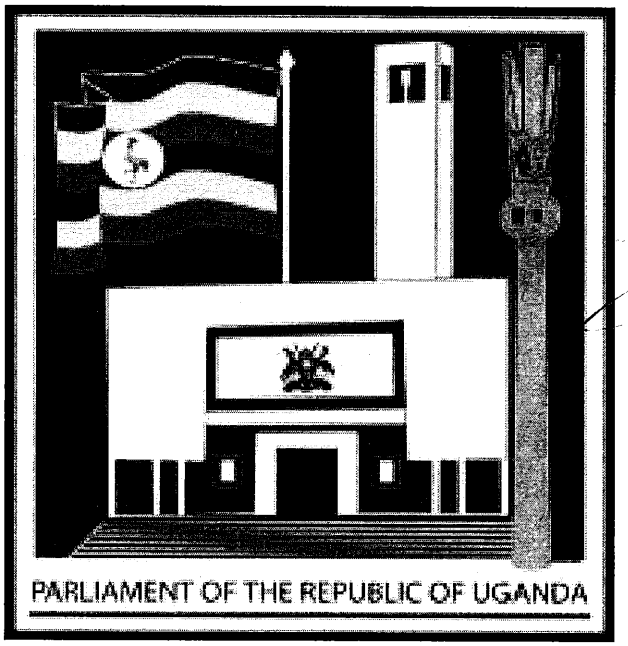
REPORT OF THE COMMITTEE ON SCIENCE AND TECHNOLOGY ON THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL, 2012



Date: **June 2017**

Parliament of Uganda

ACRONYMS

1.	ANVISA:	Brazilian Health Surveillance Agency
2.	BWC:	Biological Weapon and Toxic Convent2017ion
3.	CA:	Competent Authority
4.	CBD:	Convention on Biological Diversity
5.	CIBio:	Internal Biosafety Committee
6.	CNBS:	National Biosafety Council
7.	CPB:	Cartagena Protocol on Biosafety
8.	C*TNBio:*	National Biosafety Technical Commission
9.	C*TNBio:*	National Biosafety Technical Commission
10.	DNA:	Deoxyribonucleic Acid
11.	DSIP:	Agriculture Development Sector Investment Plan
12.	GE:	Genetically Engineering
13.	GMO:	Genetically Modified Organisms
14.	GP:	Genetic Products
15.	IBC:	Institutional Biosafety Committee
16.	ICESCR:	International Covenant on Economic, Social and Cultural
17.	IHR:	International Health Regulations
18.	LMO:	Living Modified Organisms
19.	MoSTI:	Ministry of Science, Technology and Innovation
20.	NARO:	National Agricultural Research Organisation
21.	NDA:	National Drug Authority
22.	NFP:	National Focal Point
23.	NBC:	National Biosafety Committee
24.	SIB:	Biosafety Information System
25.	TRIPS:	The Agreement on Trade-Related Aspects of Intellectual Property Rights
26.	UNCST:	Uganda National Council for Science and Technology

1.0. INTRODUCTION

1.1 Mandate of the Committee

The National Biotechnology and Biosafety Bill, 2012; (*hereafter referred to as the Bill*) was read the First Time on 5th February 2013, in the 9th Parliament. The Bill was referred to the Committee on Science and Technology, but it was unable to receive a Second and Third Reading during that Parliament. At the dissolution of the 9th Parliament, the Bill was among the Business that was saved by the Rt. Hon. Speaker.

On 15th July 2016, the Bill was among the Business that was reinstated by the 10th Parliament in accordance with Rule 221 (2) and (3) of the Rules of Procedure of Parliament. It was subsequently referred to the Committee on Science and Technology on 15th November 2016.

1.2. Background to the Bill

The Bill was intended to Provide a regulatory framework that facilitates the safe Development and application of modern biotechnology in Uganda by:

a) Designating a National Focal Point, and a Competent Authority;
b) Establishing a National Biosafety Committee and Institutional Biosafety Committees; and
c) Providing mechanisms to regulate research, development and general release of genetically modified organisms.

It should be remembered that Uganda doesn't have a specific law regulating the development and use of modern biotechnology. It should also be remembered that Uganda ratified:

i. the Convention on Biological Diversity (CBD) on 8th September 1993;
ii. the Cartagena Protocol on Biosafety on 24th November 2001; and
iii. the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing (ABS) on 25th June 2014.

Uganda is also a Party to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the

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Cartagena Protocol on Biosafety; to which it acceded on 25th June 2014.

The objectives of the CBD are conservation of biological diversity, sustainable use of components of biological diversity (*ecosystems, species and genetic diversity*); and the fair and equitable sharing of benefits arising from the utilization of genetic resources.

The objective of the Cartagena Protocol is to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology, that may have adverse effects on the conservation and sustainable use of biological diversity; taking also into account, risks to human health and specifically focusing on trans-boundary movements.

The objective of the Nagoya Protocol on Access and Benefit Sharing (ABS) is to ensure fair and equitable sharing of benefits arising from the utilization of genetic resources, including appropriate access to genetic resources and appropriate transfer of relevant technology; taking into account all rights over those resources and to technologies, as well as appropriate funding; thereby contributing to the conservation of biological diversity and the sustainable use of its components.

The objective of the Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety is to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to LMOs.

Uganda as a party to this Protocol is therefore mandated to take necessary and appropriate legal, administrative and other measures to implement its obligations under the said Protocol, without compromising its Sovereignty, in accordance with International Law, the Sovereign Rights and jurisdiction which the states have in their exclusive economic zones.

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Hon. Waluswaka James	

1.3. **Methods used in scrutinizing the Bill**

The Committee used the following methods:

i. Direct interaction with Stakeholders in Meetings; both at Parliament and at Stakeholders' work stations. (*A list of Stakeholders with whom the Committee interacted is attached herewith in Appendix A)*

ii. Inter-parliamentary Committees' Meetings were held with Chairpersons of the following Committees:
   - Agriculture Animal Industry;
   - Gender, Labour and Social Development;
   - Health;
   - Budget Committee;
   - Physical Infrastructure; and
   - Trade, Tourism and Industry

iii. Observation on research already done

iv. Attended workshops, sensitisation seminars; conferences and benchmarking study tours on biotechnology and biosafety related subjects, within and outside Uganda. (*Experiences drawn therefrom are included in the Report*)The countries visited included South Africa, Kenya, India, Argentina, Brazil, and United States of America

v. Inland Field visits to confined field trials, Agricultural Research Institutions; and Science and Technology teaching Universities

vi. Literature review of modern biotechnology

vii. Round Table Discussion, which was attended by the Rt. Hon. Prime Minister, Key Ministers and Ministry Officials; scientists; activists and farmers representatives

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2.0. FINDINGS AND OBSERVATIONS

2.1 The usefulness of modern Biotechnology

The Committee learnt that '*biotechnology*' is broadly divided into four sectors namely;

i. Medical biotechnology
ii. Agricultural biotechnology;
iii. Industrial biotechnology; and
iv. Environmental biotechnology;

The biotechnology industry is fast growing with over 1200 biotech industries, institutions and colleges from over 30 countries. It is embedded in various sectors including, but not limited to the health, security, wildlife, veterinary, industrial, environmental and agricultural sectors. The Committee observed however, that the Bill didn't adequately deal with all sectors.

It is on that basis that the Committee will at an appropriate time, table a Motion to this House, seeking Leave to introduce a Private Members Bill, which may cater for the other sectors.

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I. Medical biotechnology

By and large, medical biotechnology is still the largest of the biotechnology sector, with over 250 biotech health care products; over 400 biotech drugs already in use all over the world; and over 200 biotech drugs which are still under clinical trials in USA alone, including treatments for cancer, HIV/AIDS, Alzheimer's disease, and numerous rare conditions.

GMO Derived Drugs in use, in Uganda, include Insulin Crystals-used in the treatment of diabetes; Human growth hormone; Human blood clotting factors; Transgenic farm animals and Artemisinin.

Genetically Modified Organisms (GMO) medicines- The Committee learnt that pharmaceutical biotechnology uses animals and plants as factories to produce protein based medicines; which, in most cases a bacterium, yeast or mammalian cell is modified to enable it to produce a naturally occurring human protein by inserting the gene sequence of the protein in their DNA. The resulting medicine will be chemically very similar or identical to that normally produced in humans. An example is insulin, a diabetic drug which was first produced using genetically engineered bacteria in the early 2000s. Previously it was obtained from slaughtered cows and pigs, but this posed a challenge since some patients were allergic to the animal produced insulin.

In other cases, protein based drugs are produced using transgenic plants or animals. The gene responsible for

expression of the desired protein in humans is inserted in the DNA of the animal or plant through invitro fertilization. The fertilized egg is then placed inside the womb of the animal. The animal/plant born will be transgenic with a DNA sequence having the inserted gene. The gene expression in the transgenic animal results in the production of the proteins which end up in the fluids of these transgenic animals such as milk and blood. Live genetically modified organisms may also be used in the case of vaccines.

Pharmaceutical biotechnology therefore:

a) Helps in the development of new drugs to combat emerging diseases which would not have been possible through conventional drug development techniques;
b) Enables possibilities of developing personalized treatments through pharmmacogenetics;
c) Strengthens research through use of transgenic animals which enable human diseases to be adequately studied in animal models; and
d) Boosts research in the development of drugs, including, but not limited to HIV/AIDS, malaria and cancer. Most of the vaccines being developed use genetically modified organisms through DNA recombinant technologies. These would not have been possible without biotechnology.

Concerns of GMO medicines

Although clause 1 (2) of the Bill presupposes that there is an amendment to the National Drug Authority and Policy Act, which is in the offing to cater for genetically modified drugs, it is pertinent to note that Parliament doesn't legislate in anticipation. Nevertheless, with the assurance of Government that the law is in the pipeline, in view of the Biotechnology and Biosafety Bill, it is important to note that whereas GMO medicines present numerous benefits, there are concerns that were brought to the attention of the Committee as indicated below.

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Hon. Bwino Kyakulaga	
Hon. Abacanon Angiro G	
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Hon. Anywarach Joshua	
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a. *Reproducibility of molecules*- GMO medicines differ from conventional medicines in a number of ways. They contain complex biological molecules unlike the conventional molecules, which are simple chemical entities, whose quality can be ascertained. The inter-changeability or reproducibility of these molecules cannot therefore be perceived as obvious. Most GMO medicines (*biosimilars)* that are innovator products. However, as some of these GMO patents expire, new manufacturers producing similar drugs are set to emerge. These are literally generic versions of the original innovator biotech brands. Being biologically produced molecules, this poses a big challenge in ascertaining whether the generic and the innovator are interchangeable in every critical aspect. There is therefore no guarantee that the impurities in the biosimilars will be the same as those in the original brands, which, can pose serious health consequences

b. *Health Security Risks* -While the title seems to be all encompassing in the field of biotechnology to market and regulate only one (1) application of modern biotechnology, which is GMO, the content of the Bill has nothing to do with biosafety with regard to health laboratory services.

c. The Bill also provides for a very limited narrow scope of protection on risks associated with clinical settings. No risk assessment and management in handling infectious biological materials was provided for in the Bill. The only aspect of the Bill that is relevant to the health sector is regulating research laboratories involved in vaccine technology to comply with international obligations and ensure responsible use of that technology in Uganda, but not comprehensively to all aspects of health biosafety.

d. It should further be noted that the Bill fully accords Uganda National Council for Science and Technology (UNCST) powers as the Competent Authority with a mandate to approve the development, testing and use of GMOs in Uganda.

