, creating confusion in the regulatory framework. NEMA is still reviewing applications for open field trials for Bt corn and Bt cotton, exceeding the 45 days allowed by law.

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SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Kenya has developed a significant capacity for agricultural biotechnology research and development. The following table presents GE crops and a plant under development in Kenya.

Approved Confined Field Trials (CFTs) in Kenya

Crop	Trait	Developers	Stage of Development
Corn	Drought Tolerance/Water Efficient Maize for Africa (WEMA) -- MON 87460	[1]KALRO [2]AATF [3]CIMMYT	CFT completed; CFT conducted for six seasons at Kenya Agricultural and Livestock Research Organization (KALRO) Kiboko with positive results to move forward.

	WEMA Insect Resistance (MON 810)	KALRO AATF CIMMYT	NBA limited approval for Environmental Release/Open field cultivation to National Performance Trials (NPT). NEMA yet to issue the license/permit to proceed with the trials.
	Stack trait maize event for insect resistance and drought tolerance	KALRO AATF CIMMYT	First CFT approval granted/testing on-going
Cotton	Insect Resistance (bollworms)	KALRO Monsanto	Review for environmental release/open field cultivation application ongoing.
Cassava	Virus Resistance		
	Cassava Mosaic Disease (CMD)	KALRO [4]DDPSC [5]IITA	CFT – second season completed
	Cassava Brown Streak Disease (CBSD)	KALRO DDPSC IITA	CFT – first season completed
	Bio fortified Cassava (VIRCA Plus)	KALRO DDPSC [6]NARO IITA	One CFT season completed
	Cassava Brown Streak Virus (CBSV) and African Cassava Mosaic Virus (ACMV)	[7]MMUST	CFT – First season ongoing
Sorghum	Enhanced pro-Vitamin A levels, Bioavailable Zinc and Iron	KALRO [8]AHBFI Pioneer Hi-Bred Kenya Ltd. a DuPont Business	CFT – Seventh season ongoing
Sweet Potato	Virus Resistance: siRNA resistance to Sweet Potato virus Disease	KALRO DDPSC	CFT – First CFT season ongoing
Gypsophila Flower	Pink color flower stability	KALRO	CFT completed; Application submitted to NBA for open field cultivation/environmental release

Notes: [1]Kenya Agricultural and Livestock Research Organization; [2]African Agricultural Technology Foundation; [3]International Maize and Wheat Improvement Center; [4]Donald Danforth

Plant Science Center: [5]International Institute of Tropical Agriculture; [6]National Agricultural Research Organization, Uganda; [7]Masinde Muliro University of Science and Technology; [8]Africa Harvest Biotechnology Foundation International
Sources: International Service for the Acquisition of Agri-biotech Applications (ISAAA), 2015; FAS/Nairobi field visits/meetings with key biotech stakeholders.

Additional information on approved GE projects can be found at: Biosafety Clearing House - Kenya

b) COMMERCIAL PRODUCTION

Kenya does not commercially produce GE crops or GE seeds. Development of Bt corn and Bt cotton has stalled at open field cultivation/environmental release stage.

c) EXPORTS

Kenya does not export GE crops or products that contain GE materials to the United States or Any other country.

d) IMPORTS

The Government of Kenya banned importation of GE products (crops, processed products, and seeds) on November 21, 2012. The move was prompted by the Ministry of Health. Click on the following link to find a report on the ban: Kenya Bans Imports of Genetically Modified Foods

NBA is responsible for the approval process of import shipments of GE products. The authoritative legislation, Kenya's Biosafety Act of 2009, stipulates that the approval process should take 90-150 days. Also, 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. No GE foods and related products have entered into the Kenyan market from November 2012 to date due to the import ban.

e) FOOD AID

Kenya is a food aid recipient country. Some food aid commodities, like corn-soy blend, are GE products. Prior to the GE import ban, NBA approved imported GE corn-soy blend for humanitarian assistance through the World Food Program (WFP). Since the GE products import ban came into effect, no humanitarian assistance containing GE products has been admitted. Details of past import approvals can be found at the NBA's website: Approved Genetically Modified Products for Imports and Transit link.

