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Regulating Genetically Modified Organisms (GMOs) in Kenya:

Overlap between the Biosafety Act and Environmental Management and Co-ordination Act.

1.0 Foreword

Genetically Modified Organisms (GMOs), also referred to as Living Modified Organisms (LMOs), are products of modern biotechnology with a novel combination of genetic material. To date, GMOs have been employed in health and agriculture for over two decades. In agriculture, genetically modified (GM) crops with improved and/or novel traits have been used to boost agricultural productivity in 26 countries, with an accumulated 2.5 billion hectares planted between 1996 and 2018[1].

Approval for commercial cultivation of any GM crop is given on a case by case basis upon satisfying biosafety regulations provided by the adopting country. In Kenya, regulation of GMOs is a mandate of the National Biosafety Authority (NBA), a competent authority established in 2010 under the Biosafety Act No.2 of 2009[2]. Through this Act, NBA regulates research and commercial activities involving GMOs with a view to ensuring safety of human and animal health and provision of an adequate level of protection of the environment.

To achieve its mandate in monitoring of GMO research and commercialization activities, NBA works closely with eight regulatory agencies including; National Environment Management Authority (NEMA), Kenya Plant Health Inspectorate Service (KEPHIS), Directorate of Veterinary Services (DVS), Department of Public Health (DPH), Kenya Bureau of Standards (KEBS), Kenya Wildlife Services (KWS), Kenya Industrial Property Institute (KIPI) and Pest Control Products Board (PCPB). A synchrony of the regulatory framework under the Biosafety Act and coordination mechanisms between NBA and the eight regulatory agencies in decision-making is required for efficient regulation of GMO research, development and deployment.

Whereas the Biosafety Act establishes a transparent, science-based process for reviewing and making decisions on the development, transfer, handling and use of GMOs, the Environmental Management and Co-ordination Act (EMCA, Revised Version 2012 [1999]) negates this framework by classifying introduction and testing of GMOs as projects requiring Environmental Impact Assessment (EIA)[3]. In addition, a Special Issue of the Kenya Gazette Supplement No. 137, Legislative Supplement No. 63 of 2016, Legal Notice No.150 categorizes "major developments in biotechnology including introduction of new crops, animals and testing of GMOs" as "high risk", requiring submission of EIA reports under section 58(2) of EMCA[4].

The Biosafety Act, through its implementing authority, is sufficient to oversee safe research, development, testing and deployment of GMOs in Kenya. Whereas the Biosafety Act requires submission of Environmental Risk Assessment (ERA) for any GMO to be introduced to the environment, EMCA duplicates this regulation by seeking Environmental Impact Assessment (EIA) for the same application. Therefore, this policy overlap with EMCA introduces a bottleneck in the biosafety framework, consequently stifling the GMOs research, development and deployment process.

[1]ISAAA Brief 54, 2019. Global Status of Commercialized Biotech/GM Crops: 2018.
[2]Kenya Gazette Supplement No.10 (Acts No.2): The Biosafety Act No.2 of 2009.
[3]Environmental Management and Co-ordination Act, Chapter 387. Revised Edition 2012 [1999].
[4]Special Issue, 2016. Kenya Gazette Supplement No.137, Legislative Supplement No.63.

2.0 Capacity to Regulate GMOs Research and Development

Kenya has in place a robust policy, regulatory and institutional mechanisms for implementation of technologies and products developed from modern biotechnology. Having ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in 2003[5], the country approved the National Policy on Biotechnology Development in 2006[6] to guide research and commercialization of modern biotechnology products.

This was closely followed by enactment of the Biosafety Act No.2 of 2009 that lays down legal and institutional frameworks for governing modern biotechnology. The Act served to establish the National Biosafety Authority (NBA) in 2010 to provide supervision and monitoring of genetically modified organisms research and commercialization activities. The NBA is a robust and well-established authority in Kenya recognized for regulating biosafety and equipped with ISO 9001 certification and relevant regulations, guidelines and manuals. By April 2020, the National Biosafety Authority has handled a total of 80 GM applications; 35 for laboratory/greenhouse trials, 14 for confined field trials, 3 for environmental release and 28 for import and transit[7].

3.0 Biosafety Act

The Biosafety Act No.2 of 2009 was passed into law by the Kenyan parliament in December 2008. It received Presidential Assent in February 2009. Through the Act, the National Biosafety Authority was instituted in 2010 as the competent authority to oversee safe research, development, testing and deployment of GMOs in Kenya. The objectives of this Act are:

i. To facilitate responsible research and minimize risks that may be posed by genetically modified organisms;

ii. To ensure adequate level of protection in the development, transfer, handling and use of genetically modified organisms that may have an adverse effect on the health of the people and the environment; and

iii. To establish a transparent, science based and predictable process for reviewing and making decisions on the development, transfer, handling and use of genetically modified organisms and related activities.