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The Committee was informed that there is disparity between safety issues in clinical health laboratories and activities of UNCST related laboratories. This therefore calls for establishing measures to cater for outbreaks and safety of laboratories, in case of unintentional release of infectious materials in environments. The Committee's attention was drawn to Uganda's experience on dangerous outbreaks, including five (5) Ebola outbreaks since 2000, three (3) Marburg outbreaks and an outbreak of Crimean Congo Haemorrhagic fever; and terrorist attacks, which took place during the World Cup finals in July 2010.

e. There was expressed faer of potential misuse towards production of dangerous agents or bioengineered agents and misuse of bio agents for wrong purposes; and

f. The is likelihood that transfer of DNA material across bacterial cells may result in antibiotic drug resistance and several health risks of GMOs[1]

Recommendations

i. *The Committee recommends that the Ministry of Health, the Ministry of Science Technology and Innovation; and the Ministry of Agriculture, Animal Industry and Fisheries should jointly prepare and build capacity to be able to prevent, detect and respond to epidemics and hazardous substances;*

ii. *In response to the exponential increase in international travel and trade; and emergence and re-emergence of international disease threats, it is now time that the Government of Uganda should implement the International Health Regulations (2005) (IHR),*

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[1] Food Allergy (Bakshi 2003); Antibiotic resistance (Bernstein et al, 2003); Reproductive and Endocrin disorders (Timbrell, 2003); Hormone disruption (Alteri 1994); Birth defects and shorter life spans (Fo 1996); Cancer (Seralin et al, 2011); Immortality of sperms (Harrison et al, 1996); Sluggishness of sperm (Taylor, 2003); Digestive problems (Steinbrecher, 1996 & Hollingworth, 2002); Obesity (M Antoniou et al 2010); Sterility (Mellon, 2003); Nutritional deficiencies (A Cockburn, 2002)

which binding instrument Uganda entered into with other 195 countries on 15th June 2007. This may help to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with; and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

iii. *In the wake of modern biotechnology, the Government of Uganda should build capacity to be able to prevent, detect and respond to epidemic outbreaks and hazardous substances.*

iv. *All Government Departments should make collaborative efforts to share information pertaining to biosecurity.*

v. By way of responding to some of the medical biotechnology caution, the Committee has ensured that in its proposed amendments to the Bill, it has provided for the following, which it recommends for approval:
   - *Modern biotechnology risk management;*
   - *Promotion of public training and educational outreach to promote a shared culture of responsibility*
   - *Mitigation of biological proliferation;*
   - *Safe procedures of transfer, handling, application and utilisation of biological agents, GMOs and GMO products; and*
   - *Establishment of Laboratory licensing.*

II. ***Agricultural biotechnology*** The Committee learnt that genetically modified foods came to the forefront in 1980 when the U.S. Supreme Court Ruled and allowed the patenting of life forms for commercialization[2]. Since then thousands of genetically modified organisms were created and patented in the U.S. Some of the common genetically modified items include corn, soybean, cotton, squash, papaya, tomatoes, sugar beet, potatoes, flax,

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[2] *The Pew Institute on Food and Biotechnology, 2005*

rice, canola, baby foods, bakery products, confectionery, meat and meat products, soups, fruits and vegetables[3]. Agricultural biotechnology helps to:

a) Develop animals or plants with greater resistance to pests and diseases;
b) Create animals or plants with capabilities of producing higher yields in order to address food security issues;
c) Create raw materials that can be produced in larger quantities;
d) Create products that can enhance growth such as production of growth hormones to increase milk production in dairy cows; and
e) Develop plant materials with aesthetic features such as developing a Rose flower with a green colour.
f) Enhance nutrition

*It is thus no longer a secret that genetically modified plants and animals are already part of the food chain in the world, including Uganda. The use is manifested in various ways such as a*nimal feeds; Animal breeds through artificial insemination; and Human feed such as Cereals.

Concerns of Agricultural biotechnology

Whereas GMOs and their derivatives may prove to be of benefit, the Committee was cautioned on the following:

a) Possible health problems;
b) Creation of products with higher allergic potential exposing the population to more allergic conditions;
c) Development of crop varieties that risks affecting soil fertility;
d) Genetic pollution which may arise due to cross pollination, hence wiping out the traditional breeds;
e) Contamination of GMOs in cases where purification processes have not been properly done; for instance some GMOs are produced from bacterial strains and inadequate purification can have dire health consequences; and

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[3] Batalion, 2000; John & Umaharan, 2005

f) Toxicity

In responding to the above mentioned fears, the Committee in its proposed amendments, has provided for stringent evaluation processes, which should be evidence based, efficient, effective, predictable and well communicated to all parties concerned.

III. *Industrial biotechnology*

Industrial biotechnology is one of the methods currently used to prevent pollution, conserve resources and reduce on costs of production. It has created new markets and in a way protected the environment. Other benefits include:

a) Integrated product improvements with pollution prevention. It is reported that industrial biotechnology solved the phosphate water pollution problems in the 1970s, which pollution was caused by the use of phosphates in laundry detergent. The innovation dramatically reduced phosphate-related algal blooms in surface waters around the globe, and simultaneously enabled consumers to get their clothes cleaner with lower wash water temperatures and concomitant energy savings;

b) Working with nature to maximize and optimize existing biochemical pathways that can be used in manufacturing. The industrial biotechnology revolution rides on a series of related developments in three fields of study of detailed information derived from the cell: genomics, proteomics, and bioinformatics. As a result, scientists can apply new techniques to a large number of microorganisms ranging from bacteria, yeasts, and fungi to marine diatoms and protozoa; and

c) Enabling companies to use many specialized techniques to find and improve nature's enzymes. Information from genomic studies on microorganisms is helping researchers to capitalize on the wealth of genetic diversity in microbial populations.

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IV. Environmental biotechnology

Environmental biotechnology is the application of Biotechnology to solve the environmental problems in the environment and in the ecosystems. It helps to develop, efficiently use and regulate the biological systems and prevent the environment from pollution or from contamination of land, air and water.

The Committee was informed that there are five major types of Applications of Environmental Biotechnology. They are:

a) ***Biomarker,*** which gives response to a chemical that helps to measure the level of damage caused or the exposure of the toxic or the pollution effect caused.
b) ***Bioenergy,*** which is the collective purport of Biogas, biomass, fuels, and hydrogen. This is used in the industrial, domestic and space sectors.
c) ***Bioremediation,*** which is the process of cleaning up the hazardous substances into non-toxic compounds. This process is majorly used for any kind of technology clean up that uses the natural microorganisms.
d) ***Biotransformation***, which is used in the Manufacturing sector where toxic substances are converted to Bi-products.

Industrial biotechnology has been associated with keeping the environment safe and clean by enabling the organisms and the engineers to find useful ways of getting adapted to the changes in the environment.

It has also enabled scientists to improvise means of converting waste to re-usable products.

3.0. OBSERVATIONS ON THE BACKGROUND TO THE BILL

3.1. A regulatory framework that facilitates the safe Development and application of modern biotechnology in Uganda

While the Committee appreciates the fact that there is need to provide a framework to ensure safety of modern

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biotechnology in Uganda; it found it befitting to propose to the House a change in the name of the title of the Bill in order to align it to the intended purpose.

3.1.1. *Designating a National Focal Point, a Competent Authority and a Registrar*

Competent Authority

The Bill provides for designation of the Uganda National Council for Science and Technology (UNCST) as the Competent Authority.

The Committee would have wished to recommend to Parliament to establish an independent Authority in order to give it fair independence other than designating UNCST as the Competent Authority. However, during the Round Table Discussion on 23rd April 2017, it emerged that Government was disappointed with the performance of the already existing Authorities in Uganda; therefore, establishing a new Authority may not be the best idea.

Further noting that it is not proper for an institution to be given responsibility to take decisions, make regulations and at the same time promote GMOs;

And noting that if designated as a Competent Authority, there is likely to be a conflict of interest, the Committee noted that the Uganda National Council for Science and Technology (UNCST), which is a promoter of modern biotechnology cannot at the same time be designated the responsibility of regulating it. It is on that basis that the Committee has proposed to establish a Directorate of Biosafety within the Ministry of Science, Technology and Innovation (MSTI), which Directorate is designated as a Competent Authority.

The decision to establish a relevant Directorate of Biosafety in MSTI is backed up by experience obtained from the benchmarking study in Argentina; a developing country like Uganda, but more advanced in modern biotechnology development and application. Argentina, unlike Uganda established two Competent Authorities in accordance with the Art. 19 (1) of the Cartagena Protocol on Biosafety to the Convention on

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Hon. Kafeero Ssekitoleko	
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Biological Diversity. It established a Competent Authority responsible for the administration of the regulatory framework of Genetically Modified crops which is placed in the Ministry of Agro-industry; and a Competent Authority called Biotechnology Directorate, which is placed in the Ministry of Science, Technology and Productive Innovation.

Reporting structure of the Registration and inspection agencies

The Committee observed that the reporting structure was not well stipulated in the Bill. Reporting structures and power centres have been a cause of several misunderstandings in government structures and it should be avoided this time round. The Committee therefore recommends that the reporting structure of the biotechnology and biosafety Institutional Framework should be specified in the law to avoid ambiguities. In that regard, the Competent Authority should be the Top Most biotechnology and biosafety structure, supervising the National Biosafety Committee; to which the Institutional Biosafety Committees should report.

3.1.2. *Establishing a National Biosafety Committee (NBC) and Institutional Biosafety Committees (IBCs)*

Further borrowing from the benchmarking studies undertaken in Brazil, South Africa and Kenya, the proposed NBC and IBCs in the Bill are not comprehensively constituted to include people from relevant sectors. The Committee will therefore in its amendments propose to the House to amend the relevant clauses to make the Bill more inclusive than it is currently.

The Committee also found it necessary to enhance the functions of the NBC.

3.1.3. *mechanisms to regulate research, development and general release of genetically modified organisms*

Why hurry to enact a law to regulate modern biotechnology?- A section of Ugandans have questioned as to why there should be a hurry to enact a law to

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regulate modern biotechnology. It should be noted that the Government of Uganda, through the National Agricultural Research Organisation (NARO), is already in advanced stages, conducting research on crop plants produced through modern biotechnology in order to come up with products that overcome chronic problems such as insect and disease epidemics, drought stress, and malnutrition. A law is therefore required to provide for the safe development and release of the improved varieties resulting from biotechnology to farmers.

It should also be noted that many farmers in African countries and trade partners are already using products of modern biotechnology. Furthermore, Uganda's borders are porous, hence necessitating a law to guide access and use of such products.

It is also important to note that in a free market economy like Uganda, products are imported into the country from various parts of the world. Some of these imported products contain GMO materials that may or may not be clearly indicated. There is need to provide for identification of GM content in such products to give Ugandans an opportunity to choose to use or not to use GMO products.

A fear that biotechnology produced drugs contain harmful biotechnology chemicals

The Committee learnt that the first ever used biotechnology produced drug was quinine, an alkaloid found in the bark of the cinachona tree. This was the best chemotherapeutic agent available to combat malaria until the 1920s. Since then, other plant extracts followed. The most recent being the artemisinin extract from the leaves of Artemisia annua, a plant used by the Chinese to treat malaria.

The Committee further learnt that when medicines are produced through extracts from plants, it only undergoes purification to get the pure chemical needed for medicinal purposes. This explanation allays fears that GMO drugs contain pure biotechnology chemicals. Although GMO drugs are produced biotechnologically,

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they have no genetic residues, but are pure chemicals for medicinal use.

A law may help to alley such fears because it will have well laid out procedures of releasing the genetically modified products. Besides this confidence, the Committee also calls upon the Uganda National Drug Authority (NDA) to tighten its control measures and systems to protect Ugandans from the unlikely events that may arise out of such circumstances.

The Need to protect human life, animal and Plant health

The Bill mainly focused on crop biotechnology, but it didn't provide for stages that a genetically modified product must go through before it is released. The Committee finds it necessary to submit applications of the project to an IBC, which also submits to the NBC hence to the Competent Authority for approval. Before approval, the NBC is expected to review the proposal and make a site visit to determine whether the conditions exist for carrying out the work safely. Once the proposal is approved, development and testing can begin, and must be performed in a restricted and controlled environment. If the work site is a factory, or a confined field trial, or field trial, the Ministry of Agriculture should be in charge of supervising the experiment. Then, before the GMO product's commercial release, the NBC should evaluate whether the data collected corresponds to the established biosecurity criteria.

Prior to its marketing, the GMO product should further be subjected to a technical assessment conducted by a number of Members of the Competent Authority, who should decide whether it is advantageous or not, for the country to launch the new product on the market.

Fear of the Terminator Gene seeds

Farmers fear that they may replant seeds from GM crops, which may fail to germinate. The Committee has established that the seeds will germinate; however, the yields may be lower than the first season of planting, just like conventionally bred hybrids that many farmers are already familiar with. Nevertheless, the Committee

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in its proposed amendments has provided that terminator seed should never be developed, imported or otherwise used in Uganda.