The GE import ban also affects food aid shipments destined for other countries. Under Advisement of the U.S government, food aid destined for inland east African countries, which would ordinarily enter through the Port of Mombasa, is diverted to other ports.

f) TRADE BARRIERS

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

PART B: POLICY

a) REGULATORY FRAMEWORK

The NBA, established by the Biosafety Act No.2 of 2009, is under the Ministry of Agriculture, Livestock and Fisheries administratively, but under the Ministry of Education, Science and Technology legally. NBA is the main regulatory agency that oversees GE development in Kenya. It is responsible for regulations and policies, as well as general supervision and control over the transfer, handling, and use of GE products. Four GE implementing regulations were released following the Biosafety Act 2009:

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

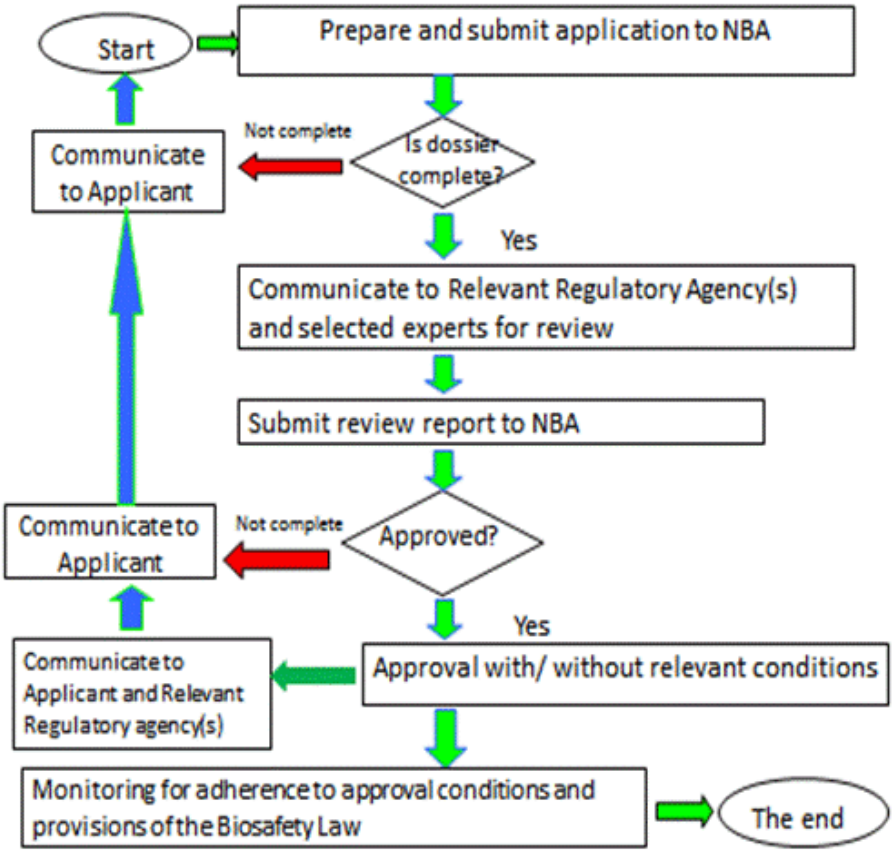
Also in draft stage is the Packaging, Transport, and Identification regulation.

NBA works together with eight other regulatory agencies that have different roles in regulating GE products:

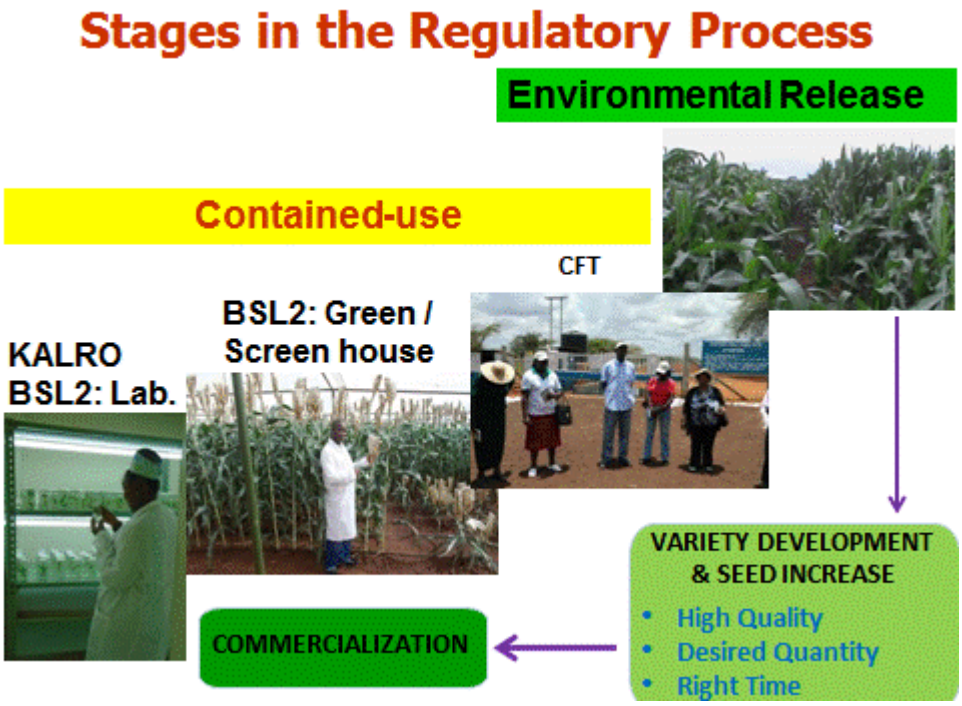
- Kenya Plant Health Inspectorate Service (KEPHIS)under the Ministry of Agriculture, Livestock and Fisheries, oversees the introduction, testing and use of biotechnology plants and seeds;
- Department of Public Health, under the Ministry of Health, safeguards consumers' health through food safety and quality control, surveillance, prevention and control of food borne diseases. The Agriculture committee has recommended the establishment of a Food Safety and Control Unit to evaluate food safety of GE foods for human consumption, and to issue import permits for GE foods;
- Kenya Bureau of Standards, (KEBS) under the Ministry of Industrialization and Enterprise Development, develops food standards, quality assurance, and testing; https://www.kebs.org/index.php?opt=standards&view=biosafety
- National Environment Management Authority (NEMA), under the Ministry of Environment, Water, and Natural Resources, oversees environmental questions and conducts environmental impact assessments. NEMA issues licenses that permit national performance trials (NPTs) on GE crops and plants.
- Pest Control Products Board, (PCPB), under the Ministry of Agriculture, Livestock and Fisheries, regulates pesticide use;
- Kenya Wildlife Service (KWS), under the Ministry of Environment and Natural Resources, handles biodiversity and biotechnology related matters in wildlife and forestry;

- Kenya Industrial Property Institute (KIPI), under the Ministry of Industrialization and Enterprise Development, handles intellectual property issues; and,
- Department of Veterinary Services (DVS), under the Ministry of Agriculture, Livestock and Fisheries, 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 following figure shows the process for approving production of GE crops developed in Kenya.



Source: NBA



Source: NBA

b) APPROVALS

No plants are registered for cultivation, import and export in Kenya. However, Kenyan research scientists have submitted applications to NBA and to NEMA for open field trials approval for Bt corn, Bt cotton, and Gypsophila flower. The 45 days required by law for NEMA to respond to applicants has passed for the Bt corn application, hence stalling the process.

c) STACKED OR PYRAMIDED EVENT APPROVALS

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

d) FIELD TESTING

Kenya has allowed CFTs for GE corn, cotton, cassava, sorghum, sweet potato, and Gypsophila flower. The trials are conducted in selected KALRO stations on less than one acre plots. No GE trials are done in farmers' fields/open field cultivation.

KEPHIS, NBA, KALRO and CIMMYT have developed NPTs guidelines, currently under review. The proposed guidelines has set up measures to control gene flow, and recommended those trials be conducted in KALRO research centers for ease of control and management. KALRO has 16 research institutes spread in all the different agro ecological zones of Kenya.

e) INNOVATIVE BIOTECHNOLOGIES

Kenya's local institutions (the universities and KALRO) are testing genome editing, and RNAi

(switching on and off of gene expression) at laboratory level for proof of concept. Generally, genome editing is viewed as a non-genetic modification technique, and therefore, not part of the regulatory process for GE products.

