TEN REASONS WHY THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL–2012 SHOULD NOT BE PASSED IN ITS CURRENT STATE

A SOCIO-ECONOMIC–LEGAL ANALYSIS
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2014
Table of Contents

Acronyms .................................................. iv
Introduction: contextualising the GMO debate ............... 1
Legal framework on biodiversity in Uganda ................. 4
The National Legal framework on Biodiversity in Uganda ... 6
Ten reasons why the National Biotechnology and Biosafety Bill, 2012 should not be passed in its current state . . 8

REASON 1: The Bill contains no provisions relating to having genetically modified Organisms products labelled hence infringing on the right to know . . 8

REASON 2: The Bill lacks adequate provisions relating to right of citizens to participation and education ................. 9

REASON 3: Inadequate Provisions relating to prevention or reduction of the risks to biological diversity and human health ................................. 11

REASON 4: Weak and uncoordinated institutional framework to handle the regulation of Modern Biotechnology ..................... 13

REASON 5: Inadequate provisions for proper and clear risk management systems 16

REASON 6: The Bill has gaps relating to access to justice by complainants ......................................................... 21

Reason 7: Inadequate investigations and unclear complaint process ................................................................. 22

REASON 8: Lack of provisions relating to access and property rights ................................................................. 22
Reason 9: The Bill is marred with broad interpretation, non-precision and confusion in definition of various terms used.

Reason 10: The Bill contains provisions with dual criminal liability.

Other Concerns

Conclusion
## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AU</td>
<td>African Union</td>
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<td>CA</td>
<td>Competent Authority</td>
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<td>CBD</td>
<td>Convention on Biological Diversity</td>
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<td>FAO</td>
<td>Food and Agriculture Organization</td>
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<td>GMOs</td>
<td>Genetically Modified Organisms</td>
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<td>GM</td>
<td>Genetically Modified</td>
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<td>HURINET–U</td>
<td>Human Rights Network–Uganda</td>
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<td>IBC</td>
<td>Institutional Bio–safety Committees</td>
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<td>NBCs</td>
<td>National Bio–safety Committees</td>
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<td>TRIPS</td>
<td>Trade Related Aspects of Intellectual Property Rights</td>
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<td>UN</td>
<td>United Nations</td>
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<td>UNCST</td>
<td>Uganda National Council for Science and Technology</td>
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INTRODUCTION: CONTEXTUALISING THE GMO DEBATE

“We strongly object that the image of the poor and hungry from our countries is being used by giant multinational corporations to push a technology that is neither known to be safe, environmentally friendly, nor economically beneficial to us. We do not believe that such companies or gene technologies will help our farmers to produce the food that is needed in the 21st century. On the contrary we think it will destroy the diversity, the local knowledge and the sustainable agricultural systems that our farmers have developed for millennia and that it will undermine our capacity to feed ourselves” – 24 African Delegates to the FAO Extraordinary Session of the Commission on Genetic Resources, June 1998

The need to address world hunger and ensure food security has long been at the forefront of the international agenda and advocates of biotechnology have since presented it as a way to address world hunger. At the 2002 World Food Summit, following several decades of unmet goals on eliminating hunger, food insecurity and malnutrition, the Food and Agriculture Organization (FAO) formally and controversially endorsed biotechnology as a way to address hunger.

Using this emphasis on the need to address hunger, Genetically Modified foods have spread worldwide both as a result of potential benefits and also because of questionable claims of significantly increased crop yields that
TEN REASONS WHY THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL-2012 SHOULD NOT BE PASSED IN ITS CURRENT STATE

could decrease hunger.\textsuperscript{1} Over 80% of the populations in Uganda depend on subsistence agriculture for their livelihoods.