Fear of Environmental degradation by GM crops

The Committee considered allegations that genetically modified crops can potentially cause environmental problems that result directly from the engineered traits. The public is hereby informed that the Committee in its proposed amendments has ensured that the release of any genetically modified crops to farmers is done after thorough assessments to ensure that the crops pose no significant negative effects on the environment. To that effect, a liability clause has been proposed to address circumstances of both unintentional and intentional release as well as mitigation measures in case of emergencies.

Fear of Monopoly of seed distribution by seed companies

The government of Uganda put in place systems and programmes to ensure a diverse and sustainable agricultural sector, as stipulated in the Agriculture Development Sector Investment Plan (DSIP). There will therefore be no monopoly of seed distribution. Uganda is a free market economy and farmers will choose to grow what they want; and to buy from any company of their choice.

Labelling

The Committee observed that there was no provision in the Bill to provide for labeling of GMO products. As a party to the Cartagena Protocol, the Committee has in its proposed amendments provided for that documentation accompanying Genetically modified organisms that are intended for intentional introduction into the environment, should clearly identify the GMOs as such. The documentation should also specify the identity and relevant traits and/or characteristics among others.

Protection of indigenous varieties

A section of Stakeholders expressed a need to protect the indigenous materials. Other stakeholders expressed

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fears that indigenous seed would be wiped out by diverse and complex causes of crop genetic diversity losses, which include ecosystem destruction, forest cutting, bush and charcoal burning, agricultural expansion, diversification and changing agricultural practice, natural disasters, climate change, pests and diseases, changes in dietary preferences and use habits, pollution, population expansion, land fragmentation, introduction of new high yielding varieties, invasive species and uncontrolled harvesting from the wild were all acknowledged by scientists.

The Committee visited the Uganda National Gene Bank at Entebbe and established that it has a holding capacity of 5,000 accessions. This is however far less than the estimated 500,000 accessions that represent Uganda's PGRFA diversity. Although its holding capacity is 5000 accessions, at the time of the Committee's visit, there were only 3,781 accessions (samples) representing 149 species; of which, 85 were crops species of the known 96 crops species in Uganda. Other than the indigenous materials stores in Uganda. Excess materials are transported to Spain for safe custody. Spain has a Gene bank that has the capacity to keep the materials for 50 years.

Recommendation

The Government of Uganda should increase funding in national conservation for the future. It should also rehabilitate and sufficiently equip the Uganda National Gene bank at Entebbe, in addition to protecting its land from encroachers.

Laboratory Experiment

The Committee observed that while there exists guidelines for establishment of general laboratories, there is need to establish biosafety requirements, for the issuance of permits to operate GMO laboratories or activities related to GMOs and their by-products; an issue that was omitted in the Bill. This omission has been addressed by amending the schedules.

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GMO free Zones and Isolation distances between GMO crops and Non-GMO crops-a section of the public had suggested restriction of GMO activities to specific Zones in addition to providing minimum isolation distances between genetically modified crops and non-genetically modified crops, to allow the coexistence of different production systems in the field. The Committee decided not to create GMO free zones because of the fragmented nature of Uganda's farming systems and the existence of various human rights concerns.

Criminal Offenses- Proposals have been made by the Committee to provide for specific specific penalties for criminal offences especially with regard to the following:

a) Release or disposal of GMOs into the environment in a way that is contrary to the standards established by the Competent Authority and by the agencies and entities of registration and inspection;
b) The offense resulting in damage to another's property;
c) Offences causing harm to the environment;
d) Offense resulting in serious bodily injury to another person; and
e) Offenses resulting in death.

4.0. HUMAN RIGHTS COMPLIANCE OF THE BILL IN ACCORDANCE WITH THE INTERNATIONAL TREATY AND CONVENTION OBLIGATIONS ON HUMAN RIGHTS

4.1. Human rights concerns that have been adequately catered for in the Bill

The committee interacted with the Human rights Commission and established that the following had been adequately catered for in the Bill.

a. The proposed legal framework facilitates safe Development and application of biotechnology. This is a positive human rights in the realization of the right to adequate standard of living and adequate food for Ugandans under Art. 11 of the International Covenant on Economic, Social and Cultural Rights (ICESCR.)

b. The proposal to protect confidential business information is an important provision especially in

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light of sensitivity of scientific and biotechnology experiments. Although the Competent Authority is expected to avail information to the public, the regulatory system must balance the competing interests of the applicant, who may want to keep some information confidential for business purposes. A regulatory system with no protection for trade secrets and proprietary information, might not receive any application because private enterprises wouldn't be able to successfully market a product if certain information isn't kept confidential. This is clearly provided for in the Bill.

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4.2. Human rights concerns that have not been adequately catered for in the Bill

In the Bill, the following human rights concerns arise.

a) Inadequate public awareness and participation;
b) Lack of clear safety standards to ensure food safety and security;
c) Inadequate safety standards of approving a genetically Modified Organism (GMO);
d) Inadequate provisions related to fair and equitable sharing of benefits from utilising genetic resources;
e) Limited access to information; and
f) Inadequate oversight mechanisms.

Inadequate public awareness and participation- There was inadequate public awareness and participation of the general public about the introduction of GMOs and biosafety. Awareness involved a few stakeholders. Likewise, as was in practice, even the Bill had not provided for public participation and awareness. The Bill provides that the Competent Authority may promote awareness, but it doesn't specify the right of the public to participate in the decision making process; yet Art. 23 of the Cartagena Protocol on Biodiversity (CPB) obliges party states to promote and facilitate public awareness, education, participation and access to information concerning safe transfer, handling and use of living modified organisms, in relation to the conservation and sustainable use of biological diversity.

The Committee has therefore proposed an amendment to the Bill, which allows the public to be consulted in decision making process regarding GMOs, which is in line with the precautionary principle, which forms the basis of the African Union's Revised Model Law on Biodiversity.

<u>*Lack of clear safety standards to ensure food safety and security-*</u> It is noted that the Bill provides for facilitation of safe use of biotechnology in order to address food security. For this to be done, the Bill gives a comprehensive definition of GMO, but the definition in the Bill doesn't distinguish GMOs based on the products which GMOs produce. The Bill doesn't also adequately address issues of food safety and security, for instance there are no laid out procedures of what would be considered in conducting food safety assessments.

Recommendation

The Committee recommends that the Bill should provide for identification of GMOs for any person manufacturing or importing a GMO

<u>*Inadequate safety standards of approving a genetically Modified Organism (GMO)-*</u> Although the Bill provides for institutions that would approve GMO at various stages and lays out the requirements for approval in schedules, it doesn't explicitly lay out the criteria for the refusal or granting of the approval. It doesn't provide for whether the criteria will be based on risk to the environment, animal or human health, or food safety and security.

It is also not clear whether the criteria provided in the Bill would be applied on possible environmental impacts caused by GMOs including loss of biodiversity because of dominance of GMO strains or the direct and indirect side effects of GMOs on life support systems in the environment such as air, water and soil.

The Bill further didn't outline which socio-economic considerations would include impacts on farmers' income and welfare, ethical values, cultural practices

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such as the knowledge, innovations of indigenous and local communities in saving and multiplying seed in order to sustain food systems and food security.

The Committee considered the above omissions and proposed in the schedule, a criteria for refusal or granting of the approval of a GMO. The criteria indicates the most recent peer reviewed information about the GMO and the Competent Authority may be given an option to conduct the risk assessment

The Committee further proposed in the schedule, explicit details of what constitutes socio-economic considerations in the event of introduction of GMOs.

Risk and safety assessment and management -The Committee noted the concern that the Technology has both potential risks and benefits that should be evaluated before a decision is taken to transfer the technology to farmers and consumers. While the Bill provides for the different stages in the development of a genetically Modified Organism (GMO) from approval of each stage of research, risk and safety assessment and management; general release into the environment; and import, export and transit process for GMOs in line with Art. 2 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, the Committee has proposed amendments to *provide for the case risk assessment*

Limited access to information-The Bill provides for publishing an approval for general release in the Gazette or official website of the Competent Authority, to which a small section of the public have access. In order to make the public aware of the GMO produced, its benefits and risk assessment to the health and environment; the Committee has proposed a provision to publish in national newspapers and appropriate electronic media. This may also enable the public to respond to any issues raised.

A provision has also been proposed for a time frame within which the public should respond to the Competent Authority and vice versa.

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Inadequate oversight mechanisms- The Bill omitted the central role of the Ministry of Agriculture, Animal Industry and Fisheries in the process, yet this ministry is responsible for any agricultural developments in Uganda; and it has a primary role to play in ensuring food security. This has however been catered for in the proposed amendments.

Offences and penalties- While some scientists argued that corporate bodies invest in sectors that have limited risks; and that if the penalties are high, the law may discourage potential investors into this technology; the Committee observed that the sanctions and redress for breach of the provisions that were provided in the Bill are very light.

It was further observed that liability was vaguely defined giving protection to corporations which may commit offences. Penalties to body corporates were also not specifically spelt out, while the restoration order redress is limited to restoration of the environment and levying of a charge and liability which doesn't encompass redress in case of harm to human and animal health or damage to the livelihood of communities

Proposals have also been made to make the penalties for breach of the provisions of the Act more stringent, taking into account the high level of risk attributed to the development of GMOs and potential adverse effect caused to public health and environment.

Liability was also extended to include compensation in case of harm to human and animal health which may have suffered due to the release of a GMO.

5.0. GENDER COMPLIANCE OF THE BILL

5.1. Fair and equitable sharing of benefits from utilising genetic resources

Inadequate provisions related to fair and equitable sharing of benefits from utilising genetic resources

The Committee observes that it is only fair to provide for sharing of benefits that arise from the use of genetic resources in light of the intricacies of intellectual property rights of GMOs. It was further noted that biotechnology

companies with patent rights don't only have patent rights to restrict the use of GMOs, but could also inevitably control the saving, sharing and multiplication of seed and the cost of patented seed. This is of great concern in Uganda where the greater percentages of farmers are not well conversant with the Patent Rights and may not be able to afford patented seed.

In view of the above concern, the Committee has proposed an explicit criteria in the schedule to guide the Competent Authority on when to approve the introduction of GMOs.

6.0. GENERAL RECOMMENDATIONS

6.1. ***Institutional framework*** -The National Biotechnology and Biosafety Bill should establish an institution responsible for establishing the biosafety requirements for the issuance of permits to operate laboratories, institutions, or companies carrying out activities related to GMOs and *GMO* bi-products.

6.2. A Biosafety Directorate should be established in the Ministry of Science, Technology and Innovation, with a clearly spelt out mandate to establish technical standards regarding GMO research and the commercial use of GMOs and their bi-products based on the assessment of their risk to human, animal health; and the environment, among other functions.

6.3. The Competent Authority should comprise of multi-disciplinary professionals, who should be responsible for providing technical support and advice to the Government of Uganda. The Competent Authority should be able to update the Ministry on the emrging modern biotechnologies; as well as establishing technical safety standards and providing technical advice regarding the authorization of activities involving research and the commercial use of GMOs and their bi-products, based on the assessment of their risk to human health and the environment.

6.4. The functions of the National Biosafety Committee should be enhanced.

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6.5. ***Laboratory Experiment*** Biosafety requirements, specifically for the issuance of permits to operate GMO laboratories or activities related to GMOs and their bi-products should be established.

6.6. **Labelling** - Consumers must be informed about the GMO content of a product marketed as food for human or animal consumption.

6.7. ***Ecological and environmental concerns***- while it is appreciated that the Biotechnology and Biosafety Bill should be passed with amendments if Uganda is to achieve the National goals of poverty eradication, improved healthcare, food security, industrialisation and the protection of the environment, it should also be recognised that Art. 39 of the Constitution of the Republic of Uganda entitles every Ugandan to a clean and healthy environment.

Government of Uganda should therefore defend and preserve the environment for the present and future generations. To ensure the effectiveness of this right, Government should preserve the diversity and integrity of the country's genetic patrimony, and should supervise entities dedicated to research and manipulation of genetic material.

