



**RESPONSE TO THE REPORT OF THE PARLIAMENTARY
COMMITTEE ON SCIENCE AND TECHNOLOGY ON THE
BIO-TECHNOLOGY AND BIO-SAFETY BILL BY
THE MINISTER OF SCIENCE, TECHNOLOGY AND INNOVATION,
DR ELIODA TUMWESIGYE (MP)
3RD OCTOBER 2017**

RT HON SPEAKER

1.0 INTRODUCTION

Uganda's Vision 2040 envisages a transformed Country from "a predominantly Peasant to a Modern and Prosperous Country", while the Second National Development Plan (NDPII) seeks to strengthen Uganda's Competitiveness for Sustainable Wealth Creation, Employment and Inclusive Growth. Science, Technology and Innovation (STI) are essential to the achievement of the National Vision and the National Development Plan and therefore the engine for sustainable economic growth, development and transformation. STI contributes new knowledge, skills and the requisite capabilities for increased productivity and welfare improvement of the population. The strategic role of scientific innovation in uplifting other sectors of the economy such as Agriculture, Industry, Health, Energy, Education, Environment, and services and enhancing technological development, has been vividly highlighted in the 5-year National Development Plans [NDP II: 2016/17 – 2019/20], the NRM manifesto, the 23 Presidential Strategic guidelines, the National Science, Technology and Innovation Policy (2009), Innovation Strategy for Africa (STISA 2024) and Sustainable Development Goals (Agenda 2030) and the recently adopted Paris agreement on Climate change.

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Science, technology, engineering and innovation (STEI) are vital for achieving Uganda's transition to a middle-income status and knowledge-based society. As Uganda aspires for faster sustainable and inclusive growth, the STEI ecosystem with the advantages of a large demographic dividend and the huge talent pool will need to play a defining role in achieving the national vision. The STEI ecosystem must thus become central in the national development process.

New structural mechanisms and models may be needed and the strengthening of the STEI eco-system is indispensable for solving pressing societal challenges which include among others:

- (i) Hunger and Malnutrition,
- (ii) Limited access to quality health services for all at all ages,
- (iii) Poverty (need increased employment generation and wealth creation),
- (iv) Environmental and climate change effects,
- (v) Limited access to clean and sustainable energy,
- (vi) Inadequate access to quality education (lack of knowledge and skills)
- (vii) Limited access to safe water and sanitation.

Uganda has a total surface area of 241,550.7 square Km out of which 200,523.2 Square KMs is land and 41,027 square KMs are open water bodies. Approximately 72% of our land (144,374 square KMs) is arable and out of this only 63% (91,151 square KM) is under farming but this also threatened by climate change with a possibility of desertification in some areas. Our population is now approaching 40M, in 2020 it is projected at 41.5M, in 2030 at 56.9M, and by 2040, it will 75.6 M and will reach 101.8M by 2050. An estimated 70% of our population is below the age of 30. We need to apply science, technology & innovation to solve the above societal challenges including harnessing Uganda's agricultural potential to feed, give jobs and generate wealth for this largely young population.

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2.0 BACKGORUND

As Colleagues as mentioned above, Science, Technology and Innovation (S T & I) are the drivers of socio-economic growth and transformation the world over. Science, Technology and Innovation development is an important determinant of progress and transition from pre-industrial to innovation led and knowledge-based societies. The National Development Plan II (NDP II) (Page 197) recognises Science, Technology and Innovation as a critical avenue for economic development. Therefore, the extent to which a country has harnessed Science, Technology and Innovation has a direct bearing on its level of development. Bio-technology is one of the elements of the Science, Technology and Innovation (STI) Eco-system. Biotechnology refers to any technique that uses living organisms or substances from living organisms to make or modify a product, improve plant, animal breeds or micro-organisms for specific purposes. Biosafety on the other hand means the safe development, transfer, application and utilization of biotechnology and its products.

- 2.1 Biotechnology has been used in Uganda for many years to process wine and beer, in the production of cheese and yoghurt, leavening bread and extraction of cobalt. Biotechnology has therefore been variously applied in health sector, industrial sector, agriculture, and environmental management. However Modern biotechnology which involves the use of genetic engineering techniques to transfer useful characteristics is relatively new yet its use creates enormous opportunities.
- 2.2. Bio-technology, if well exploited can: reduce diseases on crop, livestock and forest resources, improve food and nutrition security, improve health delivery, protect the environment and spur national economic development. The potential of biotechnology as one of the scientific tools for economic transformation is further underscored in the second National Development Plan (NDP II) 2015/16 – 2019/20.
- 2.3 Colleagues, will recall that in its efforts to enhance its Science, Technology and Innovation agenda, the country adopted its National Bio-technology and Biosafety Policy in April 2008. The Policy provides a framework for a safe application of bio-technology in order to contribute to Uganda's economic growth and transformation. The Policy further provides for the



enactment of a law to provide a regulatory framework for the safe development and application of Bio-technology.

3.0 PROBLEM STATEMENT

3.1. As Colleagues are aware, Uganda is persistently faced with intractable challenges in its agricultural, health, environmental and industrial sectors among others. These challenges include inter-alia:-

- (i). Crop diseases such as banana bacterial wilt, cassava brown streak virus, potato blight, coffee wilt, and Maize Lethal Necrosis Disease (MLND);
- (ii). Animal diseases like tick borne diseases (FMDI) (Trypanosomiasis Nagana);
- (iii). Unpredictable weather and drought occasioned by climate change;
- (iv). Environmental waste management including management of municipal waste and industrial effluence; and
- (v). Emerging and re-merging diseases

3.2. The Potential for utilization of agricultural technological innovations, such as modern bio-technology, to spur economic and social development was recognized by the global community way back in 1992. Agenda 21, the action program of the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro, noted that modern biotechnology 'promises to make significant contribution in enabling the development of, among other things, enhanced food security through sustainable agricultural practices'. In line with UNCED, the African Union (AU) High-Level African Panel on Biotechnology in its report of August 2007 recommended: "Agricultural biotechnology holds the promise of improving food security and better nutrition. AU member states must invest in agricultural biotechnology to address long-term issues such as nutrient deficiency, and needed improvements to overall agricultural productivity." Bio-technology can therefore be used to address some of the challenges in Uganda's agricultural sector.