Since inception, the National Biosafety Authority has developed biosafety regulations to guide various activities in GMOs research and development. So far, four regulations have been developed and published;

1. Contained use, 2011
2. Environmental release, 2011
3. Export, import and transit, 2011
4. Labeling 2012

The four regulations ensure that;

a. Research on genetic modification is done under appropriate experimental conditions;

b. Open cultivation of genetically modified crops is safe for human health and the environment;

c. There is safe movement of genetically modified materials in and out of the country; and

d. There is efficient tracking of genetically modified products in the food supply chain and information availed to the consumer.

[5]Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2000.
[6]A National Biotechnology Development Policy, 2006.
[7]http://ke.biosafetyclearinghouse.net/approvedgmo.shtml

4.0 Environmental Management and Co-ordination Act (EMCA)

The Environmental Management and Co-ordination Act (EMCA) of 1999 was assented and commenced as an Act of Parliament in January 2000. The purpose of this Act is to;

i. Provide for the establishment of an appropriate legal and institutional framework for management of the environment;

ii. Provide legal and administrative co-ordination of diverse sectoral initiatives in improving the national capacity for management of the environment;

iii. Uphold the environment as the foundation of national economic, social, cultural and spiritual advancements.

4.1 EMCA Regulation of Genetically Modified Organisms

The Environmental Management and Co-ordination Act, Revised Edition 2012 [1999] classifies major developments in biotechnology including the introduction and testing of genetically modified organisms as projects to undergo Environmental Impact Assessment (EIA) [Second Schedule, Section 58(1), 4.]3.
In the year 2016, a Special Issue of the Kenya Gazette Supplement No. 137, Legislative Supplement No. 63, Legal Notice No.150 went ahead to categorize "major developments in biotechnology including introduction of new crops, animals and testing of GMOs" as "high risk", requiring submission of EIA reports under section 58(2) of EMCA4.

5.0 GMOs Regulation Overlap

Whereas the Biosafety Act No.2 of 2009 requires submission of Environmental Risk Assessment (ERA) for any GMO to be introduced to the environment, the Environmental Management and Co-ordination Act (Revised Edition 2012 [1999], and Legal Notice No.149) duplicates this regulation by seeking Environmental Impact Assessment (EIA) for the same application. This regulatory overlap introduces a bottleneck in the biosafety framework, stifling GMOs research, development and deployment process. In addition, the overlap results in duplication of roles and mandates between the regulatory authorities implementing the two Acts namely; the National Biosafety Authority (NBA) and the National Environment Management Authority (NEMA).

The Legal regime that regulates the "major developments in biotechnology including the introduction and testing of genetically modified organisms, is the Biosafety Act, 2009 which is very comprehensive with its Authority and mechanisms for risk assessment and which is in conformity with the various International Instruments(Convention on Biological Diversity , the Cartagena Protocol, Nagoya Kuala Lumpur Protocol etc) signed and ratified by Kenya and therefore form part of the Laws of Kenya within Article 2(4) and (5) of the Constitution.

To seek to regulate "major developments in biotechnology including the introduction and testing of genetically modified organisms" in terms of risk assessment through subsidiary legislation in a gazette notice without any scientific parameters, not only conflicts with sections 18 to 32 of the Biosafety Act on Risk Assessment but also contravenes section 13(a) of the Statutory Instruments Act which requires that every Statutory Instrument conforms to the Constitution, the Act under which it is made and any other written law.

6.0 Grounds of illegality of the Gazette Notice No 149 – 155 of the Environmental Management and Co-ordination Act

a. Regulations were not submitted for tabling in Parliament contrary to section 11(1) of the Statutory Instruments Act.

b. No public participation in contravention of Article 10 and 118 of the Constitution and sections 5, 5A and the Schedule to the Statutory Instruments Act (No. 23 of SI).

c. No consultation with the Authority and with lead agencies in contravention of Article 259(11) of the Constitution and section 58(4) of EMCA.

d. Paragraph 8(g) of the Legal Notice No. 150 on the amendment to Schedule II of EMCA is in conflict with Part III of the Biosafety Act, 2011 hence a contravention of section 13(a) of the Statutory Instruments Act, which calls for conformity with any other written law.

e. Contrary to section 11(2) of the Statutory Instruments Act, there was no explanatory memorandum made for the Regulations providing for the Legislative context, policy background etc which would have guided on the scientific proof behind including Biotechnology events as high risk requiring Environmental Impact Assessment.

7.0 Recommendations for Addressing the Overlapping Regulatory Requirements

To address the overlap of GMOs regulatory requirements between the Biosafety Act and Environmental Management and Co-ordination Act, the following interventions are put forward;

a. Removal of major developments in biotechnology including the introduction and testing of GMOs from the category of "projects to undergo Environmental Impact Assessment (EIA)" (EMCA, Revised Edition 2012 [1999], Second Schedule, Section 58(1), 4.)

b. Removal of major developments in biotechnology including introduction of new crops, animals and testing of GMOs from the "high risk" project category requiring submission of EIA reports (Kenya Subsidiary Legislation, Legal Notice No.150 of 2016).

c. Inter-institutional validation of GMOs Environmental Risk Assessment (ERA) report as scientifically sufficient evidence that products thereof do not present any adverse effects to the environment.