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AP 116/264/01

30th May, 2018

Hon. Nsaba Buturo
MP Bufumbira County East

Hon. Tayebwa Thomas
MP Ruhinda North County

**RE: PROPOSED AMENDMENT ON A BILL FOR AN ACT ENTITLED THE
BIOSAFETY AT, 2017**

I received your letter dated 9th April, 2018, submitting proposed amendments to a Bill which was returned by H. E. the President that was passed by Parliament for an Act entitled, The Biosafety Act, 2017.

However, I wish to advise that you harmonize the proposed amendments with the Committee on Science, Technology and Innovation before you come to the House.

Rebecca A. Kadaga (MP)
SPEAKER OF UGANDA PARLIAMENT



THE PARLIAMENT OF UGANDA

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Plot Nos. 16 - 18 Parliament Avenue

In any correspondence on
this subject please quote No.

9th April 2018

**The Rt. Hon. Speaker
Parliament of Uganda
Kampala**

Received by me
Speaker's office
0414 377 100
0414 346 806
9/4/18

**RE: PROPOSED AMENDMENTS ON A BILL FOR AN ACT ENTITLED THE BIOSAFETY
ACT, 2017**

In line with Rules 133 (4) and 142(5) of the Rules of Procedure and Directive of Speaker issued on 9th January 2018, this is to submit proposed amendments to a bill returned by the President that was passed by Parliament for an Act entitled the Biosafety Act, 2017.

Attached please, find proposed amendments made in response to the President's letter and report of the Committee on Science, Technology and Innovation on the above mentioned Bill.

During the Committee of the Whole House, we the undersigned Members seek your indulgence to move the proposed amendments.

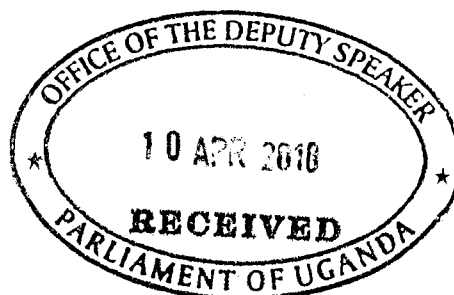
Thanking you in advance for your positive consideration.

Yours sincerely

Nsaba Buturo
Nsaba Buturo (MP)
Buwambira County East

Tayebwa Thomas (MP)
Ruhinda North County

c.c. Rt. Hon. Deputy Speaker of Parliament
c.c. Clerk to Parliament



PROPOSED AMENDMENTS MADE IN RESPONSE TO THE PRESIDENT'S LETTER AND REPORT OF THE COMMITTEE ON SCIENCE, TECHNOLOGY AND INNOVATION ON A BILL FOR AN ACT ENTITLED THE BIOSAFETY ACT, 2017

a) Short Title

Amend the short title to read as follows;
"The Genetic Engineering (Animal and Plants) Act"

Justification

To restrict the scope of genetic engineering to plants and animal i.e. agricultural products that are targeted for regulation by the proposed Bill. This too excludes human cloning. Hence addressing the concern raised by the President.

The proposed amendment made by the Committee is misleading for the Bill does not adequately address Biosafety concerns for instance it does not address issues on bioterrorism, bioethics, biopiracy and polluter pays principle among others. This necessitates an elaborate law on biosafety.

b) Clause 3 – Interpretation

Introduce interpretation of 'genetic engineering' and 'genetically engineered material' to read as follows


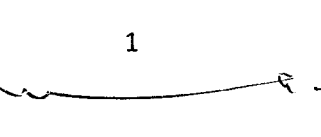
'genetic engineering' means a process through which an organism's or product's genetic constitution of cells is artificially altered as a result of introduction or elimination of specific genes that alter hereditary traits of a plant or animal cell.

Replace 'genetically modified organism or GMO' with 'genetically engineered material' and define it as follows

'genetically engineered material' means an organism or material produced through genetic engineering.

Justification

The proposed amendments and definitions are clearer and understandable as compared to those proposed by the Committee.