Government should also ensure that an Environment Impact Assessment has been carried out, and a report on the results issued by a relevant authority and made public before any GMO activities take place.

6.8. ***Restrictions on Releasing Organisms into the Environment***- GMOs or their bi-products should not be released into the environment:

i. without a favourable technical decision issued by the Competent Authority in consultation with the NBC;
ii. during trade operations, without a favourable technical opinion issued by the Competent Authority in consultation with the NBC;
iii. without a license issued by the appropriate institution or environmental entity; or

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iv. without the approval of the Competent Authority in consultation with the NBC.

6.9. **Report of accidental release-** Any accidental release of a GMO, GM plant and its bi-products; or a GMO from a laboratory, must be immediately reported to the Competent Authority.

6.10. **Liability Regime** -Without prejudice to the application of the penalties that have been proposed in this report, anybody responsible for damage to the environment and to third parties should jointly be liable for their compensation or full reparation.

6.11. **Offences and penalties-** The release or disposal of GMOs into the environment in a way that is contrary to the standards established by the Competent Authority and by the agencies and entities of registration and inspection should be punishable. The punishment should increase by a given percentage e.g. one-sixth to one-third if the offense results in damage to another's property; one-third to one-half if harm is caused to the environment; one-half to two-thirds if the offense results in serious bodily injury to another person; and two-thirds to double if the offense results in death.

6.12. Individuals acting in an autonomous capacity shouldn't be allowed to develop activities and projects involving GMOs, unless they are attached to existing Institutional Biosafety Committees.

6.13. **Unfair practices by seed companies**- Unfair practices by seed companies which may want to take advantage of their absolute monopoly to take control over agricultural biotechnology should not be entertained by Government.

6.14. If not avoided, provisions on agreements to be signed between farmers and seed companies should be void of unnecessary restrictions to farmers before they gain access to the respective companies' seeds, which restrictions may in turn cause farmers to surrender their other important rights, such having privacy on

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their farms, preventing farmers from saving seeds and reproducing them individually or even replanting the seed. The Committee has ensured that if there is need for any royalty to be collected, it has been provided for in the proposed amendments, otherwise it is not necessary.

6.15. **Increase funding and support to the Ministry of Health**- Government should increase funding and make timely release of funds to the Ministry of Health to enable it to enhance the capacity of its biotechnology laboratories; strengthen real time bio-surveillance and reporting; set up Public Emergency Operations Centres (PHEOC); set up a bio safety and bio security facility and to upgrade imaging equipment for safety against radiation.

6.16. Procedures and security measures should be established to contain and prevent unintentional exposure to pathogens and toxins or their accidental release to society.

CONCLUSION

In conclusion, Rt. Hon. Speaker and Hon. Members, on a global perspective, the biggest challenges are how to adapt the production of food in view of the climate changes; and how to develop further the role of agricultural biotechnology in combatting the global challenge. Crop varieties that are more resilient to drought, flooding, saline or acid soils and temperature extremes resulting from climate change may be needed, and adaptation-related technologies, including biotechnology, may play their part. Several GMO crops with these traits are already being researched on in Uganda and are in advanced stages. The enactment of an enabling law will therefore enhance the safe development of modern biotechnology.

Rt. Hon. Speaker I beg to move that the Report be adopted.

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PROPOSED AMENDMENTS TO THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL, 2012

Short Title
Amend the short title to read as follows;
"The National Biosafety Act".

Justification:

To ensure safety and regulation of modern biotechnology and its products.

CLAUSE 1 Application.
Clause 1(1)
Rephrase sub-clause (1) to read as follows:
"This Act applies to the use of modern biotechnology, research, safe development, application and general release of GMO products."

Justification
To provide a wider application and scope of coverage of the Bill.

Clause 1 (2)
Substitute for the words *"genetically modified drugs"* appearing in lines one and two, the words *"drugs manufactured using modern biotechnology."*

Justification
To ensure proper use of the phrase

CLAUSE 2 Objectives of the Act.
Rephrase the entire clause to read as follows:

The Objectives of this Act are-

i. *To regulate the research, development, application and use of modern biotechnology and its products;*
ii. *To provide for the establishment of procedures for bio-ethical considerations in modern biotechnology research;*
iii. *To create and strengthen consumer protection, public awareness of and participation in modern biotechnology;*
iv. *To regulate development and application of modern biotechnology to ensure sustainable use of biological*

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diversity, taking into account risks to human health, safety during trans-boundary movements, food security, and industrialization;

v. *To build capacity in modern biotechnology research, development, innovation and regulation;*

vi. *To regulate technology transfer and ensure equitable benefit-sharing in the development and use of modern biotechnology and its products;*

vii. *To build strong institutional relationships among modern biotechnology and biotechnology stakeholders.*

Justification

To harmonize the objectives of the Bill with the subject matter of the Bill, to legislate in accordance with the requirements of the Cartagena Protocol on Biosafety, to involve the public in the modern biotechnology development and strengthen consumer protection.

CLAUSE 3 Interpretation

Interpretation of "biosafety".

Insert the word *'modern'* between the words "of" and "biotechnology" appearing in line two.

Justification

To restrict the application of the phrase to modern biotechnology only.

Interpretation of "biotechnology."

Delete the interpretation of the word "biotechnology."

Justification

To limit the Bill to modern biotechnology only.

Insert the following words for interpretation

"contained use" means any activity in which products of genetic modification or genetic engineering processes are cultured, stored, used, transported, destroyed or disposed of, and for which a physical barrier or a combination of physical barriers together with chemical or biological barriers or both are used to limit contact thereof with the environment

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Justification
The definition is important for the research process. While biotechnology products have to be tested as provided for in the Bill, the same products need contained usage as part of research or normal usage of the products. There is need to provide for contained usage of GMO products, as a step after contained testing and part of the necessary procedures.

"genetically modified product" means a product made from or containing a GMO material or materials whether manufactured, processed or otherwise created;

"inspector" means a person appointed under section 34 of this Act;

"person" includes a company or association or body of persons corporate or unincorporated;

Justification
For clarity.

CLAUSE 4 Designation of National Focal Point.
Substitute for the words "the environment" appearing in line one, the words *"science, technology and innovation".*

Justification
To provide for the focal point to be housed in the Ministry responsible for science, technology and innovation because designating the Ministry responsible for environment as proposed in the Bill was relevant at the time when there was no Ministry responsible for science and technology.

CLAUSE 6 Competent Authority
Substitute for clause 6 the following;

1. There is established within the Ministry of Science, Technology and Innovation, a Directorate responsible for biosafety, for purposes of implementing this Act.

2. The Directorate shall consist of staff appointed by the Public Service Commission to carry out the functions of the Competent Authority and they shall be proffessionals in modern biotechnology and biosafety.

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3. The Directorate shall be headed by a director who shall act as the secretary to the National Biosafety Committee.

Justification
There should be a separate body from the Uganda National Council for Science and Technology (UNCST) to regulate GMOs in the country since UNCST is a promoter of science and technology in Uganda.

CLAUSE 7 Functions of The Competent Authority.
Clause 7 (1) (a)

Insert the word "*research*" immediately before the word "development" appearing in line one.

Justification
To include research for approval by the Competent Authority.

Clause 7 (1) (b)
Substitute for the word '*biotechnology*' appearing in line one, the phrase "*modern biotechnology*", and wherever it appears in the Bill'.

Justification
For specificity.

Clause 7 (1) (c)
Insert the word "*research*" between the words 'during' and 'development' appearing in line two.

Justification
To broaden the provision to cater for research.

Clause 7 (1) (d)
Rephrase the entire paragraph as follows:
"(d) to consider and ensure enforcement of necessary measures to avoid adverse effects on the environment, biological diversity, human health and on socio-economic conditions arising from modern biotechnology and its products; "

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Justification
To broaden the provision to include enforcement.

Clause 7 (1) (f)
Delete the word '*standards*' appearing in line one.

Justification
A separate provision on standards has been introduced.

Insertion of new paragraph
Insert a new paragraph immediately after paragraph (f) to read as follows:

"*to liaise with the appropriate government agencies to prescribe the standards for regulating modern biotechnology and its products*"

Justification
To provide for the involvement of other government agencies responsible for standards.

Clause 7 (1) (i)
Insert the words "*create and*" between the words to and promote appearing in line one.

Justification
To provide for creation of awareness

Insertion of new paragraphs
Insert the following new paragraphs immediately after paragraph (g)-

- *to receive and screen completeness of GMO applications;*
- *to register all research institutions required to be registered under this Act;*
- *to keep a register of institutional biosafety committees;*
- *to prepare and issue certificates, permits and advance informed agreements;*
- *to inspect and monitor any person or activity authorized or approved under this Act;*

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Justification
To broaden the functions of the Competent Authority since the clause that provided for the office of the registrar has been deleted from the Bill.

Clause 7 (2) (a)
Delete the expression '*or any other person*' appearing in line one.

Justification
To avoid abuse.

Clause 9 Establishment Of The National Biosafety Committee

Clause 9 (2)
Substitute for sub-clause (2) the following:
The National Biosafety Committee shall consist of the following-

i. five persons with atleast ten years experience from any of the following fields;breeding and genetics, agronomy, pathology, molecular biology, food science, toxicology, ecology, microbiology, pharmacology, soil science, industrial chemistry;
ii. a representative of the academia from any public university;
iii. a lawyer nominated by the Uganda Law Society;
iv. a representative of the Uganda National Council for Science and Technology;
v. a representative of farmers nominated by a nationally recognised farmers' umbrella association;
b. a representative of the Uganda National Bureau of Standards with experience and knowledge of standards of modern biotechnology and its products; and
i. any other relevant modern biotechnology fields as may be recommended by the Competent Authority from time to time.

Justification
To provide for a technical National Biosafety Committee.

Clause 9 (3)
Delete the words "*chairperson and*" appearing in line one.

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Hon. Kafeero Ssekitoleko	
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Justification
Consequential amendment arising from the amendment of sub-clause (2)

Insertion of a new sub-clause
Insert a new sub-clause immediately after sub-clause (3) as follows-

"The members of the committee shall elect a chairperson from among members of the committee appointed under sub-section (2) (a)."

Justification
To provide for the election of a chairperson of the Committee.

Clause 9 (7)
Insert the words "*within sixty days*" immediately after the word "person" appearing in line two.

Justification
To ensure efficiency.

Insertion of a new sub-clause
Insert a new sub- clause immediately after sub-clause (7) as follows:

"The chairperson of the committee shall lose his or her seat when he or she ceases to be a member of the committee or where a vote of no confidence is passed against him or her by the members of the committee."

Justification
To provide for circumstances under which a chairperson loses his or her seat.

Clause 9(8)
Substitute for the words "*on recommendation of the Competent Authority" appearing in line two,* the words "*in consultation with the Minister responsible for finance*".

Justification
To provide for the involvement of the Minister responsible for finance in determining the remuneration of the members of the committee.

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CLAUSE 12 Registrar of biotechnology and biosafety.

Delete the entire clause.

Justification

Consequential amendment arising from the amendment of clause 6.

CLAUSE 13 Functions of a Registrar

Delete the entire clause.

Justification

Consequential amendment arising from the amendment of clause 12.

CLAUSE 16 Stages of Research.

Clause 16(2)b)

Delete the word **'and'** appearing after the word testing.

Justification

For continuity of the provision

Insertion of a new paragraph

Insert immediately after paragraph (c) the following:

"Contained use"

Justification

To provide for contained use as a stage of Gmo research and development.

CLAUSE 17 Approval for each stage of research

Clause 17 (a)

Insert immediately after the word 'from' appearing in line one, the words "*the competent Authority through*"

Justification

To ensure the involvement of the Competent Authority in the approval of laboratory experiements.

Clause 17 (b) (i)

Insert immediately after the word 'from' appearing in line two the words "*the competent Authority through*".

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Justification
To ensure the involvement of the Competent Authority in the approval of laboratory experiements.

Insertion of two new paragraphs
Insert two new paragraphs under clause 17 as follows-

"in case of contained use, from the competent Authority"

"in case of social environmental impact assessment from the National Environment Management Authority."

