



THE REPUBLIC OF UGANDA

**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)  
3<sup>RD</sup> 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.



## **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 9<sup>th</sup> 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 un-ethical 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 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 grammatically 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