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c) **Clause 6 – Establishment of Competent Authority**

Amend Clause 6 to read as follows

Establishment of Competent Authority

- 1) *There is established the Genetic Engineering Council as a competent authority for purposes of implementing this Act.*
- 2) **The Council is a body corporate with perpetual succession and a common seal** and may, for the discharge of its functions under this Act -
 - (a) *acquire, hold and dispose of moveable and immovable property;*
 - (b) **sue and be sued in its corporate name;** and
 - (c) **do all acts and things as a body corporate may lawfully do.**
- 3) *The Minister may give directions in writing to the Council with respect to the policy to be observed and implemented by the Council, and the Council shall comply with those directions.*
- 4) *Directions given by the Minister under subsection (3) shall not adversely affect or interfere with the independence of the Council or the performance of the functions and exercise of the powers of the Council under this Act.*
- 5) *The Minister shall cause a copy of any directions given to the Council under subsection (3) to be published in the Gazette.*
- 6) *The Council shall be domicile in a ministry as may be directed by the President.*

Justification

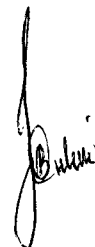
As earlier articulated there are inadequate provisions regarding biosafety. Hence the proposal for the competent authority to be referred to as 'Genetic Engineering Council' instead of 'National Genetic Engineering and Biosafety Council' as proposed by the Committee.

Although there is convergence as regards council being corporate body that can be sued and executes lawful undertakings, it is essential to articulate the need for it to acquire and dispose of property.

It is important to empower the Minister to offer policy guidance to the Council as and when need arises. The proposed amendments do prescribe the limits and medium of the directives. This has been very effective in Brazil which is usually referred to as leading producer of genetically engineered materials.

Article 117 of the Constitution stipulates that any Minister is individually accountable to the President for the administration of their Ministries. Based on

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this it is acceptable that the President prescribes a home ministry responsible for genetic engineering.

d) New Clause – Composition of the Council

A new Clause and head note 'Composition of the Council' is introduced after Clause 6 to read as follows

Composition of the Council

- (1) *The Council shall consist of a Chairperson and six other members appointed by the President with the approval of Parliament.*
- (2) *The members of the Council shall be persons of high moral character and proven integrity and who are qualified in genetic engineering disciplines with at least ten years' experience.*
- (3) *A person shall not be appointed to the Council who—*
 - a) *has been convicted of an offence under this Act or of an offence involving dishonesty or fraud by a competent court in Uganda or elsewhere;*
 - b) *is an undischarged bankrupt, or has made any assignment or arrangement with his or her creditors;*
 - c) *has been convicted of an offence and sentenced to a term of imprisonment of six months or more by a competent court in Uganda or elsewhere; or*
 - d) *is a Member of Parliament, a Minister or a member of a local government council.*

Justification

The Committee did not propose composition of the Council and level of experience required to serve on the Council. Hence the proposal on the number, required experience and professional discipline of Council members.

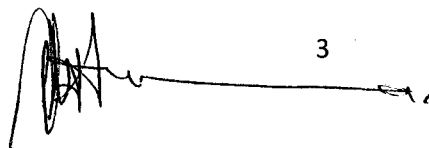
Furthermore there is no need for a board. A Board would increase administrative costs and make Members of the Council subordinate to the Board.

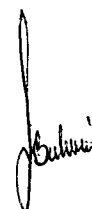
e) New Clause – Tenure of office of members of the Council

A new Clause and head note 'Tenure of office of members of the Council' is introduced to read as follows

Tenure of office of members of the Council

- 1) *A member of the Council shall hold office for five years, on a part time basis and is eligible for reappointment for two more terms, except that of the first*

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members to be appointed to the Council, two shall be appointed to hold office for four years.

- 2) A member of the Council may, at any time, resign his or her office in writing addressed to the President.
- 3) The Council shall meet for the discharge of its functions at least twelve times a year.
- 4) The President may, at any time, with approval of Cabinet remove a member of the Council only for -
 - a) inability to perform the functions of his or her office arising from infirmity of body or mind;
 - b) misbehaviour or misconduct;
 - c) incompetence;
 - d) absence from more than three consecutive meetings of the Council, or absence from Uganda for more than twelve months without reasonable excuse;
 - e) bankruptcy or insolvency; or
 - f) conviction for a criminal offence, in Uganda or elsewhere, in respect of which the maximum penalty exceeds six months imprisonment without the option of a fine.
- 5) Where it appears to the President that there is cause to remove a member under subsection (3), the he or she shall notify the member concerned in writing and shall give the member an opportunity to submit his or her explanation to the President.
- 6) Where a member is removed from office under this section, resigns or dies, the President shall appoint another qualified person to replace the member and to hold office for the remainder of the term of the removed member.

Justification

To provide for part time tenure of the Council of office of members of the Council, frequency of meetings and mode of removal of a member.