f) COEXISTENCE

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

g) LABELING

The Kenyan government requires mandatory labeling of foods and feed containing at least one percent, by weight, of GE content. No labeling is required if the GE content is less than one percent of the total weight and the product has been approved by NBA as safe. For labeling regulation details visit:
Labeling Regulations 2012 and 2012 Kenya Agricultural Biotechnology Report

h) MONITORING AND TESTING

NBA is responsible for approving imports of GE products, while KEPHIS, KEBS, and Port Health (Department of Public Health) monitor and test agricultural commodities and food products imports at ports of entry for compliance to the set standards and requirements. However, the Kenyan government has limited personnel and testing facilities for evaluating agricultural products for GE content.

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

i) LOW LEVEL PRESENCE (LLP) POLICY

NBA has drafted a low level presence and adventitious presence policy guidance that awaits consultation with stakeholders.

j) ADDITIONAL REGULATORY REQUIREMENTS

Kenya's National Assembly Agriculture committee has proposed additional testings' to evaluate safety of GE foods for human consumption. These include acute and sub-acute toxicity testing; chronic toxicity; and long-term and epidemiological surveillance. The committee wants all GE products to pass preliminary, independently varied, 90-day animal feeding tests that will qualify the GE producer for issuance of a Class A permit from the Food Safety and Quality Control Unit of the Ministry of Health. The permit should be for a limited period not exceeding two years.

k) INTELLLECTUAL PROPERTY RIGHTS (IPR)

The Kenya Industrial Property Institute (KIPI) handles intellectual property issues that may pertain to genetic engineering, including patents, trademarks, utility models, industrial designs, and technovations.

l) CARTAGENA PROTOCOL RATIFICATION

Kenya was the first country to sign the Cartagena Protocol on Biosafety (CPB) on January 29, 2000. Kenya ratified the Protocol in 2002 and it entered into force on September 11, 2003. The international regulatory agreement requires countries to address environmental safety and human

health by ensuring safe handling, transport, and use of GE products. NBA is Kenya's focal point of the CPB and shares data with the Biosafety Clearing House, a mechanism set by CPB to facilitate information exchange on GE product development and to assist member countries in complying with their obligations under the protocol.

m) INTERNATIONAL TREATIES/FORA

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), and the aforementioned CPB. Generally, these international frameworks seek to protect the environment and human health without unduly hindering international trade, aim to be transparent and in harmony with international trade regulations, and are science-based.

n) RELATED ISSUES

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.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Debate on biotech crops and bioengineered foods remains contentious and political. Some non-governmental organizations have exposed Kenyan consumers to negative messaging, while Kenyan agricultural research scientists, university professors and students, seed companies, and other pro-biotech non-governmental organizations continue to provide positive messaging.

b) MARKET ACCEPTANCE/STUDIES

Studies conducted by the CIMMYT, KALRO, and Kansas State University over five years revealed that Kenyan consumers are generally not aware of bioengineered foods. Processors and retailers showed a higher level of awareness, especially with regard to GE foods.

Survey Group	Number Surveyed	Awareness (%)	
		Biotechnology	GE Crops
Urban consumers in Nairobi	612	46	38
Rural consumers in Western Kenya	121	16	13
Eastern Kenyans	400	63	31
Gatekeepers at milling companies	32	67	87
Supermarkets	40	83	79

Source: CIMMYT

Surveys and studies conducted in Kenya reveal that, although many respondents have heard about genetic engineering in agriculture, most are not informed about the science. Studies also indicate that most Kenyans wish to learn more about GE, regardless of their current perceptions.

A 2011 study, conducted by Hannington Odame and Elijah Muange and sponsored by the UK's Department for International Development (DFID), asked Kenyan farmers and agro-dealers about their awareness and perceptions of GE seeds. The study was conducted in high-rainfall Uasin Gishu and low-rainfall Machakos. Among the results, summarized in the table below, they found that about 60 percent of respondents would buy GE seeds but wanted more information. More details are available in the report Agro-Dealers and the Political Economy of Agricultural Biotechnology in Kenya