Biodiversity is estimated to contribute about $1\text{billion} million in Uganda per year in monetary, non–monetary and informal sectors, and through provision of ecological services.\textsuperscript{2} Aware that many Ugandans go hungry, and others are malnourished, the move to promote food sovereignty has been recommended by several stakeholders both in the private and public sector as a means to enhance food security for the populace.\textsuperscript{3}

To address the concern above, the \textit{National Biotechnology and Biosafety Bill, 2012} was tabled before Parliament in February 2013. The Bill provides for the safe development and use of modern biotechnology; and mechanisms to regulate research, development and use of genetically modified organisms. The Bill's objective includes providing for development and general release of Genetically Modified Organisms (GMOs) in Uganda. The Bill also provides for a regulatory framework to facilitate safe development and application of biotechnology.

Whereas if taken on its face value, the Bill seems to ride on the noble cause of contributing to hunger reduction by enhancing technology and scientific research using GMO, in the same measure, it raises more questions than provides answers. This analysis focuses on key human rights, economic and social issues that the bill raises. The provisions therein are tested against the Constitution of the Republic of Uganda, 1995 as amended and different international human rights instruments that Uganda is party to and obligated to uphold, respect and promote. The analysis highlights the need to accord robust provisions on issues governing the right to information, right of citizens to participate in various processes, right to health, the right to food and right to clean environment through clear and proper risk assessment mechanisms with particular reference to Uganda's obligations under Cartagena Protocol on Biosafety to the Convention on Biological Diversity to which Uganda is party to. It concludes that, in its current form, the Bill is short of the necessary fundamental safeguards to the underlying

\textsuperscript{2} Uganda Factsheet on Biodiversity; Accessed at http://www.ecouganda.org/attachments/article/112/Uganda%20Factsheet%20on%20Biodiversity.pdf 9/1/2013
\textsuperscript{3} Attaining food sovereignty implies that one eats food of good quality, with the nutrients that the body needs, and also one must take food in sufficient quantities.
human rights, environment and economic related risks involved in GMOs to the populace.

Special and deliberate emphasis is put on Genetically Modified Organisms in the analysis. This involves application of genetic engineering (GE) technology which is manipulation of living organisms to produce goods and services useful to humans. It is distinguished from traditional tools in that it is a transgenic approach that develops products (such as seed varieties) through insertion of genetic material from different species into a host plant.4

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4 The products derived using these techniques are commonly referred to as Genetically Modified Organisms (GMOs).
LEGAL FRAMEWORK ON BIODIVERSITY IN UGANDA

a) Uganda’s Obligation On Biodiversity at The International and Regional Level

Uganda is a Party to the Convention on Biological Diversity (CBD) which it signed on 12th June 1992 and ratified on 8th September 1993. Uganda is also party to the Cartagena Protocol on Bio–safety, signed on 24th May 2000 and ratified on 24th November 2001. The CBD has three objectives: Conservation of biological diversity, sustainable use and equitable sharing of the benefits arising from the utilization of genetic resources. The objective of the Cartagena Protocol on Bio–safety is to ensure adequate levels of protection in the field of the safe transfer, handling and use of LMOs/GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.

Regionally, the African Union endorsed the African Model Law on Safety in Biotechnology during the 74th Ordinary Session of the AU Council of Ministers in Zambia in July 2001 and revised in 2007. The Council urged its member states to use the Model Law to draft their own national legislation. The African Modern Law on Safety in Biotechnology recognizes that while biotechnology might hold much promise for the improvement of human well–being, it equally has potentially adverse effects on the environment, biological diversity and human health.
Uganda is also a Party to the following biodiversity related Conventions and agreements as tabulated below:\textsuperscript{5}

**Table 1. International Instruments that may be applicable to GMOs that Uganda is a party to;**

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<th>No.</th>
<th>Name of Instrument</th>
<th>Date of Assent</th>
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<td>2.</td>
<td>Ramsar Convention on Wetlands</td>
<td>Signed on 4\textsuperscript{th} March 1988 and ratified on 4\textsuperscript{th} July 1988.</td>
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<tr>
<td>3.</td>
<td>The Lusaka Agreement on Cooperative Enforcement Operations directed at Illegal Trade in Wild Fauna and Flora</td>
<td>Signed on 8\textsuperscript{th} September 1994 and ratified on 12\textsuperscript{th} April 1996.</td>
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\textsuperscript{5} Uganda is obliged to implement the Conventions and agreements.
2.1 THE NATIONAL LEGAL FRAME WORK WORK ON BIODIVERSITY IN UGANDA


1. National Objective XIII of the Constitution requires the State to protect important natural resources, including land, water, wetlands, minerals, oils, fauna, and flora on behalf of the people of Uganda.