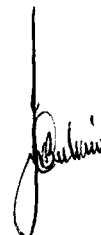
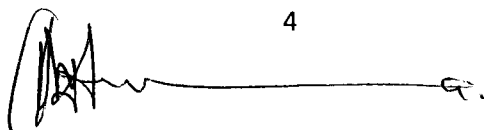
f) New Clause – Independence of the Council

A new Clause and head note 'Independence of the Council' is introduced to read as follows

Independence of the Council

The Council shall, subject to the declared policy of the Government and except as is otherwise provided in this Act, be independent in the performance of its functions and duties and exercise of its powers and shall not be subject to the direction or control of any person or authority.

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Justification

To provide independence of the competent authority as it executes its mandate.

g) New Clause – Remuneration of members of the Council

A new Clause and head note 'Remuneration of members of the Council' is introduced to read as follows

Remuneration of members of the Council

The Chairperson and the members of the Council shall be paid such remuneration as shall be specified in their instruments of appointment.

Justification

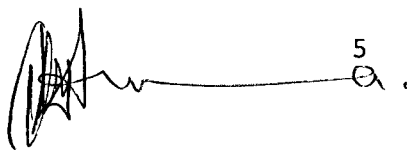
To provide for instrument of appointments and remuneration of members of the Council.

h) New Clause – Secretariat

A new Clause and head note 'Secretariat' is introduced to read as follows

Secretariat

- 1) *The Council shall have a secretariat, which shall be headed by an Executive Secretary.*
- 2) *The functions of the Secretariat are -*
 - a) *to implement the policies or decisions of the Council;*
 - b) *to recommend to the Council proposals for the formulation of policies of the Council;*
 - c) *to establish and maintain relationships with national, regional and international organisations, institutions and agencies as may be appropriate for facilitating the implementation of the policies, and the carrying out of the functions of the Council;*
 - d) *to perform any other function as the Council may direct.*
- 3) *The Executive Secretary and other staff shall be appointed by the Council upon terms and conditions specified in instruments of appointment.*
- 4) *The Executive Secretary shall be a person of high moral character and proven integrity, with relevant qualifications and experience in genetic engineering disciplines; qualifications in law and public administration shall be an added advantage.*
- 5) *The Executive Secretary shall be an ex-officio member of the Council.*

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6) *The Executive Secretary is, in the performance of his or her functions, answerable to the Council.*

Justification

To provide for a Secretariat to offer administrative and technical support to the Council.

i) New Clause – Functions of the Executive Secretary

A new Clause and head note 'Functions of the Executive Secretary' is introduced to read as follows

Functions of the Executive Secretary

- 1) *The Executive Secretary shall be responsible for the day to day operations and administration of the Council.*
- 2) *Subject to this Act and to the general supervision and control of the Council, the Secretary is responsible for -*
 - a) *the implementation of the policies and programmes of the Council and reporting on them to the Council;*
 - b) *the proper management of the funds and property of the Council;*
 - c) *the organisation and control of the staff of the Council; and*
 - d) *performing any other duty that may be assigned to him or her by the Council.*

Justification

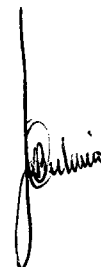
To provide for functions of Executive Secretary who shall be in charge of the day to day operations of the Secretariat and Council.

j) New Clause – Criteria for Decision Making

A new Clause and head note 'Criteria for Decision Making' is introduced after Clause 13 to read as follows

'Criteria for Decision Making

- (1) *The Competent Authority shall not grant any approval unless it considers that the research, contained testing, confined field testing, release, export, import or transit of genetically engineered material shall –*
 - a) *benefit the country without causing any risk to human and animal health, non-genetically engineered plant or animal, biological diversity or the environment;*



- b) contribute to sustainable development;
- c) not have adverse socio-economic impacts; and
- d) conform to the ethical values and concerns of communities and does not undermine community knowledge and technologies.

(2) The Competent Authority shall, as a condition for approval, require an applicant to furnish evidence of insurance cover or a bond for performance and observance of the obligations under this Act.'

Justification

The Committee did not make any proposal regarding criteria for decision making by the competent authority.

The proposed criteria will be essential in addressing among others the concerns in the President's letter (paragraphs 1, 4 and 5) regarding protection of indigenous farming practices, prevention of environmental pollution, poisons and dangerous bacteria.



k) New Clause – Access to Genetic Resources and Benefit Sharing

A new Clause and head note 'Access to Genetic Resources and Benefit Sharing' is introduced to read as follows

'Access to Genetic Resources and Benefit Sharing

- (1) The right to determine, control and regulate access to genetic resources found in Uganda is vested in the Government for the benefit of the people of Uganda and shall be exercised in accordance with the National Environment Act or any other relevant Act of Parliament.
- (2) Notwithstanding sub section (1), a person or entity engaging in a genetic engineering activity shall not access genetic resources unless that person or entity has obtained written consent and entered into an accessory agreement with the relevant lead agency, local community or owner of the genetic resource as the case may be.
- (3) The agreement referred to in sub section (2) shall among other requirements stipulate the market value of the genetic resources which will be determined on a case by case basis by the Competent Authority.
- (4) Any benefits and or intellectual property rights accruing to the genetic resources shall be a joint ownership of the collector and local community or owner.