3.3. While the potential for use of bio-technology in addressing the challenges in the Agriculture Sector is recognised, there is also concern on the suitability of bio-technology especially with safety issues on the environment and human health. The concerns on the application of Bio-technology can be

objectively addressed by having in place a law that promotes and regulates the use of Bio-technology.

3.4. Colleagues may wish to note that currently, there is no specific law regulating research in, development and use of biotechnology in Uganda. The law that Uganda National Council for Science and Technology (UNCST) uses to handle the research aspects of modern biotechnology does not explicitly and exhaustively cover issues relating to regulation of modern biotechnology and mechanisms for its safe use. In order for Uganda to safely harness and benefit from the power of biotechnology, it is therefore necessary to enact a specific law on biotechnology and biosafety. It is in this context, this spirit that the government of Uganda drafted a Bill entitled the national biotechnology and biosafety bill 2012.

3.5. Colleagues may wish to note that:

- (i). The proposed law provides for regulation of all modern biotechnology activities (excluding pharmaceuticals) including; Lab and field research, import, export, transit and general use.
- (ii). Elaborate risk and safety assessment procedures are required under the proposed law.
- (iii). The proposed law mandates relevant regulatory agencies to build relevant capacity and engage the public during decision making for general use.

RESPONSES TO THE OBSERVATIONS AND RECOMMENDATIONS OF THE JUNE 2017 MAJORITY REPORT OF THE COMMITTEE OF PARLIAMENT ON SCIENCE AND TECHNOLOGY

2.0 COMMITTEE FINDINGS AND OBSERVATIONS

2.1. The usefulness of modern biotechnology

1. The committee proposes to introduce a private members bill to cater for other sectors of biotechnology

Hon. Minister's response

The bill already caters for all forms of modern biotechnology as applied in environmental management, industry, and agriculture. Specifically for medical applications in the manufacture and distribution of drugs, the National Drug Authority, established under the National Drug Authority and Policy Act already has the mandate to regulate the manufacture, distribution, and use of all medicines, regardless of the process of development.

Clause 1 of the Bill states that “This Act applies to research and general release of a GMO”, without reference to the different sectors.

2. The committee proposes to license bio-medical laboratories within this law

Hon. Minister’s response

Bio-medical laboratories and related services are already regulated under the Allied Health Professionals Act of 1996. Additional oversight is provided by the National Drug Authority in the regulation of bio-medical laboratory supplies and equipment.

I propose that this law restricts itself to laboratories where modern biotechnology, including genetic engineering, activities are conducted.

3. The Committee recommends that the Ministry of Health, the Ministry of Science, Technology, and the Ministry of Agriculture, Animal Industry and Fisheries jointly prepare and build capacity in response to epidemics

Hon. Minister’s response

The Government has established efficient mechanisms to address any epidemics in agriculture and health, and effective systems are already in place.

This law will address safety of biotechnology, which involves techniques that use living organisms to make or modify a product, improve plants, animals, or micro-organisms for specific uses.

4. The committee proposes amendments that provide evidence based, efficient, predictable and well communicated decision making procedures

Hon. Minister’s response

I agree with the committee that biosafety decision making should be evidence based, efficient, effective, predictable, and well communicated. This is the international best practice.

3.0 OBSERVATIONS ON THE BACKGROUND TO THE BILL

3.1.1 Regulatory framework for modern biotechnology

The committee recommends that;

1. The title of the proposed law be changed

Hon. Minister’s response

Hon. Members, I propose that the title of the law be maintained as the “National Biotechnology and Biosafety Act”. This will allow the Competent Authority, and indeed the law to address the process of development (biotechnology techniques), and the products of biotechnology such as GMOs.

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3.1.1 Designating a National Focal Point, A Competent Authority, and Registrar

The Committee recommended that:

1. The Government establishes a Directorate of Biosafety within the Ministry of Science, Technology and Innovation that is designated as the Competent Authority

Hon. Minister's response

My Ministry has already established a directorate for science policy and regulation within its structures. This directorate is expected to handle all matters of science regulation.

While I agree with the Committee that a directorate is necessary within the Ministry of Science, Technology and Innovation, I propose that the directorate for science regulation is designated the Competent Authority.

I further propose that my Ministry will strengthen a department for biosafety, headed by a commissioner, who will be responsible for full implementation of the proposed law.

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

The Committee proposes to amend the composition of the NBC to be more inclusive

Hon. Minister's response

Hon. Members, while I agree that the National Biosafety Committee needs to be inclusive, I do not agree with the Committee's assumption that the composition in the bill is not inclusive. On the contrary, the bill includes all relevant expertise, sectors and stakeholders.

3.1.3 Mechanisms to regulate research, development, and general release of genetically modified organisms

The committee makes assumptions that:

1. The bill focusses on crop biotechnology
2. The bill does not provide for stages of research and development
3. Crop yields from genetically modified crops will be lower in the second and subsequent seasons of planting

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Hon. Minister's response

Hon. Members, I would like to inform the house that the proposed law addresses different applications of biotechnology to various sectors. No clause of this bill restricts the law to crop biotechnology.

The bill provides under Clauses 16, 17, 18, 19, 20, 21, 22, 23, and 24, different stages of research and development, and the respective approval procedures for each stage.