2. National Objective XXVII on Environment provides for the State, including local governments to promote the rational use of natural resources so as to safeguard and protect the biodiversity.

3. Article 39 provides for the right of every Ugandan to a clean and healthy environment.

4. Article 237(2)(b) requires Government or a local government to hold in trust for the people and protect natural lakes, rivers, wetlands, forest reserves, game reserves national parks and any land to be reserved for ecological and touristic purposes for the common good of all citizens.

5. Article 245 provides for Parliament to enact laws intended to protect the environment from abuse, pollution and degradation as well as for managing the environment for sustainable development and promoting environmental awareness.

B. National Laws on Environment and Biodiversity


C.Policy Framework & Action Plans on Biodiversity in Uganda


TEN REASONS WHY THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL, 2012 SHOULD NOT BE PASSED IN ITS CURRENT STATE

REASON 1: The Bill contains no provisions relating to having genetically modified Organisms products labelled hence infringing on the right to know

A. Analysis Note
A comprehensive labeling and traceability system is a key feature of a bio–safety law in accordance with article 18 of the Cartagena Protocol. The identification should include relevant traits and characteristics given with sufficient detail to enable traceability and facilitate verification. The bill makes no explicit provisions about labeling of GMO products thereby denying the populace their right to choose products free from GMOs. The truth about biotechnology must be shared with consumers without propaganda so that they can make well–informed decisions about whether to purchase GM products or not to purchase GM products.

Additionally, labeling is also important because it enables the public to hold accountable companies whose products may have caused harm/damage to both humanity and the environment.

The labeling is one way of ensuring that this information gets through to educate the public in an unbiased way, ensuring consumer choice and awareness of the issues surrounding use of modern technology like in GMOs.

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6 ‘Labeling’ means any written, printed, or graphic matter that accompanies a food or is displayed near the food, including that for the purpose of promoting its sale or disposal.

7 Article 18 of the Cartagena Protocol states that in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, each party shall take necessary measures to require that living modified organisms that are subject to international trans–boundary movement within the protocol are handled, packaged and transported under conditions of safety taking into consideration relevant rules and standards.
B. Proposal

- The Bill should provide for labeling requirements as central to the process of releasing GMOs into the market. The provision incarnate in the Bill should provide for spelling out of regulations by the relevant Minister to comprehensively address the procedure of labeling. The regulations should spell out issues concerning Food safety assessment before labeling; Labeling and packaging requirements; Monitoring inspection and compliance; genetically modified organisms labelling register; Offences and penalties among other critical issues.

- Clause 44 (2) (c) should be amended to include ‘labeling’ to read as ‘…Minister may after consultation with the Competent Authority make regulations for handling, transport, labeling and packaging of genetically modified organisms;

**REASON 2: The Bill lacks adequate provisions relating to right of citizens to participation and education**

A. Analysis Note

Globally, public participation is recognized as an important tool for promoting sustainable economic growth and development. Therefore, public participation with regard to biosafety and biotechnology is a necessity and is not a matter of choice in the development of a national bio–safety law system. It is also important to note that given the concerns surrounding biotechnology, significant public involvement in bio–safety legislation process is an essential strategy for building public confidence in the legal and regulatory process.

HURINET–U takes cognizance of the import of Clause 7 (1) (I) which mandates the Competent Authority to ‘promote awareness and education concerning activities regulated under the Act and to co–ordinate public participation.’ In the same vein, Clause 8 also provides for mandatory co–operation of the Competent Authority with government departments, agencies, and ministries in the implementation of the law.