Justification
To provide for socio-environmental impact assessment report to be presented before approval to grant research can be given

Insertion of a new sub clause
Insert a new sub-clause under clause 7 as follows:
"The Competent Authority shall, before the approval of any stage of research, ensure that an indigenous seed variety is preserved in the National Gene Bank."

Justification
To provide for safe keeping and securing of indegeneous seed varieties.

CLAUSE 18. Approval of export, import or transit of a GMO
Clause 18 (2)
Substitute for the entire sub-clause, the following-
"A person who contravenes this section commits an offence and is liable upon convinction to a fine not exceeding two hundred and forty currency points or imprisonment not exceeding ten years ~~of years~~ or both.

Justification
To make the provision more deterrent.

CLAUSE 19 Laboratory Experiment
Insertion of new sub-clause
Insert a new sub-clause immediately after sub-clause (1) to read as follows:

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" (2) A person who is not attached to any research institution, and wishes to engage in a GMO laboratory experiment shall before commencing research, notify an institutional biosafety committee of his/her choice".

Justification
To create an avenue for private scientists to carry out research

Clause 19 (3), (4) and (5)
Insertion of two new sub-clauses
Insert two new sub-clauses immediately after sub-clause 3 to read as follows:
"(4) The Competent Authority shall upon receipt of the notification, publish the notification in a news paper of wide circulation requesting for public views."

Justification
To enhance public participation in the development of modern biotechnology

"(*5) The public shall send their written views to the Competent Authority within a period not exceeding fourteen days from the time of publication of the notice."*

Justification
To provide a time frame within which the public shall respond to the published notification.

Rephrase and re-number sub-clauses (3), (4) and (5) to read as follows:

(7) The institutional biosafety committee shall within seven days after receipt of the notification under subsection (1) or (2), notify the Competent Authority of the application.

(8) The Competent Authority shall within thirty days after receipt of the notice in subsection (3) give directions to the institutional biosafety committee regarding the notification for research.

(9) The institutional biosafety committee shall within twenty one working days of receiving the directions, respond to the person who notified the institutional biosafety

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committee under subsection (1), informing the person whether to proceed or not to proceed with the experiment.

Justification
For proper chronological order.

Clause 19 (6)
Insert the word '*biosafety*' between the words 'institutional' and 'committee' appearing in line one of sub-clause (6) and renumber the sub-clause as (8).

Justification
For consistence with its usage in the Bill.

Clause 19 (7)
Substitute for the words "*the institutional biosafety committee shall be taken to have approved the experiment*" appearing in line three of sub-clause (7) with the words "*the person shall apply directly to the competent Authority*" and renumber the sub-clause as (9).

Justification
To avoid abuse.

Insertion of a new sub-clause
Insert a new paragraph to read as follows:
The public shall send their written views to the Competent Authority within a period not exceeding fourteen days from the time of publication of the notice

Justification
To provide a time frame within which the public shall respond to the published notification

CLAUSE 20 Application for Approval to conduct Contained Testing of a Gmo
Clause 20 (1)
Insert immediately before the word '*institutional*' appearing in line three the words "*the Competent Authority through*".

Justification
To ensure involvement of the Competent Authority in the process of approval.

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Clause 20 (7)

Substitute for the words "the committee shall be taken to have approved the contained tesing" with the words "*the person shall apply to the Competent Authority*"

Justification

To ensure involvement of the Competent Authority in the approval process.

CLAUSE 22 Application for Approval for General Release of a Gmo

Clause 22 (3) (b)

Insert the words "*a newspaper of wide circulation*" immediately after the word 'Gazette' appearing in line one.

Justification

To ensure that the public receives sufficient notice.

Clause 22 (4)

Rephrase sub-clause (4) to read as follows:

"A ministry or agency of Government to which a notice is sent under subsection (3) or any other person shall, within forty-five days from the receipt of the notice or date of publication of the notice, make a presentation to the Competent Authority in respect of the application."

Justification

To make the provision mandatory and to provide for more time within which the agency or ministry should make a presentation.

Clause 23 Application for import, transit or export of a Gmo

Clause 23 (2) (b)

Insert a new sub-paragraph immediately after sub-paragraph (iii) to read as follows-

"A report from a relevant government ministry, department or agency indicating that the product intended for import is necessary for use in Uganda; and that there is no alternative non-GMO material or product readily available."

Justification

To protect the country from dumping of Gmos and Gmo products.

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CLAUSE 24 Review of Applications by National Biosafety Committee

Clause 24 (2) (b)

Substitute for the words 'two hundred and seventy', the words 'one hundred and twenty'.

Justification

To reduce the time within which to consider an application for general release of a GMO.

Clause 24 (3) (a)

New insertion

Insert two new sub-clauses immediately after sub-clause (3) to read as follows:

"4. The National Biosafety Committee may request for more time within which to review the application from the competent Authority; and where approved, the applicant shall be notified accordingly by the committee."

"5. The Competent Authority may extend the period requested for in sub paragraph 3 (i) for period not exceeding 14 working days."

Justification:

Review of application for imports requires more time to avoid dangerous materials from being brought into the country.

CLAUSE 25 Expedited Review of Applications

Delete the entire clause.

Justification

To avoid manipulation of the applications review process.

CLAUSE 26 Conditional Approval

Delete the entire provision.

Justification

To avoid abuse of the approval process

CLAUSE 28 Order to stop Gmo activities.

Substitute for clause 28 the following;

"Order to stop a GMO activity or destroy a GMO

(1) The Competent Authority may, in addition to stopping a GMO activity, order for the confiscation or destruction of a GMO or a GMO product where –

a) human or environmental safety is compromised

b) a person is conducting a GMO activity without or beyond approval; or

c) additional scientific or technical information relating to the adverse effect of the GMO activity, GMO or GMO product has become available

(2) A person carrying out a GMO activity shall bear the cost of stopping the GMO activity, destroying a GMO or a GMO product under this section.

Justification

To provide for the destruction of GMO and the responsibility of the cost of destroying a GMO.

Insertion of a new clause

Insert a new clause immediately after clause 28 as follows:

"Labelling of a GMO or a GMO product

(1) A person involved in the research, development, general release, importation, transit, exportation of a GMO or a GMO product shall ensure that the GMO or GMO product is conspicuously labelled inconformity with any regulation made by the minister

(2) A place where an activity involving a GMO or a GMO product is carried out shall be conspicuously labelled by the applicant or person to whom approval is given to carry out a GMO activity, indicating the activity being carried out.

(3) A person who contravenes this section commits an offence and shall upon conviction be liable to a fine not exceeding one thousand currency points or six years of imprisonment or both."

Justification

To provide for labelling.

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CLAUSE 30 Unintentional release and emergency measures

Clause 30 (2)

Insert the words ***"in writing"*** immediately after the word "Authority" appearing in line three.

Justification

To provide a formal way of informing the Competent Authority about unintentional release.

Insertion of a new sub-clause

Insert a new sub-clause immediately after sub clause (2) to read as follows:

"The applicant shall take appropriate measures to migitate the risks arising out of the unintentional release of a GMO."

Justification

To ensure that the applicant takes precautionary measures to alleviate an unintentional release of a GMO.

Clause 30 (3)

Rephrase sub clause (3) as follows:

The Competent Authority shall ensure that appropriate measures are taken by the applicant or a person to whom approval is given under this act to mitigate the risk arising out of the unintentional release of a GMO within twenty four hours upon receipt of this information.

Justification

To ensure that mitigation measures are taken as soon as the unintentional release happens.

Insertion of three new sub-clauses

Insert three new sub-clauses immediately after sub-clause (3) as follows-

"4. For purposes of this section, an application for approval under this Act shall be accompanied by evidence of availability of mitigation funds in case of unintentional release."

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"5. The applicant or person to whom approval is given shall bear the cost of mitigation under this provision."

"6. A person who contravenes this section commits an offence and shall upon conviction be liable to a fine not exceeding one thousand Currency Points or six (6) years imprisonment or both."

Justification

To oblige the person who is carrying out a Gmo related activity to make good the damage caused under unintentional release.

CLAUSE 31 Restoration Order

Clause 31 (1)

Substitute for the word *'may'* appearing in line one the word *'shall'*.

Justification

To make the provision mandatory

Clause 31 (2) (b)

Delete the expression 'taken by an authorized person' appearing in line four.

Justification

To avoid ambiguity since the authorized person would be working on behalf of the Authority.

Insertion of a new sub clause

Insert a new sub-clause immediately after sub-clasue (2) to read as follows:

'A person who contravenes this section commits an offence and is liable upon conviction to a fine not exceeding one thousand currency points or imprisonment not exceeding six years or both.'

Justification

To provide for a penalty

CLAUSE 32 Contents Of A Restoration Order

Clause 32 (c)

Delete the words *'or such further period as may be prescribed in the Order'* appearing in lines two and three.

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Justification
To prescribe strict a time line within which a restoration order shall be effected.

Clause 32 (d)
Delete the paragraph

Justification
It is redandunt

CLAUSE 34 Appointment of Inspectors
Clause 34 (1)
Substitute for the word "may" the word "shall".

Justification
To make the provision mandatory.

CLAUSE 35 Powers of an Inspector
Clause 35 (1)
Delete the expression 'subject to sub section (2)' appearing at the beginning of the provision.

Justification
It is redundant.

Clause 35 (1) (a)
Insert the phrase 'Gmo material' between the words 'information' and "or" appearing in line two.

Justification
To broaden the provision.

Clause 35 (3)
Insert the phrase 'Gmo material' between the word 'information' and 'document' appearing in line one.

Justification
To broaden the provision.

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CLAUSE 37 Offences and Penalties

Clause 37 (a)

Increase the currency points to 'two hundred and forty' and the term of imprisonment to 'ten years'.

Justification

To make the provision more deterrent.

Clause 37 (c)

Increase the currency points to 'ninety six' and the term of imprisonment to 'four years'.

Justification

To make the provision more deterrent.

Clause 37 (e)

Increase the currency points to 'forty eight' and the term of imprisonment to 'two years'.

Justification

To make the provision deterrent.

Clause 37 (f)

Substitute for subclause (f) the following;

"uses a GMO to deliberately harm or injure the environment or human health commits an offence and is liable on convinction to life imprisonment."

Justification

To make the provision deterrent.

Clause 37 (g)

Reduce the currency points to twelve and the imprisonment period to a period not exceeding six (6) months.

Clause 37 (h)

Substitute for paragraph (h) the following;

"(h) Introduces a terminator seed, or a gene that is genetically modified or engineered to make any offspring of a crop sterile, or unable to reproduce or uses genetic use restriction technology; commits an offence and is liable on conviction to a fine not exceeding five hundred currency points or imprisonment not exceeding seven years or both."

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Hon. Kafeero Ssekitoleko	
Hon. Bwino Kyakulaga	
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Justification

To provide for a penalty against any one who may introduce a terminator gene.

CLAUSE 38 Offences by a Corporate Body

Clause 38 (a)

Substitute for the word 'and' appearing in the first line, the word 'or'.

Justification

To ensure that the provision caters for a circumstances where liability may arise from either the director or the officer and not necessarily both.

CLAUSE 39 Protection of Confidential Business Information

Clause 39 (2) (d)

Delete the words 'as well as information on which the Competent Authority and the applicant disagree as to its confidentiality' appearing from lines four to six.

Justification

The Competent Authority should be left with the discretion to determine which information should be kept confidential.

CLAUSE 40 Protection from Personal Liability

Amend the clause by deleting the word 'council' from the sentence.

Justification

Consequential amendment following the amendment of clause 6

CLAUSE 42 Transitional Provisions

Substitute for the entire clause as follows:

"Any approval granted by the Uganda National Council for Science and Technology for research of a GMO before commencement of this Act shall be subject to review by the Competent Authority."

Justification

To provide for review of the approvals given by the Uganda National Council for Science and Technology under this Act.

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Hon. Kafeero Ssekitoleko	
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CLAUSE 44 Regulations
Clause 44 (2) (c)
Insert the words *'labelling'* between words *'identification'* and *'and packaging'*

Justification
To allow the Competent Authority and Minister to develop detailed procedures and guidelines on how to label different products from different genetically modified organisms (GMOs) under specific marketing, distribution, and use systems.