Genetically modified crops will be cultivated the same way as conventionally developed crops. Yields from crops such as bananas, cassava, sweet potato, beans, rice, and soybeans that are either vegetatively propagated or are self-pollinated will not be affected in subsequent plantings. However, if hybrids for maize are planted, whether GM or not, yields will reduce in other seasons because of the natural biology of these crops.

The committee further recommended that:

1. That the government should increase funding in national conservation and rehabilitate and sufficiently equip the National Gene Bank

Hon. Minister's response

I agree with the committee recommendation.

Hon. Members, the Ministry of Agriculture, Animal Industry and Fisheries is at advanced of developing a comprehensive policy that will ensure effective conservation and sustainable use of plant genetic resources.

My Ministry will cooperate with all relevant agencies such as the National Environment Management Authority, and different ministries to ensure that all animal, plant and microbial resources are conserved and sustainably utilized

The Committee further recommended that:

2. Biosafety requirements for operating laboratories need to be included in the proposed law:

Hon. Minister's response

Hon. Members, the functions of the Competent Authority under Clause 7 (1) (f) include prescribing conditions, standards and procedures for biotechnology research and development.

4.0 HUMAN RIGHTS COMPLIANCE

4.1. Addressing human rights concerns

The Committee recommends that:

1. The public is consulted in the decision making process

Hon. Minister's response

I agree that the public should be consulted in the decision making process. Whereas the committee made reference to the revised African model law on



biodiversity, this document is non-existent but I am aware of the Revised African Model Law on Safety of Biotechnology, to which among many other national and international reference materials, was used in the drafting process for this bill.

The committee further recommended that:

2. The bill should provide for identification of GMOs for any person processing or importing products from GMOs

Hon. Minister's response

I agree with the Committee recommendation. My Ministry as the Competent Authority shall prescribe regulations to ensure products are appropriately labeled

Risk assessment and safety standards for approving genetically modified organisms

3. The Committee observed that there is no criteria for approval or denial of applications

Hon. Minister's response

Rt. Hon. Speaker and Hon. Members, I would like to inform the house that all procedures, forms, and guidance provided in this proposed law form part of the detailed criteria for approval or rejection of applications.

Furthermore, Clause 29 (3) clearly states that "The institutional biosafety committee or Competent Authority shall not approve an application, where the evaluation shows that the risk cannot be avoided or mitigated".

I agree with the committee proposal that risk assessments must be conducted on case by case basis, which is the international best practice.

5.0 GENDER COMPLIANCE

The Committee has recommended that:

1. An explicit criteria to guide the Competent Authority on when to approve the introduction of GMOs

Hon. Minister's response

Hon. Members, I agree that there is need for criteria for approval that takes into consideration gender implications. My Ministry as the Competent Authority shall prescribe regulations for socio-economic considerations, including gender specific implications, as included in the Forms in Schedule 3.

6.0 GENERAL RECOMMENDATIONS

Hon. Minister's response

Rt. Hon. Speaker, I note the general recommendations made by the committee, which emphasize the earlier specific considerations. My Ministry will cooperate with other responsible Ministries and agencies to address issues raised by the committee that are beyond the scope of this law.



RESPONSES TO THE JUNE 2017 MINORITY REPORT OF TWO MEMBERS OF THE COMMITTEE OF PARLIAMENT ON SCIENCE AND TECHNOLOGY

Observations by the members

1. Level of public awareness

The Honourable members make an assumption that there has been limited consultations on this bill, and the science of biotechnology

Hon. Minister's response

Rt. Hon. Speaker, my Ministry, and our devoted national agencies and scientists have held nationwide consultations and sensitization for past 20 years on matters of biotechnology and biosafety. The consensus from these consultations has been unanimous that a law is essential and must be enacted guide the use of biotechnology for national development. This process resulted into the National Biotechnology and Biosafety Policy which was adopted in 2008. Subsequently, Government initiated and conducted nationwide stakeholder consultations to prepare the National Biotechnology and Biosafety Bill. This bill was approved by Cabinet in October 2012, published in the Gazette in November 2012, and introduced into Parliament in February 2013.

The bill was committed to the Science and Technology Committee of the 9th Parliament in February 2013. The Committee held consultations with all key stakeholders, including farmers associations, civil society, scientists, academic institutions, regulators, government agencies, policy makers, and religious leaders, among others. This process resulted into a comprehensive report of the then Committee on Science and Technology, that was presented to Parliament in November 2013. The report concluded that Parliament should enact the law to regulate biotechnology. This report is now the record of Parliament.

Honourable members, national agencies have continued to sensitise the public and key stakeholders in different forums at grassroots, radio, newspaper, television, public meetings through the years, a record of which I present to the members.

From November 2016, the Bill was recommitted to the Committee on Science and Technology for scrutiny as guided by the Parliamentary Rules procedure after the lapse of the previous Parliament.



Rt. Honourable, Speaker, a record of stakeholder consulted by the Committee alone, is presented the report by the Majority Report of the Committee. In February, this year, the Committee placed adverts in two newspapers of nationwide circulation calling for public views on the same bill. The committee further went and collected views from several districts in central, western, northern and eastern Uganda. A major outcome was that the public was ready for this bill and indeed were demanding for improved products from biotechnology research to address their challenges.

2. Impact of the bill

The members presenting the minority report indicate that this bill was prepared without adequate considerations on its impact in the country

Hon. Minister's response

Honourable members, I would like to inform the house that the development of this bill has undergone extensive review of opportunities and challenges to its enactment, dating as far back as the year 2001. All expert guidance concluded that this law is necessary now and will positively impact our economy, and will ensure safety of our people and the environment.