Aspect of GE Seeds	Agree (%)			Don't Know (%)		
	Uasin Gishu	Machakos	Avg.	Uasin Gishu	Machakos	Avg.
Alleviate food shortage	78.0	81.5	**79.4**	12.2	11.1	**11.8**
More Nutritious	12.2	38.5	**22.4**	34.1	34.6	**34.3**
More Yield	63.4	77.8	**69.1**	19.5	18.5	**19.1**
Tolerate drought better	43.9	70.4	**54.4**	34.1	22.2	**29.4**
Resist pest better	42.5	63.0	**50.7**	27.2	29.6	**28.4**
Resist herbicide better	19.5	48.1	**30.9**	39.0	40.7	**39.7**
Contaminate local varieties	51.2	42.3	**47.8**	17.1	30.8	**22.4**
Dangerous to human health	50.0	40.7	**46.3**	30.0	29.6	**29.9**
Injurious to non-target organisms	42.5	36.0	**40.0**	40.0	32.0	**36.9**
More expensive	53.7	75.0	**61.5**	17.1	20.8	**18.5**
Require more expertise to trade	63.2	58.3	**61.3**	21.1	12.5	**17.7**
Would trade in GM seeds	48.8	75.0	**57.4**	26.8	25.0	**26.2**

Another study, conducted by Simon Chege Kimenju of the University of Nairobi and Hugo De Groote of CIMMYT, indicated that approximately 70 percent of Nairobi consumers would pay the same price for GE or non-GE corn meal. More details are available in the report Consumers' Willingness to Pay for Genetically Modified foods in Kenya.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

International Livestock Research Institute (ILRI) research scientists have plans to develop disease-resistant cattle for Africa using state of the art technologies including cloning and

gene insertion. Trypanosomiasis is a zoonotic disease that has wide spread impact on both human health and livestock production across Africa. ILRI scientists estimate its impact to be over $1 billion losses annually to the African economy.

These technologies will help reduce disease incidence protecting both human and livestock health, across the continent. It will also improve livelihoods for African farmers through increased livestock productivity. ILRI's headquarters is located in Nairobi, Kenya.

Trypanosomiasis, also known as Nagana in cattle and sleeping sickness in humans, is a chronic debilitating and fatal disease, reportedly affecting over 70 percent of the reared cattle. The ILRI scientists have successfully 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 new cloned Boran cow with a baboon gene that will make it resistant to trypanosomiasis.

The ILRI and KALRO scientists are also developing recombinant viral vaccines under contained use at the ILRI facility to control infections caused by members of the Mycoplasma mycoides cluster. Two trials are ongoing. There is also a CFT on a novel Rift Valley Fever vaccine in sheep, goats, cattle, and camel. The ultimate goal is to improve on the health of the livestock and on their productivity.

Livestock disease diagnostic test kits have also been developed and validated, awaiting commercial release. For example, latex agglutination test kit for CCPP (CAPRITESTR). With early detection, some of the livestock diseases can be controlled.

The key institutions involved in livestock biotechnology research and development include; ILRI, KALRO, and the Institute of Primate Research. NBA regulates application of biotechnology in livestock. Information on NBA-approved livestock projects can be found in their website: Approved Contained Use Research Activities including Livestock Biotechnology

b) COMMERCIAL PRODUCTION

Not Applicable

c) **EXPORTS**

Not Applicable

d) **IMPORTS**

Kenya will need to import transgenic products such as cow fibroblasts, blastocysts, sperm, and possibly transgenic live animals to facilitate development of the trypanosomiasis resistant cow.

e) **TRADE BARRIERS**

Not applicable

PART E: POLICY

a) **REGULATORY FRAMEWORK**

The NBA covers both plants and livestock, but no regulations have been developed specifically for animal biotechnology. However, NBA has protocols/ guidelines on experiments under contained use for livestock research in animal biotechnology.

b) **INNOVATIVE BIOTECHNOLOGIES**

Not Applicable

c) **LABELING AND TRACEABILITY**

Not applicable

d) **INTELLECTUAL PROPERTY RIGHTS (IPR)**

Unknown

e) **INTERNATIONAL TREATIES/FORA**

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

f) **RELATED ISSUES**

Not applicable

PART F: MARKETING

a) **PUBLIC/PRIVATE OPINIONS**

Not applicable/Unknown

b) **MARKET ACCEPTANCE/STUDIES**

Not Applicable