Clause 44(2)(e)
Substitute for paragraph (e) the following-
"(e) Specifying the safety levels and standards for safety of Gmo's and Gmo products on the recommendation of the National Bureau of Standards."

Justification
To provide for the role of the National Standards Council to prescribe safety levels and standards for a GMO or a GMO product.

Clause 44 (2) (g)
Delete the words 'not exceeding a fine of forty eight currency points or imprisonment not exceeding twenty four months or both'

Justification
To allow the Minister exercise discretionary powers depending on the circumstances of each case.

SCHEDULE 2
Paragraph 4 Power to co-opt
Insert a new sub-paragraph (3) immediately after sub-paragraph (2) to read as follows:
"(3) The Committee may recommend to the Competent Authority the appointment of any additional members of the committee as may be required from time to time."

Justification
To provide for appointment of necessary additional members to the Committee.

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SCHEDULE 3, FORM 1
Part A: Particulars of the Applicant
Insert immediately after paragraph 1, the following;
2. Nationality
3. Qualification"

Justification
To obtain detailed particulars.

Paragraph11
Rephrase the entire paragraph to read as follows;
"11. Name, nationality and addresses of persons proposed to be involved in the research activities"

Justification
For specificity and to obtain detailed particulars of the person involved in research.

Schedule 3, Form 3
Paragraph 7.1
Substitute for the word 'livestock', the word 'animal'.

Justification
To make the provision more encompassing by including livestock.

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Hon. Awor Betty Engola	
Hon. Babirye Kabanda	
Hon. Biyika Lawrence	
Hon. Burundo Alex	
Hon. Elotu Cosmas	
Hon. Gafabusa Richard	
Hon. Kahunde Hellen	
Hon. Kamusiime Innocent	
Hon. Katusabe Atkins	
Hon. Macho Geoffrey	
Hon. Mafabi Ishma	
Hon. Mayoga Florence	
Hon. Mutebi D Ronnie	
Hon. Mutonyi Rose	
Hon. Mwine Mpaka	
Hon. Nakate Lillian	
Hon. Namujju Cissy D	
Hon. Ngabirano Charles	
Hon. Nyakecho Annet	
Hon. Obua D. Hamson	
Hon. Oguzu Lee Denis	
Hon. Sabiiti Denis	
Hon. Sematimba Peter	
Hon. Ssemmuli Anthony	
Hon. Timuziga Micheal	
Hon. Waira Majegere	
Hon. Waluswaka James	

MEMBERS OF THE COMMITTEE ON SCIENCE AND TECHNOLOGY WHO CONSENTED TO THE REPORT ON THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL, 2012

S/N	Name(s)	Signature
1.	**Hon. Kafeero Ssekitoleko Robert**	
2.	**Hon. Bwino Fred Kyakulaga V/CP**	
3.	Hon. Abacanon Angiro Charles Gutomoi	
4.	Hon. Amule Ruth Doreen	
5.	Hon. Anywarach Joshua Carter	
6.	Hon. Atuhaire Jacklet	
7.	Hon. Awor Betty Engola	
8.	Hon. Babirye Mary Kabanda	
9.	Hon. Biyika Lawrence Sango	
10.	Hon. Burundo Musingo Alex	
11.	Hon. Elotu Cosmas	
12.	Hon. Gafabusa Richard Muhumuza	
13.	Hon. Kahunde Helen	
14.	Hon. Kamusiime Innocent Pentagon	
15.	Hon. Katusabe Godfrey Atkins	
16.	Hon. Macho Geoffrey	
17.	Hon. Mafabi Ishma	
18.	Hon. Mayoga Nambozo Wamala Florence	
19.	Hon. Mutebi David Ronnie	
20.	Hon. Mutonyi Rose Masaaba	
21.	Hon. Mwine Rwamirama Mpaka	
22.	Hon. Nakate Lillian Segujja	
23.	Hon. Namujju Cissy Dionizia	
24.	Hon. Ngabirano Charles	
25.	Hon. Nyakecho Annet	
26.	Hon. Obua Denis Hamson	
27.	Hon. Oguzu Lee Denis	
28.	Hon. Sabiiti Denis	
29.	Hon. Ssematimba Peter Simon	
30.	Hon. Ssemmuli Anthony	
31.	Hon. Timuziga Kamugisha Micheal	
32.	Hon. Waira Kyewalabye Majegere	
33.	Hon. Waluswaka James	

APPENDIX A

STAKEHOLDERS WITH WHOM THE COMMITTEE INTERRACTED

1. The Rt. Hon. Prime Minister/Leader of Government Business, Ruhakana Rugunda
2. Prof. Celestino Obua- Chancellor, Mbarara University of Science and Technology (MUST)
3. Dr. Elioda Tumwesigye- Minister of Science, Technology and Innovation (MoSTI)
4. Dr. Maxiwel Otim Onapa- Deputy Executive Secretary/Uganda National Council for Science and Technology (UNCST)
5. Mr. Obong David- Permanent Secretary/MoSTI)
6. Ms. Irene Wanganya- Food Safety Coordinator/National Drug Authority (NDA)
7. Mr. Mark Kamanzi- Head of Legal Services/NDA
8. Mr. Senkungu Ismail- Technical Rep./Pharmaceutical Society of Uganda
9. Ms. Debora Wendiro- Head of Department of Microbiology/Uganda Industrial Research Institute
10. Mr. Eric Lerner Kagezi- Senior Prog. Asst/Uganda Biotechnology and Biosafety Consortium
11. Ms. Lonyo G. Ocheng Prospero- Coordinator/Uganda Biotechnology and Biosafety Consortium
12. Ms. Patricia Bageine Esalu-Deputy Executive Director/Uganda National Bureau of Standards (UNBS)
13. Ms. Hellen Wenene- Legal Counsel/Uganda National Bureau of Standards (UNBS)
14. Ms. Jacqueline Uwesya- Head of Microbiology Division/Uganda National Bureau of Standards (UNBS)
15. Dr. Fred Bisso- President/Uganda Medical Association (UMA)
16. Dr. Oundo Christopher - Vice President/Uganda Medical Association
17. Dr. Joseph Okia- Technical Adviser/Uganda Medical Association
18. Dr. Ambrose Agona- Director Genral/National Agricultural Research Organisation (NARO)
19. Dr. Titus Alicia- Principal Res. Officer/NARO
20. Dr. Andrew Kiggundu- Sen. Res. Officer/NARO
21. Dr. Geoffrey Alinaitwe- Principal Res. Officer/NARO
22. Mr. Ekoot Benjamin- Deputy CEO/Uganda and Tropical Institute of Development Innovations- (TRIDI)

23. Mr. Clet Wadui Masiga- Principal/TRIDI
24. Mr. Gimeyi Paul- Accounts Officer/ TRIDI
25. Mr. Sabunyo Noah- Social Worker/TRIDI
26. Mr. Kigongo Richard- Agricultural Ext. Worker/TRID
27. Mr. Ouma Geoffrey- Farmer/TRIDI
28. Mr. Kiboma Micheal- Farmer/TRIDI
29. Mr. Mirimu Hannington- Farmer/TRIDI
30. Dr. Sebastian Rwengabo- Research Fellow/Advocates Coalition for Development and Environment (ACODE)
31. Ms. Barbra Ntabirwehi- Research fellow/Advocates Coalition for Development and Environment (ACODE)
32. Ms. Marilyn Kabalere- Advocacy Officer/CAPCA (Central Archdiocesan Province Caritas Association)
33. Ms. Kemigisa Divine- Prog. Officer/Southern and Eastern Africa Trade Information and Negotiations Institute (SEATIN)
34. Ms. Harriet Ndagire Ssempebwa- Vice Chairperson/PELUM & Member of KULIKA Uganda/PELUM Uganda Board
35. Ms. Hellen N. Kasujja- Deputy Executive Director/CIDI (Community Integrated Development Initiatives)
36. Mr. Sifuna Daniel - Administrative Asst/Agency for Cooperation and Research in Development (ACORD)
37. Ms. Dinah Tumukunde- Ag. Head of Research/Joint Clinical Research centre (JCRC)
38. Dr. Cissy Kityo- Deputy Executive Director/JCRC
39. Dr. Francis Ssali- Director/Clinical Services/JCRC
40. Mr. Jonathan Kayondo- Senior Research Officer/Uganda Virus Research Institute (UVRI)
41. Dr. Louis G. Mukwaya - Technical Advisor/UVRI
42. Mr. Mako Musagara- Administrator/UVRI
43. Mr. Lawrence Kamuhanda- Librarian/Mbarara University of Science and Technology (MUST)
44. Ms. Judith Owokulinansa – Micro Biology Post graduate student/MUST
45. Mr. Asaph katarangi Kaburura- Lecturer/MUST
46. Dr. Dr. Tumulimbise Namasseh – Lecturer/MUST
47. Dr. Jack Bazira - Sen. Lecturer/MUST
48. Ms. Peace Mbabazi- University Secretary / MUST
49. Samuel Malang- Dean-FOM/MUST
50. Mr. Ahimbisibwe B. Frank- Lecturer/MUST
51. Prof. C. Tushabomwe Kazooba- MUST
52. Prof. Nixon Kamukama- DVC(F&A)/MUST
53. Eng. Patrick Mujunansi- Univ. Engineer/MUST
54. Dr. Cleophas Karooma- Senior Lecturer/IIIR-MUST
55. Dr. Eunice A. Olet- Ag. Dean FOS/MUST
56. Sr. Dr. Jane Yatulm- Ag. HoD Biology/ MUST-Faculty of Science
57. Dr. Imelda Kimeza - Senior Lecturer Psychology/MUST

58. Mr. Jerome Kabakyenga- Professor/Director MUST-MNCHI/FOM
59. Ms. Robina F. Nakakeeto- Deputy Sec.(Planning)/MUST Planning
60. Mr. Wasswa William- Ag. Dean FAST/MUST FAST
61. Mr. Tumuhimbise Angella Senior CBEF/ MUST CHD
62. Mr. Richard Onyuth Apecu- HoD-Med.Lab.Sciences/ MUST-FOM
63. Dr. Dhikusoka Tefula Moses- Livestock Resarch Officer/ NARO-MBARZARDI
64. Mr. Twinomuhangi Teage- HR/AO/ NARO-MBAZARDI
65. Mr. Muhindo Geoffrey- Finance Officer/ NARO-MBAZARDI
66. Mr. Bukenya Pison- Sen. Accounts Asst/ NARO-MBAZARDI
67. Mr. Kalaali Daniel- Asst. Procurement Officer/ NARO-Mbarara
68. Mr. John Sendawula- SLM Specialist/ MAAIF-MBAZARDI
69. Mr. Aturinda Amos Wentow- Agronomist/ NARO-MBAZARDI
70. Mr. Kalungi Fatumah- Admin. Asst./ NARO-Mbarara
71. Mr. Nakyajja H. Grace- Accounts Asst./ NARO-Mbarara
72. Mr. Muhumuza John Bosco- Crop Entomologist/ MBAZARDI
73. Mr. Muzira Robert- Soil Scientist/ MBAZARDI
74. Mr. Aheisibwe Ambrose Rwaheru- Research Officer/SOCI-Econ/ NARO-KACHWEKANO ZARDI
75. Mr. Paplius Dias Tibiilika- Research Officer/ NARO KACHWEKANO ZARDI
76. Ms. Orikiriza Sheila- Research Asst./ NARO-KAZARDI
77. Ms. Anne Kabeshongore- Administrative Assistant/ NARO-KACHWEKANO ZARDI
78. Ms. Najjuma Faith- Accts. Asst./ NARO-KAZARDI
79. Mr. Nkoyoyo George- Research Assistant/ NARO-KAZARDI
80. Mr. Rweigyema Hirary- Farmer
81. Mr. Tumwesigye John Bosco-
82. Ms. Maureen Turyashemererwa- Crop Technician/ NARO-KAZARDI
83. Ms. Birungi Dismus- Driver/ NARO-KAZARDI
84. Mr. Nzeirwe Dennis- D/RDC/ Kabale District
85. Baguma Gerald- Research Asst /KAZARDI
86. Mr. Arinaitwe Abel- Research Scientist/ KAZARDI
87. Mr. Karugaba John- Seed Producer/farmer
88. Mr. John Bahizi- Seed Multiplier
89. Mr. Charles Byarugaba- Director CKB/ Clean & Quality Seed Potato Prod. Enterprise
90. Mr. Baryahisahe Nathan- Seed Potato Producer/ Rubanda District
91. Mr. Gumisiriza Christopher- Seed Potato Multiplier
92. Mr. Kellen Kisiizi- Seed Producer/ Bukinda-UNSPPA
93. Mr. Ayesigye Henly- Seed Multiplier/ KAHARO-UNSPAA
94. Mr. Mutambi William- Seed Potato Producer/ Chairman-UNSPPA
95. Mr. Mugarura Edmund- Production Specialist/ IFDC
96. Mr. Kukundakwe Norman- Field Officer
97. Mr. Rubaramira Kenneth- Farmer
98. Dr. Brenda Kirundgi Katali- Research Scientist
99. Mr. Mbabazi Kanansio Kakohoso- Broadcast Journalist