There is no explicit law in Uganda that makes an impact assessment an exclusive precondition for a bill to be considered by Parliament. Only a certificate of financial implications is a pre-requisite for a bill of be tabled in Parliament, which was duly submitted to the House in 2013.

The Bill was approved by Cabinet based on the fact that it met all the guidelines for approving the Bill.

3. Comprehensiveness of the bill

The minority report makes a claim that the bill is focused only on agricultural biotechnology.

Hon. Minister's response

Honourable members, whereas there has been some controversy surrounding agricultural biotechnology from some sections of civil society, scientific evidence shows that biotechnology is widely applied in medical, industry and environmental management. On the specific issue of genetic modification, in Uganda, the manufacturing sector already utilizes numerous applications of GM



technology development of detergents, enzymes, and mineral extraction. Research is already underway in Uganda to improve microorganisms to manage oil waste as we enter the oil economy. In the medical field, we use more than 100 medical preparations, including medicines and diagnostic kits, developed using GM technology. Key examples are insulin and hepatitis vaccines.

Whereas medicines are regulated under the National Drug Authority and Policy Act, any modern biotechnology process or product development in the rest of the sectors mentioned above shall be regulated by this Act. Nothing in this Bill explicitly restricts the bill to regulation of agricultural biotechnology though Uganda has made significant progress in agricultural biotechnology research. This negative perception has been championed by civil society actors for other interests.

4. Bio-ethical considerations

The minority committee report makes a claim that the bill does not give sufficient ethical considerations

Hon. Minister's response

Honourable members, the spirit of National Biotechnology and Biosafety Bill is essentially about ethics in biotechnology research, development, and utilization. In science, the concept of safety and ethics are inseparable. For example, it would be unethical to develop a product which is not safe. This bill provides for explicit procedures for ensuring safety in biotechnology development. Similarly, under this proposed law, it will be an offence to conduct any activity involving modern biotechnology without approval. In addition, the bill provides detailed procedures for ethical considerations that will be prescribed as ethical issues are complex in society and are likely to evolve with advancement in science.

5. Extent of modifications to the bill

The members make a claim that the bill has undergone significant modifications by the majority members report

Hon. Minister's response

Honourable members, the spirit, objective and sense of the bill have remained the same. The justification the minority members give are possibly on the basis of minor typographical or grammatical corrections which do not significantly affect the purpose of the proposed law. The only provision changed included the

proposed change in the Competent Authority, which is not substantial as it does not bring new agencies but utilizes already existing mechanisms under the Ministry of Science, Technology and Innovation. The proposed change in the title is not substantial. No rule of Parliament speaks to the extent of modification of any bill by Parliament as this would constrain the authority of Parliament to make laws for the good governance of our country.

6. Certificate of financial implications

The minority report makes claim to the need for a new certificate of financial implications in light of proposed amendments by the majority members

Hon. Minister's response

My Ministry has already established a directorate for STI regulation within its structures, which will handle all matters of science regulation, including biosafety as recommended by the majority committee report. No new structures are expected to be established, thus no new burden created.

7. Purported external influence

The minority members make a claim that the majority report does not address the risk of external influence

Hon. Minister's response

Honourable members, I would to assure the committee that this has been prepared by the Government of Uganda to address regulation of biotechnology. Scientific research world over is collaborative in nature, as Uganda is not a scientific island. My ministry has allocated funds to undertake research in strategic areas of national importance including research in biosciences.

I also propose inserting a new clause on **Policy Committee on Biotechnology and Biosafety** after clause 8. The functions of the Policy Committee among others will include *“considering the Bio-economy strategy and other socio-economic issues related to Biotechnology and Biosafety; and considering matters of national interest related to Biotechnology and Biosafety”*. The Policy Committee will be chaired by the Prime Minister.



8. Misleading amendments

The Minority committee members make claim that the amendments are intended to mislead the members

Hon. Minister's response

Honourable Members, the Proposals from the Majority report are in line with the spirit of the Bill as already described above, although I am not fully in agreement with some of the proposals such as the proposal to change the title of the proposed law.

9. Expeditious Approval of the Bill

The Minority members make claim that the passage of this bill has been expedited

Hon. Minister's response

Rt. Hon. Speaker, I would like to reiterate that this bill is one of the bills that has undergone extensive consultations spanning over the 20 years. This includes the consultative process that led to the development of the National Biotechnology and Biosafety Policy.

RESPONSES TO SOME OF THE OTHER GMO RELATED CONCERNS

1.0 SAFETY OF BIOTECHNOLOGY PRODUCTS AND GMOS

- The National Biotechnology and Biosafety Bill and the National Biotechnology and Biosafety Policy have been developed to address safety in the use of biotechnology;
- The Bill provides for clear safety testing of all products of GMOs, from the early research stage to commercialisation and consumption. Food and other products from GM technology are vigorously tested for safety to humans, animal, and the environment. Clauses 15 to 32 in the bill spell out the procedures for ensuring safety of products by regulatory laboratory research, field testing, safety testing, and general release of GMO products in Uganda;



- In agriculture, food from GM crops have been consumed worldwide for 21 years, including in Uganda and a lot of research on effect on GMOs in human health conducted diligently with no single demonstrated health effect on human life or animal life. All international food safety agencies have approved food from GM crops; and
- Instead, GM technology is now utilised in advanced economies to treat complicated diseases such as cancer, HIV through gene therapy techniques.