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Justification

The proposed amendment is more comprehensive than the clause on 'Benefit Sharing Agreement' as proposed by the Committee. It provides an alignment to current law that regulates genetic resources in Uganda i.e. National Environment Act. Furthermore it prescribes a procedure of accessing and sharing benefits of genetic resources. This addresses concerns in paragraph 1 of the President's letter.

Ideally the best option would be to develop an independent law on Access to Genetic Resources and Benefit Sharing. It is on this basis that the proposed amendment provides for any other relevant Act of Parliament. This would directly lead to the implementation of the Convention on Biological Diversity and any protocol to the Convention which deals with access to biological resources and traditional knowledge associated with biological resources and the sharing of benefits arising from their utilisation. Malaysia took this path and passed 'Access to Biological Resources and Benefit Sharing Act 2017'.

1) Clause 15 – Stages of Research

Introduce new sub clauses to read as follows

- '(3) Any person or entity or body corporate who engages in research of genetically engineered material shall endeavor to safeguard human dignity and value human life'.*
- (4) Every stage of research under subsection (1) shall require a biosafety quality certificate issue by the Competent Authority.*
- (5) The Competent Authority shall establish the criteria and procedures for the request, issuance, review, extension, suspension and cancellation of a biosafety quality certificate referred to under sub section (4).*

Justification

This is one of the clauses that the President referred for reconsideration for which the Committee makes no proposed amendment.

The Proposed amendments will ensure that human life is protected from any risks or impacts arising from research or release of genetically engineered materials.

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The proposed amendment will be essential in addressing among others the concerns in the President's letter regarding protection of indigenous farming practices, prevention of environmental pollution, poisons and dangerous bacteria.

The proposed biosafety quality certificate is a critical tool for holding accountable any person or entity or body corporate who engages in research of genetically engineered material. Hence addressing President's concern of holding accountable a developer of any genetically engineered material and protecting consumers from dangerous material.

m) Clause 16(2) – Preservation of Indigenous Varieties

Amend Clause 16(2) to read as follows

*'(2) The Competent Authority shall, before the approval of any stage of research, **require the applicant to obtain written confirmation from relevant institution on whether the indigenous animal or seed variety is preserved in the National Gene Bank.**'*

Justification

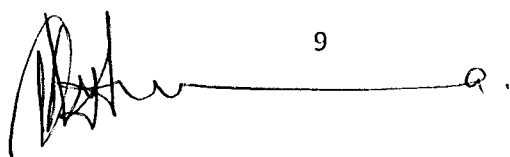
To ensure that the applicant wholesomely and explicitly bears the burden of confirming whether the animal or seed variety under research is preserved in the National Gene Bank.

n) Clause 26 – Labelling of a Genetically Engineered Material

Amend Clause 26(1) to read

'Labelling of a Genetically Engineered Material

*(1) A person involved in the research, development, general release, importation, transit, **exportation** or trade of a genetically engineered material shall ensure that the genetically engineered material or genetically engineered product is **clearly visible and notably labelled 'contains genetically engineered material'**.*

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Introduce new sub clauses immediately after to read as follows

- (1A) In labelling genetically engineered materials, a person shall ensure that
- a) for pre-packaged materials, the words 'genetically engineered (name of ingredient)' or 'genetically engineered (name of food)' appears on the label;
 - b) for non-pre-packaged materials the words 'genetically engineered materials' or 'genetically engineered (name of organism)' shall appear on, or in connection with, the display of the material.

(1B) In addition to the inclusion of the words 'genetically engineered' as required under subsection (1A), there shall be additional labelling and information requirements for genetically engineered foods that have altered characteristics in relation to –

- a) one or more significant composition or nutritional parameters having values outside the normal range of values compared to conventional counterpart food or feed or ingredient thereof not produced using genetic engineering techniques;
- b) the level of anti-nutritional factors or natural toxicants that are significantly different in comparison to the existing counterpart food, feed or ingredient not produced using genetic engineering;
- c) the genetic modification that raises significant ethical, cultural and religious concerns regarding the origin of the genetic material used in the genetic modification; and
- d) the particular reactions, allergies or other side effects where it is known that a particular reaction, allergy or other side effect may be caused.