100. Mr. Nshabire Orald- Procurement Asst./ KAZARDI
101. Mr. Kyooma John- Research Asst./ KAZARDI
102. Mr. Muhereze Ronald- Research Asst./ KAZARDI
103. Mr. Agaba Dennis- Chairperson NYauburugurukire I
104. Owembabazi Shaina- Research Asst./ KAZARDI
105. Kasirye Joseph- Finance Officer/ KAZARDI
106. Alfred Byanyima- Farmer/Rubanda District
107. Kembabazi Maryvian- KAZARDI/ Lab Technician
108. Gerald Kwikiriza- Fisheries Aquaculture Scientist/ Kachenkano-ZARDI
109. Arinda Osbert- Research Asst./ Kachenkano-ZARDI
110. Kobusingye Evas- Lab Technician/ Kachenkano-ZARDI
111. Etiang Joseph- Soil Fertility Scientist/Kachenkano-ZARDI
112. Mateeka Benon- Tissue Culture Lab/KAZARDI
113. Eric Magembe- CIP/ Scientist
114. Dr. Andrew Kiggundu- Senior Research Officer/ NARL, Kawanda
115. Gard Turyamureeba- Senior Research Officer/ NARO-Kachwenkano ZARDI
*116. Hon. Fredrick Gume Ngobi- Minister for Cooperatives/Ministry of Trade, Tourism and Industry
117. Hon. Dr. Jane Ruth Aceng- Minister of Health
118. Mr. Ahimbisibwe Stanley- Ag. Commissioner/Trade-Ministry of Trade, Tourism and Industry
119. Mr. Atek Kagirita - NB Coordinator/Ministry of Health
120. Mr. Steven Aisu - Head Public Health Lab/Ministry of Health
*121. Hon. Fredrick Gume Ngobi- Minister for Cooperatives/Ministry of Trade, Tourism and Industry
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124. Mr. Atek Kagirita - NB Coordinator/Ministry of Health
125. Mr. Steven Aisu - Head Public Health Lab/Ministry of Health
126. Mr. Kawoya Fredrick - Manager, Policy Advocacy and campaigns/Action Aid Uganda
127. Ms. Jenipher Achaloi - Project Cordinator/Lecturer (Action Aid Uganda)
128. Dr. Olupot Giregon - Lecturer/College of Agricultural Environmental Sciences- Makerere University
129. Dr. Okurut Tom - Executive Director/NEMA

130. Mr. Francis Ogwal - Natural Resources Manager/NEMA

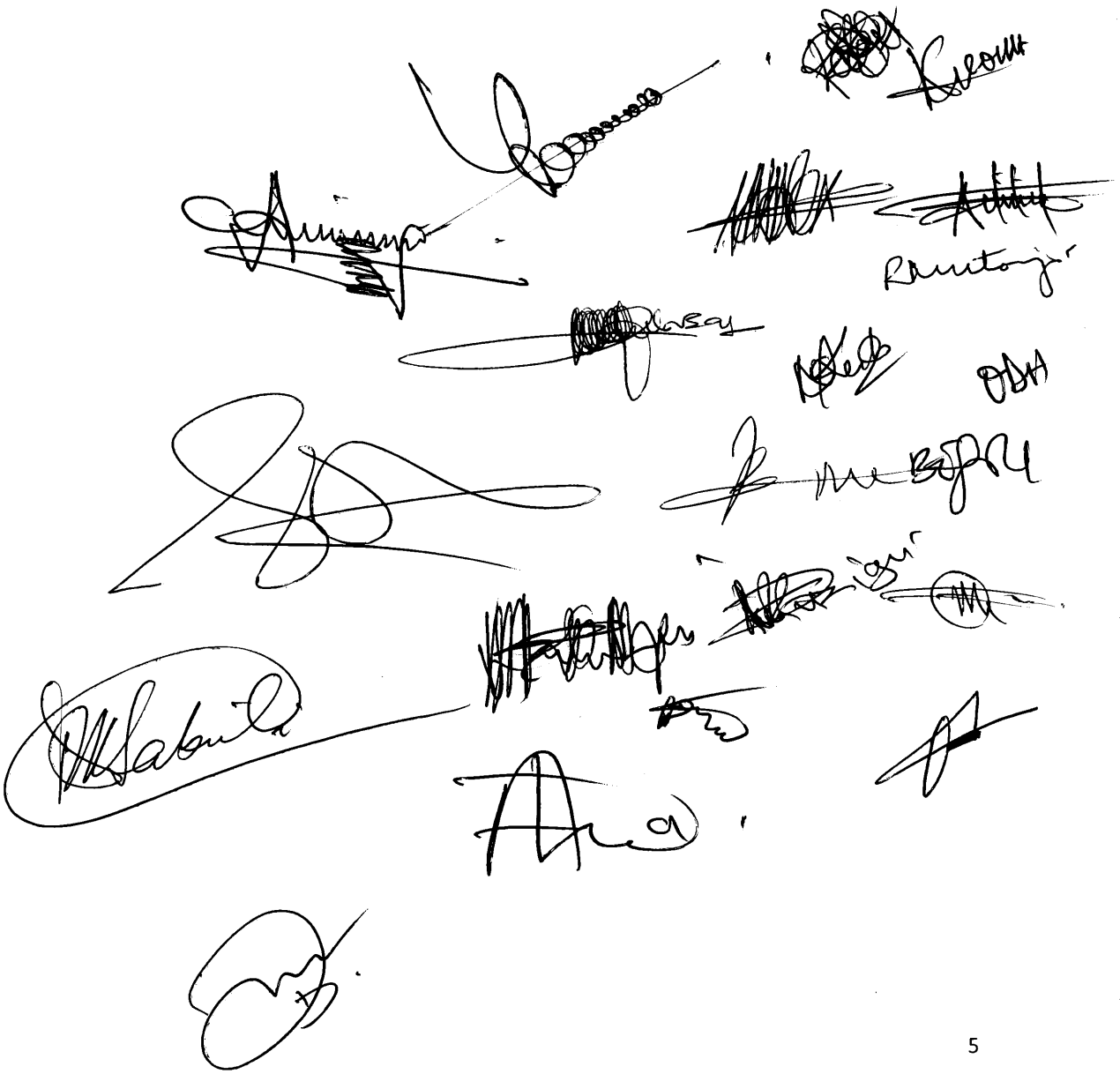
131. Mr. Silas Obukosia - Program & Legal Officer/ABNE-NEPAD

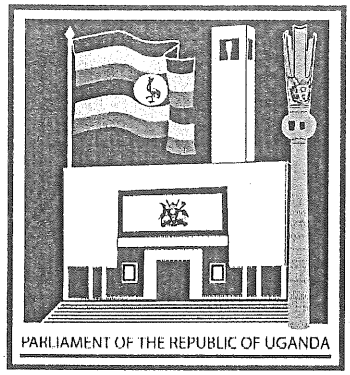
132. Mr. Woldeyesu Sinebo - Programme Officer/ABNE-NEPAD

133. Mr. Owachi William Godwins -Finance & Administration Manager/CDO

134. Dr. Serunjogi Lastus K. - Technical Advisor/CDO

135. Mr. Lugojja Fred - Information and Monitoring officer/CDO





PARLIAMENT OF UGANDA

A MINORITY REPORT ON
REPORT OF THE COMMITTEE ON SCIENCE AND TECHNOLOGY
ON THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL, 2012

JUNE 2017

1.0 INTRODUCTION

Technology is evolving at a very fast rate in a number of spheres. Technological advancements such as biotechnology are premised on mastery of nature and knowledge so as to develop products that are unique in composition and usability. However given its immense claimed benefits and adverse effects, there is need for wide public involvement, consciousness consideration and regulation.

In a bid to provide a regulatory framework on biotechnology, a National Biotechnology and Biosafety Bill 2012 was tabled in Parliament, scrutinised and a report generated by the Committee on Science and Technology.

Pursuant to Rule 194 of the Rules of Procedure of the Parliament of Uganda, I hereby present a dissenting opinion from the opinion of a majority of the Committee on Science and Technology.

2.0 AREA OF DISSENT

I dissented with the majority of the Committee regarding the recommendation to approve the Bill with amendments on the following grounds:

1) Inadequate Public Consultation
2) Lack of Impact Assessment
3) Incomprehensiveness of the Bill
4) Inadequate Bioethical Considerations
5) Substantial Modification of the Bill
6) Inadequacy of Certificate of Financial Implication
7) Risk of External Influence
8) Misleading Amendments
9) Expeditious Approval of the Bill

3.0 DISSENTING OBSERVATIONS

3.1 Inadequate Public Consultation

Although the Committee noted in its report under section 4.2 that "*there was inadequate public awareness and participation of the general public about the introduction of GMOs and biosafety*", the majority of the Committee recommended in contravention of the provisions of the Constitution and the Cartagena Protocol on Biodiversity (CPB).

The National Objective and Directive Principle of State Policy X as enshrined in the Constitution of the Republic of Uganda stipulates that:

> *"The state shall take all necessary steps to involve the people in the formulation and implementation of development plans and programmes which affect them".*

Article 23(2) of CPB also requires that Parties (read Government of Uganda) shall in accordance with their respective laws and regulations consult the public in the decision-making process regarding living modified organisms. The cited provision further stipulates that the party (read Government of Uganda) shall make the results of such decisions available to the public while respecting confidential information in accordance with Article 21.

To the contrary, the Ministry of Science, Technology and Innovation failed to convince the Committee that the public was adequately consulted and involved in developing the Bill whose provisions would affect them.

The Committee report highlights under section 2.1(l) regarding medical biotechnology that GMOs can lead to health risks such as food allergy; antibiotic resistance; reproductive and endocrine disorders; hormone disruption; birth defects and shorter life spans; cancer; immortality of sperms; sluggishness of sperms; digestive problems; obesity; sterility; and nutritional deficiencies.

In addition, modern biotechnology is a technology under corporate control, protected by patents and other forms of intellectual property rights, and therefore contrary to farming traditions of saving and exchanging seeds[1]. In countries such as Brazil[2] that have embraced GMO foods, legal battles with the corporate GMO producers have arisen and are ongoing due to limitations in multiplications, demand for royalties and need to sign Technology License Agreements before utilisation of products. This raises a risk of affecting Ugandan farmers' culture and livelihood systems which involve seed preservation, multiplication, diversification and distribution. Farmers need readily available and affordable seeds that have no legal constraints.

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[1] Altieri, M.A., 2002.The Case Against Agricultural Biotechnology: Why Are Transgenic Crops Incompatible With Sustainable Agriculture In The Third World?

[2] In October 2013, Judge Alex Nunes Figueiredo blocked Monsanto's demands of farmers signing the agreement as a condition to buy RR2 Intacta soybeans. The judge said that Monsanto is unfairly taking advantage of its favourable position in the market as the only technology provider of RR2 Intacta, in forcing farmers to "to comply with clauses that are burdensome, if not illegal" as a condition of purchasing the product. Signing of an agreement for use of technology would allow employees of Monsanto to monitor cultivations and to enter farms to control planting, on the grounds of preventing the spread of this new technology.

Despite the effects highlighted above, the Committee did not circulate any public notice in any newspapers of wide circulation so as to invite views from any interested Ugandan or institution. For instance in the recently concluded Parliamentary Outreach in Arua district, traditional leaders, religious leaders, district leaders and community leaders raised concern about the lack of their involvement in the development, sensitisation and processing of the Bill.