Allegation that GM causes cancer was not valid:

- The cornerstone publication that linked GMO to cancer (Seralini *et al.* 2012), has since been retracted by the Journal for misinterpretation of results and conclusions (Food and Chemical Toxicology (2014) 63: 244; and only republished by another Journal to archive mistakes in scientific methodology and interpretation (Environmental Sciences Europe, 2014;
- The Senior Author to the controversial paper (Seralini GE) recently published another work in a more prestigious Journal, clarifying that tumors observed in his earlier publication (Seralini *et al.*, 2012) resulted from environmental contaminants in the feeds used, and not from genetic modification (Mesnage *et al.*, 2015;
- Seralini *et al.*, 2012, claimed that Roundup Ready herbicide caused more tumors than GMO maize, and that Roundup was more toxic at the lowest dilutions Roundup ready is a major formulated glyphosate -based herbicide used in agriculture worldwide, including Uganda, where the herbicide is used both before and after planting in non-GM crop fields to control weeds. Unavoidably, the residues are washed from farms into major water sources. Mammals and humans may be exposed to herbicide residues by agricultural practices, or when they enter the food chain. As such, those who genuinely believed Seralini *et al.*, should also believe that Roundup is a higher public health concern than GMO foods. Roundup Ready herbicide is still on sale in Uganda, where it is often used in ordinary (non-GM) farms.

Causes of cancer appear largely unknown, and many food products have been implicated. Specifically, several non-GM products have since been



shown to cause cancer, even by the World Health Organization (WHO). These include the following:

- Johnsons baby powder; whence in February 24, 2016, a jury in Missouri awarded \$72 million to the family of a woman who died of ovarian cancer after using baby powder for decades as a hygiene product. It contains talcium powder. Talc is a mineral that is structurally similar to asbestos, a known carcinogen.
- Salted or smoked fish – prostate, stomach and colorectal cancers (Torfadottir et al. 2013, PLoS ONE 8(4): e59799). Smoked foods contain higher levels of nitrates, nitrites, and salts.
- Processed meats or unprocessed red meat carcinogenic to humans – colorectal and prostate cancer (WHO IARC, 2015; Lancet Oncology, 2015).
- Mouthwash (such as Colgate) – Overuse may lead to oral cancer: Alcohol content raises risk of carcinogens in mouth lining according to major publications: Aqudo et al. Oral Oncology, 2014; Farah & McCullough, Australian Dental Journal, 2008.

2.0 SUSTAINABLE USE AND CONSERVATION OF INDIGENOUS SEEDS

- This law is specifically going to ensure that the science of biotechnology is used to improve the local varieties and seeds;
- The law provides for strengthening existing competent authorities to make sure that the biotechnology and its products have little or no negative impacts on our indigenous varieties;
- Our farmers will chose the crops and animals they want to grow. This law only provides **safety measures** for crops and livestock from GM technology; and
- Our government has gone ahead to keep all our important indigenous seeds in seed/gene banks, especially when our farmers chose not to grow them.

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3.0 LIABILITY AND COMPENSATION FOR DAMAGE RESULTING FROM BIO-TECHNOLOGY WORK

- The Government recognises that all modern technologies when misused can result in harm. For this reason, Clauses 31 and 32 in the Bill comprehensively cover the liability of persons whose actions cause damage to human health, the environment, society, including explicit measures to restore the conditions to as near as possible to the state before the damage occurred. Rewording these clauses with the words 'liability and redress' can be done if this clarifies matters to stakeholders.
- **Our Constitution under Article 28**, guarantees every person a 'Right to a fair hearing'. Any imposition of a legal regime that would not give a person a right to a fair hearing would be un-constitutional and inconsistent with the fundamental dignity of our citizens and our country. Liability should and must always be channelled to the responsible person for causing damage as guaranteed by our constitution. **Article 50 of our Constitution** gives rights to any person to seek redress from competent courts for any infringement of their fundamental rights and freedoms and the redress may include compensation.

4.0 DOES THE BILL PROVIDE ADEQUATE MECHANISMS FOR LABELLING?

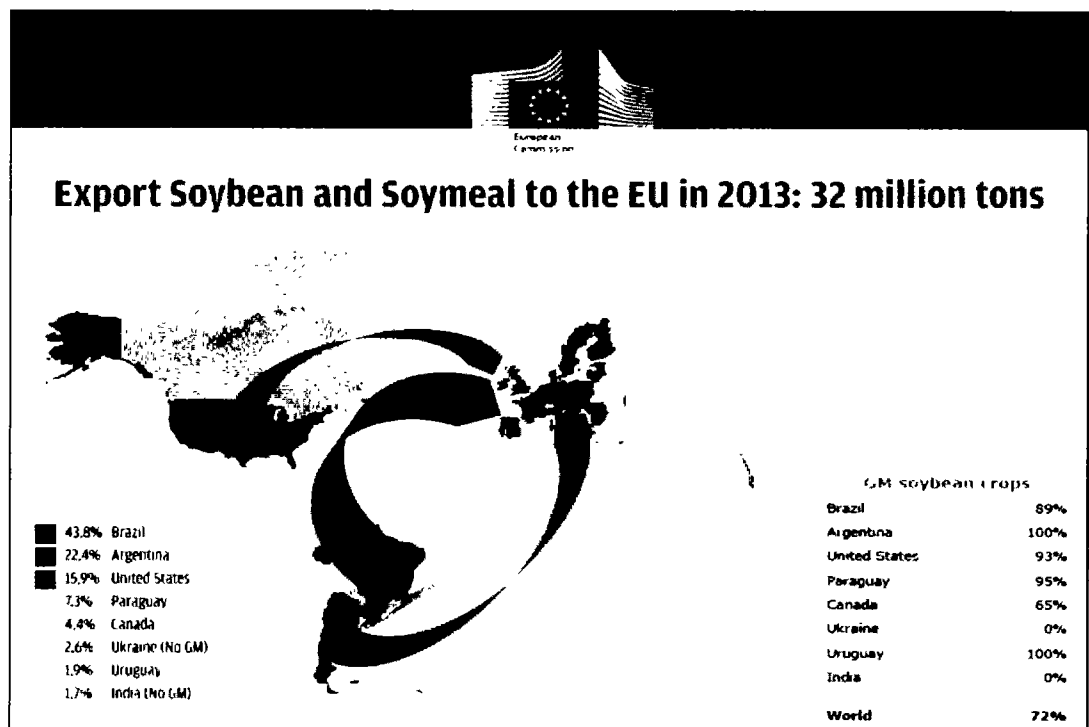
- Under **Clause 44 (2) (c)**, the Bill empowers the Minister to provide clear regulations for handling, transport, **identification**, and packaging of genetically modified organisms. Identification is synonymous with labelling, but for avoidance of doubt, the Parliamentary Committee on Science and Technology recommended adding the word 'labelling' in this clause;
- The methods of labelling have to be elaborated in the regulations to cater for the multitudes of possibilities of GMO products and the nature of the market systems in our country, cognisant of formal and informal trade, product exchanges, fresh produce, nature of crops or livestock and their products, medicines, etc; and