(1C) Genetically engineered materials shall not be described or labelled in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect.

Introduce new sub clause (4) to read as follows

(4) The Minister shall in consultation with the Competent Authority by statutory instrument make regulations for the purpose of handling any incidental matters related to labelling and branding of genetically engineered materials.

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a.



Justification

The proposed amendment by the Committee dealt away with requirement of Minister making any regulation regarding labelling of genetically engineered material. However it is essential that provisions are made for incidental labelling matters to be addressed by statutory instrument as and whenever need arises.

The proposed amendments seek to ensure that act provides for more elaborate labelling provisions so as ensure adequate consumer protection and abate any risk that may arise due to delayed issuance of statutory instrument.

o) New Clause – Notification for application of patent

A new clause and head note 'Notification for application of patent' is introduced after Clause 27 to read as follows

'Notification for application of patent

Any person applying for a patent of a genetic engineering technology or genetically engineered material, whether in or outside Uganda, in relation to a genetic resource or traditional knowledge associated with a genetic resource accessed in Uganda shall notify the Competent Authority in writing within thirty days from the date of the application'.



Justification

To provide for any opportunity to the Competent Authority to raise any objections to patenting of genetic engineering technology or genetically engineered material so as to address concerns related to monopoly of patent, modification of genetic resources and benefit Sharing as raised in the President's letter (paragraph 1). The proposed amendment has been effective in Malaysia.

p) New Clause – Coexistence of Farming Practices

A new clause and head note 'Coexistence of Farming Practices' is introduced after Clause 28 to read as follows

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'Coexistence of Farming Practices

- (1) A person who cultivates any genetically engineered plant shall prevent any contamination or mixture of the genetically engineered plant with any non-genetically engineered plant.
- (2) A person who keeps or owns genetically engineered animal shall prevent any cross-breeding between genetically engineered and non-genetically engineered animal.
- (3) The Minister in consultation with the Competent Authority and with approval of Cabinet may declare any part of the country to be free of genetically engineered materials.
- (4) The declaration made in subsection (3) shall be published in a gazette and published in newspapers of wide circulation.
- (5) Any district may petition the Minister through a district council resolution to declare their area a genetically engineered materials free area in accordance with this Act.
- (6) A petition referred in subsection (5) shall be disposed of within forty five days from the date the petition is submitted to the Minister and decision taken communicated to the Petitioner and Parliament.
- (7) The Minister shall in consultation with the Competent Authority and with approval of Cabinet by statutory instrument make regulations for isolation measures to prevent any contamination or mixture of the genetically engineered material with any non-genetically engineered material.
- (8) Any person who contravenes this section shall be held strictly liable as provided in Section 35 of this Act.'

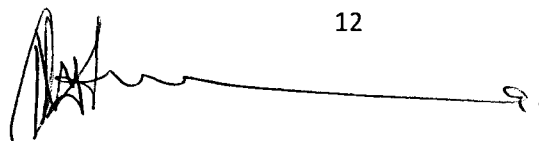
Justification

The proposed amendments are more explicit than those proposed by the Committee as far as declaration of areas free from genetically engineered materials so as prevent them mixing with indigenous varieties. Hence addressing President's concern in paragraph 3 of his letter.

q) Clause 35 – Liability for Damages

Amend Clause 35 to read as follows

A person **or entity** responsible for an activity relating to genetic engineering under this Act shall be **strictly** liable for any damage, harm, inconvenience or loss



caused to the **community livelihood, indigenous knowledge systems or technologies**, environment, biodiversity, ecosystem, species of flora and fauna, or human and animal health.

Justification

This is one of the clauses that the President referred for reconsideration for which the Committee makes no proposed amendment.

To provide for strict liability for damage, harm, inconvenience or loss caused by any person or entity through genetically engineered technologies and materials.

r) Clause 36 – Offences by a Body Corporate

Insert a new clause immediately after Clause 36 to read as follows

*'Where an offence under this Act is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of any person, being a director, manager, secretary or other officer of the body corporate, agent, dealer or a person who was purporting to act in such capacity, that person shall, as well as the body corporate be strictly liable and adequately compensate for damage, harm, or loss caused to the **community livelihood, indigenous knowledge systems or technologies**, environment including biodiversity, **ecosystem**, species of flora and fauna, or human and animal health.*

Justification

This is clearer, more elaborate particularly regarding aspects of the environment that may be affected and encompasses all aspects proposed by the Committee. The proposed amendment addresses paragraph 1 of the President's letter.

I beg to move.

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