Parliament as the peoples' representative is expected to fulfil its mission of being people-centred by ensuring that legislation, oversight and policy making processes entail the views of the public and address the demands of all[3].

Based on the above, the Bill should be referred back to the sponsor and people adequately involved in its development as required by the Constitution of the Republic of Uganda and Cartagena Protocol on Biodiversity. This will ensure that the Bill protects and advances the interests of the people of Uganda.

3.2 Lack of Impact Assessment

While the majority report was able to highlight under section 2.1 that biotechnology presented both benefits and costs, it does not indicate whether benefits to the country outweigh the costs.

It is best practice in Uganda that every bill is informed by Regulatory Impact Assessment (RIA). This is articulated in the *'Guide to Regulatory Impact Assessment'* published by the Cabinet Secretariat in the Office of the President. RIA is an analysis of the likely costs and benefits associated with the introduction of a new policy or law or regulation.

Contrary to the above, it should be noted that the Bill was developed and tabled without ascertaining opportunity cost to the country which should have been ascertained through RIA. Therefore government and the committee were not in position to determine whether passing of the Bill would the country more than the costs.

The Bill should be referred back to sponsor and Regulatory Impact Assessment undertaken. This will be essential in determining the Bill's

[3] Parliament of Uganda Strategic Plan 2016/17 – 2019/20 - Pg. 17

opportunity cost so as inform decision making by government and Parliament.

3.3 Incomprehensiveness of the Bill

The majority report under section 2.1 notes that the Bill only seeks to advance agricultural biotechnology while neglecting other forms of biotechnology such as industrial, environmental and medical biotechnology. The Bill places emphasis mainly on manipulation of genes to produce agricultural GMOs. Therefore the Bill is limited in scope for it does not cater for all forms of biotechnology hence its incomprehensive. The proposed amendments also do not widen the scope to holistically cater for other forms of biotechnology.

Furthermore GMOs are a subdivision of biotechnology. Unfortunately the Bill and proposed amendments are majorly relating to GMOs not biotechnology as a whole. Of the 44 clauses, 23 (52%) are regarding GMOs i.e. Clauses 15 – 37, 11 (25%) pertain structural arrangements i.e. clauses 1 – 14 while remaining 23% largely pertain preliminary and miscellaneous provisions.

The intent to introduce a Private Member's Bill to cater for other forms of biotechnology as indicated under section 2.1 points to the need to widen the scope of the Bill. It is prudent that biotechnology should not be legislated in a piecemeal manner. It should be legislated holistically and can be achieved through redrafting.

The Bill should be referred back to the sponsor and its scope widened so as to holistically cater for biotechnology.

3.4 Inadequate Bioethical Considerations

The majority report makes no reference to bioethics yet it is a core element of biotechnology as indicated in the National Biotechnology and Biosafety Policy. Bioethics stipulates what should and should not be done when developing biotechnology products.

The Policy notes that there is an apparent lack of a code of ethics in biotechnology research in Uganda. Ethical considerations in biotechnology research therefore, do not exist save for certain aspects that are addressed by the more general national guidelines on research ethics. The code of bioethics should enable the development and exploitation of biotechnology

in accordance with acceptable societal norms. This is a key factor in shaping public attitude and consumer acceptance of products of biotechnology[4].

Although the Bill under Clause 44 provides for regulations on bioethical considerations, it is so crucial that the core bioethical provisions are explicitly provided for within the bill. Issues regarding bioethics are so critical for Parliament to delegate its responsibility to a Minister. It is essential that extensive bioethical provisions are incorporated within the Bill so as to address concerns raised in National Biotechnology and Biosafety Policy.

For instance the introduction of GMOs has led to a wider debate on bioethical concerns affecting social, economic and environmental spheres. These include the effects on non-target organisms, insect resistance crops, gene flow and the loss of diversity as well as the issue on interfering with nature (such as development of human embryos or human reproductive cloning) in which the modification process itself is disrupting the natural process of biological entities. Due to this, the uncertainty of the scope and the role of bioethics need to be clearly spelled out in the legal framework. If bioethical issue is not regulated in the legal framework, it can lead to endless litigation suit[5].

The Bill should be referred back to the sponsor and its scope widened so as to incorporate provisions on bioethics.

3.5 Substantial Modification of the Bill

The majority of the Committee made over 31 (70%) amendments to the 44 clauses of the Bill which if considered will substantially modify the original Bill.

Substantial amendments were made regarding objectives (principles), creation of a new directorate responsible for biosafety as a competent authority within a new Ministry of Science, Technology and Innovation. Substantial amendments were also made on functions of a competent authority. These raise a funding gap in terms of staffing, operationalisation and enforcement.

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[4] National Biotechnology and Biosafety Policy, 2008 – Pg. 11

[5] Zaiton Hamin and Siti Hafsyah Idris, 2011. Bioethical Issues on Genetically Modified Organisms (GMOs) In Malaysia: Biting Into the Legal Protection under the Biosafety Act 2007

The Deputy Speaker, during the 1st Session of the 10th Parliament, guided the House on how to process a Bill whose clauses have been amended by over 50%. The House was guided as follows:

a) The Bill substantially loses its originality and must be ordered for reprinting because it will have become a new Bill.
b) A new bill is created if amendments are more than a half of the original bill.
c) The multitudes of amendments are a vote of no confidence in the Bill.
d) If the sponsoring ministry agrees with the amendments, it should reprint the Bill that can easily be processed by Parliament.

Substantial amendments to bills have also been prohibited in many other Commonwealth countries. The substantially amended bills are referred back to the sponsor for comprehensive reconsideration, reprinting and reintroduction in Parliament as highlighted in table 1.

Table 1: Examples of legislative practices of handling substantial amendments of a bill in selected Commonwealth Parliaments

Parliament	Action
Parliament of Rwanda	Amendments related to form are neither debated nor voted for. The Plenary Sitting may decide to return a bill to its initiator.
Parliament of South Africa	Amendments are out of order if they affect the principles (objectives) of the Bill and in respect of which the Assembly has not given any instruction.
Parliament of the Common Wealth of Australia	If such changes are more than minor or technical, the revised bill or amendments and the revised explanatory memorandum will need to be approved by the relevant minister and go through the legislation approval process again.

The Bill should be referred back to the sponsor so as to comprehensively address the gaps and reprint a revised bill for reintroduction to Parliament.

3.6 Inadequacy of Certificate of Financial Implication

The majority Committee report makes no reference to the Certificate of Financial Implication in regard to the substantial amendments. The substantial

amendments contradict the commitments made in the certificate of financial implication (see appendix 1) that was issued for the Bill in 2012.

The certificate indicated that funding and implementation of the Bill will be carried out within the already existing government policy i.e. National Biotechnology and Biosafety Policy (2008) and institutional structures i.e. Uganda National Council for Science and Technology within the medium term expenditure. This was similar to the position contained in the National Biotechnology and Biosafety Policy (2008) that informed the provisions in Clause 6 of the Bill. Therefore no new structures were to be created for the implementation of the Bill. The substantial amendment to establish a directorate responsible for biosafety within the Ministry of Science, Technology and Innovation far outstretch the initial financial commitment.

The Bill should be referred back to the sponsor and new certificate of financial implication obtained before its reconsideration by Parliament.

3.7 Risk of External Influence

The Bill and the amendments by the Committee did not address the risk of external influence. This necessitates a comprehensive Regulatory Impact Assessment to critically assess and abate the adverse risks of external influence and financial sustainability in advancing biotechnology systems.

Funding for biotechnology has remained within the confines of the already below average funding levels for science and technology. The little available funding is mainly from foreign sources with research agendas that may not necessarily reflect national priorities for development[6].

For instance, financial resources for agricultural biotechnology research in the two-year period of 2010 and 2011 were largely from philanthropic organizations (38%), intergovernmental organisations (33%), and development assistance from foreign governments (14%). Direct funding for agricultural biotechnology Research and Development from the Government of Uganda constituted 3% of the total funding received in the same period[7].

[6] National Biotechnology and Biosafety Policy, 2008 – Pg. 10 - 11

[7] Y. Baguma et al, 2013. Agricultural biotechnology Capacity in Uganda. Uganda Biotechnology and Biosafety Consortium (UBBC)

This highlights that the country's progress in biotechnology relies on donors who advance their own agenda or interests. The interests may include extending risk of GMO development away from their home countries, avoiding stringent GMO legislations in their countries of origin, advancing dependency syndrome and selfish economic interests among others. These are a threat to national sovereignty and would contravene National Objective and Directive Principle of State Policy IV (ii) as enshrined in the Constitution of the Republic of Uganda. The directive principle states that the State shall endeavour to build national strengthen in political, economic and social spheres to avoid undue dependence on other countries and institutions.

The Bill should be referred back to the sponsor and a comprehensive RIA undertaken so as to assess the risk of external influence and sustainability in advancing GMOs in Uganda. This should inform the redrafting of the Bill.

3.8 Misleading Amendments

Upon realising that the public and indeed Members of Parliament may have phobia of GMOs, in a move to ensure acceptability, majority of the Committee agreed to:

a) Amend the short title from the 'National Biotechnology and Biosafety Bill' to the 'National Biosafety Bill' without undertaking the necessary redrafting of the Bill to make deterrent provisions that match the new title. This was intended at dealing away with the word 'biotechnology' which was considered to be synonymous with GMOs; and
b) Amend references made to biotechnology so as to read modern biotechnology with the intention of depicting widened scope of biotechnology. However this still is a limited scope of biotechnology because there also exists traditional and conventional biotechnology.

It is crucial to highlight that modern biotechnology is a tool or process that results into GMOs also referred to as Living Modified Organisms. The Uganda National Council of Science and Technology (UNSCT) in its publication entitled '*Frequently Asked Questions on Agricultural Biotechnology*' under question 6(Pg.1) further clarifies that 'GMO technology is often called modern biotechnology, sometime also recombinant DNA technology or genetic engineering'. The World Health Organisation (WHO, 2014) also

provides the same clarification[8]. Based on this, it is clear that modern biotechnology is synonymous with GMOs.

The Bill should be referred back to the sponsor and people adequately involved in its development as required by the Constitution of the Republic of Uganda and Cartagena Protocol on Biodiversity. This will ensure that the Bill protects and advances the interests of the people of Uganda.

3.9 Expeditious Approval of the Bill

The majority of the Committee during committee meetings asserted that if Uganda does not approve the Bill, the country will lag behind in accessing benefits of modern biotechnology particularly GMOs. It is essential to emphasise that shared understanding and commitment by the citizens and government is a critical driver to their mobilisation, participation, empowerment and inclusive growth in the implementation of any law.

Uganda was ahead in a number of aspects such as laws, development programmes and projects. However the countries that embraced them later are now far ahead. For instance on banning of polythene bags and universal accessibility to internet, Rwanda is far ahead of Uganda yet the latter spearheaded the initiatives. This is attributed to the fact that with shared understanding of citizens and government, purpose and responsibility by all citizens, the country moves faster in implementation of any law, development programme and project.

The Bill should be referred back to the sponsor so as to undertake comprehensive public involvement as required under the National Objective and Directive Principle of State Policy X of Constitution of the Republic of Uganda. This will ensure narrowing of perception gap, building confidence, attaining shared understanding, responsibility in the development and implementation of the law on biotechnology in Uganda. Only then will Uganda supersede countries that are already implementing laws on biotechnology while drawing on their lessons.

[8] World Health Organisation (WHO), 2014. Frequently Asked Questions on Genetically Modified Foods. Website: http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/. Last accessed on 26th June 2017

4.0 CONCLUSION

Honourable Members, I implore you to support the Minority report so as to refer the Bill back to sponsor for a comprehensive Regulatory Impact Assessment, involvement of people that would be affected, financial implication reassessment and redrafting.

I BEG TO MOVE.

MEMBERS ON THE COMMITTEE ON SCIENCE AND TECHNOLOGY WHO SIGNED THE MINORITY REPORT ON THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL, 2012

S/N	NAME	Signature
01	ATKINS NATUSABE	
2.	OGUZU LILIAN DENIS	