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- Labelling should be unambiguous to avoid misinforming the public and scaring people. *Anti-GMO activists use labels to scare the public from using products proven to be safe.*

5.0 TRADE WITH EU MARKETS

- Upon passage of the Law, the Policy Committee on Biotechnology and Biosafety, the Competent Authority and all relevant regulatory agencies will make sure that the socio-economic considerations including trade issues are considered before approval of any general release of GMOs or their products.
- United Kingdom (Britain) has approved environmental release of wheat that uses sun energy more efficiently.
- EU has approved 58 products containing GM ingredients (mostly for Food and Feed).
- Europe imports GM Corn, Soya etc from Brazil, China, US etc



- Europe has surplus food while Africa is faced with unprecedented hunger and malnutrition amidst growing population. **There are more babies born in Nigeria than in the whole of Europe. Currently the population of Africa is 1.3 billion, by 2030 it is projected to be 1,7 billion and by 2050 for every 4 people on this planet, one will be an African (2050 proejctions: Africa Population 2.5 billion and World population 9.8 billion).** An estimated 60-70% of Africans are now

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involved in Agriculture and yet cannot feed our people and have to depend on food aid from Europe, North America etc, where only 2% is involved in Agriculture. As much as exports to Europe are crucial, we as Africans must put food on the table and feed our people saving them from hunger, malnutrition and death.

6.0 GMO-FREE ZONES IN UGANDA

- The Parliamentary Committee for Science and Technology while scrutinizing the Bill thoroughly discussed the issue of zoning GM crop production and concluded that this would deny specific communities their rights to access relevant technologies as enshrined in the Constitution.
- Our farmers have a right to decide what they want to grow or rear depending on their markets. GMOs or this law cannot change that fact.

7.0 INTEGRATING THE PRECAUTIONARY APPROACH/PRINCIPLE

- The Government in developing this law precisely as a precaution. No GMOs product or activity shall be conducted in Uganda without approval based on safety provisions under law or its regulations.
- The precautionary approach to biosafety management simply shifts the burden of proof for safety to the person developing or intending to release the GMO or its product. Our proposed law already provides for this and goes further to empower our regulatory agencies to scrutinize any safety information related to a GMO

WHAT IS AT STAKE FOR THE COUNTRY?

Uganda will certainly be better placed with adoption of this bill into law as opposed to the status quo. When this bill is enacted, the country will:-

- (i). Have the legal basis to ensure that modern biotechnology utilisation or transit or importation into the country are safe and will pose no significant safety concerns to citizenry.
- (ii). Have the ability to immediately address pressing agricultural and health challenges using technologies developed by national scientists.

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- (iii). Have the ability to attract local and international investment opportunities in bio-based businesses – in health, industry, crop agriculture and food processing thereby promoting bio-economy.
- (iv). Create employment opportunities.
- (v). Expand needed capacity for utilisation of biotechnology tools in development.
- (vi). Roll out into the market agricultural biotechnology products that have already been developed by Ugandan scientists.

Biotechnology is a strategic tool to drive a thriving bio-economy that will provide new economic opportunities to the country, creating new industries and enterprises and providing gainful employment in health, industry (including a revamped cotton textile industry), agriculture (including producing low cost feeds), education, and environment management among others. Modest estimates suggest economic potential of more than three trillion shillings when a bio-economy is strategically and systematically integrated into our development process. **Investing in biotechnology is of strategic value. It is revolutionary like ICT and catalytic to Uganda's economy as oil and gas!**

Uganda is advanced in terms of human resource (number and quality of scientists and their output in biotechnology) and laboratory research capacity compared to many other African countries but they are rapidly catching up. We just have a short window of opportunity in this comparative advantage and we pass this law and unlock this potential ahead of others, Uganda is poised to earn big from exports of the products of biotechnology to the rest of Africa and beyond.

LEGISLATIVE AND POLICY IMPLICATIONS AND PROGRESS

Colleagues are aware that the world is now globalised in commerce, transport, communication, and governance among others. As has been experienced in Uganda in the past 10 years, and increasingly in the recent four years, the issue of GMO has attracted global debate on the merits and applicability of the science in developing countries. Success stories in India, Brazil, China, South Africa, Burkina Faso, Argentina and recently Ethiopia have further complicated the debate. Even though international scientific consensus has affirmed that food and feed products from GM crops are as safe as conventional counterparts, some stakeholders have extended the debate on GMOs, focussing on crop agriculture

to many countries including Uganda. The science of GMOs in agriculture has been fully demonstrated for more than 20 years by adopting farmers and consumers and some scholars are now turning the debate to motivation of opponents rather than the critical issues that should be addressed by a country through a carefully developed regulatory framework.

Every country that cultivates or imports GM crop products has put in place elaborate institutional systems and review systems to evaluate and assess any risk and the safety of such products. In each case, the evaluation process involves making a case-by-case science based decision on the value and potential risks from a particular GM crop product. Uganda should certainly have the national capacity to make appropriate decisions on each potential application of GM technology considering the weight of scientific evidence provided and the socio-economic role of such a product in a given community.

As the global adoption of biotech crops rise from a mere 1.7 million hectares in 1996 to a whopping 181.2 million hectares in 2014, many countries in Sub Saharan Africa (SSA) have either developed or are developing legal frameworks to regulate genetically modified organisms (GMO) and their products. As Uganda determines an appropriate level of protection for products of biotechnology and more specifically genetic engineering, social and political considerations have to be built-in within the scientific decision framework in order to calibrate the balance between controls and safety, against accessibility and benefits.

The Bill intends to enhance a policy environment to manage processes for developing, detecting, testing and assessing the safety of GM products/foods, and ensure compliance with all activities undertaken in laboratories, introduction into the environment, and import, export and transit of GMOs through Uganda.

The Government of Uganda has been committed to the strategic planning and utilisation of modern Bio-technology for national development as detailed in **Annex I.**

Furthermore, Bio-technology has been deployed with immense benefits in various sectors in the economy as detailed in **Annex II.**

CONCLUSION

Martin Luther King Junior said “ The ultimate measure of a man is not where he stands in moments of comfort and convenience but where he stands at times of challenges and controversy”. Lets overcome fear, let us replace despair with hope, lets us pass this bill to

1. Protect our borders from unauthorised entry of GMOs
2. Protect our people from consuming unsafe biotechnology products
3. Liberate our farmers from the devastation and impoverishment caused by crop diseases, animal diseases, uncontrolled use of expensive pesticides and unpredictable weather and drought occasioned by climate change.
4. Give the country opportunities to use all options and scientific tools safely available to achieve food and nutrition sufficiency for all our people
5. achieve food and nutrition sufficiency as well
6. Support our scientists to fully and safely utilize their advanced knowledge and capabilities in biotechnology to help us solve contemporary challenges especially in health, agriculture, industry and environment
7. Unlock the full potential of our economy to create wealth and jobs for our young people as well as shared prosperity for all using all facets of the bio-economy.
8. Support our Gallant leader, Fountain of Honour and President, H.E Gen Yoweri Kaguta Museveni who has overtime showed unparalleled, unprecedented and pivotal support to our scientists and Institutions and has often come out publicly to support the passage of this bill.

Madam Speaker and Colleagues, as Nelson Mandela said, let us be the masters of our fate and captains of our souls and enact the Biotechnology and Biosafety Law and Today will become the future we were worried of yesterday.

FOR GOD AND MY COUNTRY

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ANNEX I

BIOTECHNOLOGY APPLICATION IN UGANDA

- (i). In the last 20 years, the Government has committed more than UGX 20 billion towards infrastructure and human capacity development for agricultural bio-technology research;
- (ii). In 2003, the President of the Republic of Uganda, H.E Yoweri K. Museveni opened the first National Bio-technology Center at Kawanda Agricultural Research Institute; and
- (iii). The Government has also substantially invested in modern bio-technology research in the fields of human health, industry and environmental management.

Besides, the above human and infrastructural capacity is increasing as indicated below:-

- (i). At least 17 Public Institutions are conducting modern bio-technology research for agricultural development, industrial use and human health interventions;
- (ii). At least 10 Public and Private academic institutions are building capacity for conducting modern bio-technology based research in Uganda; and
- (iii). At least 250 Scientists in Uganda are actively involved in modern bio-technology research in agriculture, environment, industry and human health sectors.

Uganda is one of the African countries conducting Confined Field Trials (CFTs) for Genetically Modified crops as follows:-

- (i). The first CFT was planted in November 2007 to test banana for resistance to one of the major devastated diseases called Black Sigatoka;
- (ii). Uganda has since conducted at least 18 separate CFTs for GM crops some GM crops have been under confined field testing for more than 7 years;
- (iii). Uganda has a number of crops under CFTs in the region including staple foods, cassava, potatoes, rice, maize and banana.

Bio-technology research in Uganda is also being done for environmental management, human and animal health as below:-

- (i). GM pharmaceutical products such as insulin are already being used and there is on-going testing of HIV and Ebola vaccines which are also products of modern biotech;



- (ii). There is on-going research to use GMOs or their ingredients in the industrial sector; and
- (iii). There is also on-going research to use GMO micro-organisms for environmental management.

The Government of Uganda is supporting public awareness and dialogue on modern bio-technology as detailed below:-

- (i). The level of awareness and understanding of modern bio-technology among the majority of Ugandans is still low with a lot of misinformation; However, a steady progress is being made in the area.
- (ii). The National Bio-technology and Bio-Safety Policy and the proposed Bio-safety law provide for public participation and engagement during decision making on application of modern bio-technology; and
- (iii). A number of Public Sector agencies involved in bio-technology research, development, application and regulation have made efforts to engage the public to enhance awareness on bio-technology and bio-safety in Uganda.

Colleagues may wish to note that bio-technology has been deployed with immense benefits in various sectors of the economy in various parts of the world as detailed in **Annex I**.

APPLICATION OF BIO-TECHNOLOGY IN VARIOUS SECTORS OF THE ECONOMY

HEALTH SECTOR

- (i). The sector has utilised various biotechnology tools, including genetic modification in the past to generate various health products and services that have been safely used in Uganda.

The most common applications of biotechnology in the health sector include development of quick and accurate diagnostic tests, therapies with fewer side effects, and new and safer vaccines. Worldwide, regulatory agencies have approved 762 vaccines developed using genetic modification. Major examples of genetically modified products and services in Uganda include:

- Rapid malaria test kits
- Rapid HIV test kits
- Artemisinin based anti-malaria treatment
- Hepatitis B vaccine
- Blood clotting factors VIII used for treatment of Haemophilia
- Erythropoietin, a hormone used to produce red blood cells to treat anaemia

Other health products under research in Uganda include HIV vaccines, malaria vaccines, and Ebola vaccine.

- (ii). Even newer medical techniques such as gene therapy are based on genetic engineering technology to address challenges such as leukaemia, cystic fibrosis, sickle cell anaemia, and other genetic diseases.
- (iii). Non-GM based biotechnology applications include *in-vitro* fertilisation (IVF) that has helped several women and men have children.

Medical biotechnology products, especially drugs, are regulated by the National Drug Authority. Other services such as *in-vitro* fertilisation (IVF), organ transplants, and gene therapy are not regulated.

- (iii). Advances in biotechnology is revolutionising the delivery of health care. It is now possible to deliver **personalized medicine** based on genetic tests that can identify individual genetic variations that determine success or failure in treating diseases such as cancer. Recently, the United States Food and Drug Administration (FDA) approved a GM T-Cell based therapy

for the treatment of Acute Lymphoblastic Leukaemia. This is treatment using genetically engineered T Lymphocyte Cells (type of white blood – defence-cells) to attack and kill leukaemia (cancer of the blood cells) cells. This was the first of its kind and is expected to revolutionize treatment of auto-immune diseases, HIV and some childhood cancers.

AGRICULTURAL SECTOR

- (i) Genetic modification (GM) technology was first applied to the health and industrial sectors in the early 1970's but in the 1980's, scientists explored the potential for the science in agriculture. However, the application of biotechnology tools in agriculture, particularly genetic engineering/ GM technology has attracted significant worldwide controversy surrounding economic, ethical, safety, and ideological reasons.
- (ii). A number of biotechnology tools can be potentially applied in improving agriculture. These tools include tissue culture (to produce clean planting material), marker assisted selection and massive assorted recurrent silkworm (MARS) (to improve breeding gains in livestock and crops), disease diagnostics (to detect and quantify animal and crop diseases), artificial insemination (to improve livestock breeding), vaccine and medicine production (for livestock health), genetic engineering, and gene discovery and characterisation (to improve crops and livestock).
- (iii). Since 1994, a number of genetically enhanced crop varieties have been planted in 30 countries. In 2016, commercialization of biotech crops was 185.1 million hectares (3% increase from 2015) and a global market value of more than 15 billion US dollars, with Brazil, USA, China, India and Argentina taking the largest share (ISAAA, 2016).
- (iv). The National Agricultural Research Organization (NARO) has been involved in biotechnology research, since 2003, to address the following issues:
 - Pests and diseases in key crops like banana, cassava, maize, potato, cotton;
 - Climate change challenges like drought in maize;
 - Low soil nitrogen and water use efficiency in rice;
 - Nutrient deficiencies in banana and cassava;
 - Aflatoxin-contamination management in groundnuts;
 - Anti-tick vaccines for livestock; and

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- Production of environment management products including biodegradable plastics, biodiesel, and bioethanol.
- (v). In our own situation, His Excellency the President of Uganda flagged off the first modern agricultural biotechnology laboratory in 2003 when the government made a decision to use biotechnology for agricultural development.
- (vi). Uganda has now developed capacity for biotechnology research, development and regulation has been built in the past 20 years to a tune of over 70 billion Uganda shillings in the different liabilities. To date, we have trained over 250 biotechnology scientists working in over 15 biotechnology research facilities in public and private sectors. Scientists at NARO have made many breakthroughs becoming the first-in-the-world to produce biotechnology tools to address issues unique to Uganda.

ENVIRONMENTAL MANAGEMENT

Biotechnology offers several opportunities in environmental management and climate change mitigation. These tools have been applied to improve micro-organisms and plants to help preserve and restore the environment from the impact of pollutants and other impacts of industrialization, mining (such as oil extraction) and some agricultural practices. The major applications in Uganda now include:

- Bio-composting to speed up decomposition of organic materials including municipal waste;
- Bio-energy in production and efficient use of fuels like biogas, biomass and hydrogen for domestic and industrial purposes;
- Bioremediation, a clean-up technology utilizing naturally occurring microorganisms to degrade hazardous substances into less or non-toxic compounds in domestic and industrial waste.
- Tissue culture and genetic modification of trees to produce fast maturing tree species to address climate change challenges and environmental degradation
- Development of bio-degradable plastic using cassava starch (promising on-going research at NARO)



INDUSTRY

Many industrial processes in the country, including the brewing industry are inherently dependant on biotechnology tools such as fermentation. The main industrial processes using biotechnology include:

- Food processing (yoghurt, cheese, bread). Cheese production now is based on the use of enzymes produced using genetic engineering.
- Brewing
- Production of detergents and cleaning products. GM derived enzymes are a key ingredient in detergents
- Textiles – globally now dependent on GM crops especially GM cotton
- Bio-sensors and bio-reactors. These tools are enabling our scientists, regulators, and business community to perform necessary tests for toxins (for example aflatoxins in grain) and other key reactions in industrial processes.

ENERGY AND MINERAL EXTRACTION

- (i). Advanced economies have now included biofuels as a key component of their energy plans. Uganda is moving steadily to enhance use of biomass energy generation and biofuels. Our researchers at Makerere University UIRI and the National Agricultural Research Organisation have already established biofuel systems to provide alternative energy sources.
- (ii). Mineral extraction and processing by using specialised micro-organisms has been used by our country for the past 15 years. Our cobalt extraction plant in Kasese uses this approach.