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The provisions fall short of providing for a clear procedure on awareness raising and public participation in the decision making process of biotechnology development. Clause 8 is restrictive in as far as it does not mention other players such as civil society, academia, farmers and the general public. The Cartagena Protocol on bio–safety requires all parties to promote and facilitate public awareness, education and participation of all stakeholders.9

B. Proposal
Parliament should adopt Article 5 of the African Modern Law on Biotechnology relating to public awareness and participation

Art 5 of the African Modern Law on Biotechnology provides a model provides:

1. The Competent Authority shall, upon receipt of the information make available the said information to the public and relevant government authorities.

The Competent Authority shall make available to the public:

i. Information on any genetically modified organism or a product of a genetically modified organism, which has been granted or denied approval for making, import, contained use, release or placing on the market; and

ii. Any risk assessment report with respect to the genetically modified organism or the product of a genetically modified organism.

3. The Competent Authority shall promote awareness and education of the public and those conducting activities on genetically modified organisms or products of genetically modified organisms subject to the law concerning bio–safety matters through the publication and dissemination of this law, as well as guidance documents and other materials aimed at improving the understanding of bio–safety and related authorization and notification requirements.

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9 Article 23 of the Cartagena Protocol states that parties shall promote and facilitate public awareness, education and participation concerning safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity taking into account risks to human health. In doing so, parties shall cooperate as appropriate, with other states and international bodies.
4. The Competent Authority shall establish a mechanism of public participation and shall arrange for a public consultation and/or public hearing with regard to any proposed making, import, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism, this fact shall be announced nationally not less than 30 days before the decision is made shall be given for consultation.

5. The public may make comments within such a period and in such a manner as may be specified by the Competent Authority. The Competent Authority shall, in making or reviewing its decision, take into account the views and concerns of the public.

REASON 3: Inadequate Provisions relating to prevention or reduction of the risks to biological diversity and human health

A. Analysis Note
It has proven difficult so far to predict the impacts of this on the environment and human health. It is on the basis of these concerns that an internationally binding Bio-safety Protocol to regulate the safety of international trade in GMOs was adopted under the auspices of the UN Convention on Biological Diversity on 29th January 2000.

Under the Cartagena protocol the state parties are mandated to ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health. In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements.

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10 The objective of the protocol is: “to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements.”

11 Article 2 (2) of the Cartagena Protocol on Bio-safety to the Convention on Biological and Diversity
effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on trans boundary movements.

The Cartagena Protocol therefore recognizes the precautionary principle as a means of regulating any undertaking for the import, contained use, release or placing on the market of genetically modified organisms and products of genetically modified organisms\(^\text{12}\) the Model Law also embraces the precautionary principle and recognizes the sovereign right of every country to require a rigorous risk assessment of any GMO for any use before any decision regarding the GMO is made. It captures the essential elements for a liability and redress regime, which should be incorporated into domestic bio–safety legislation. It also provides stricter controls regarding the introduction and use of genetically modified food as food aid.

The Bill makes an attempt to mitigate risk to biodiversity and human health. Clause 29 of the Bill provides that the applicant shall carry out an assessment of \`any risk associated with a GMO and submit a risk and safety assessment report to the relevant authorities which shall evaluate the risk in accordance with prescribed safety standards.\(^\text{13}\) Clause 29 (3) bars the Competent Authority from approving an application which does not show that the risk is unavoidable or can't be mitigated. Under clause 30, where unintentional release occurs, the applicant is mandated to inform the Authority of such an accident within twenty four hours of such risk and the authority is meant to take appropriate measures.

Whereas this is a novel initiative the precautionary approach should be widely applied such as where accidents occur the general public should be widely informed through the media. The Bill in question has raised controversy because of some health, scientific and environmental questions which are not yet completely resolved in respect to GMOs.

**A. Proposal**
- Risk assessment should be conducted by an independent body. It is doubtful that the applicant who is seeking to be granted permission to carry out a genetic engineering activity will produce an adverse risk assessment for the proposed work or reveal the findings if they negate

\(^{12}\) African Model Law on Safety In Biotechnology
\(^{13}\) Clause 29 (2)
his chances of being granted a license. It defeats the well founded principle that a man cannot be a judge in his/her own case more so if the judging otherwise against self, can occasion commercial loss.

- All applications must contain emergency plans to manage unintentional environmental releases
- There is need to ban the commercial release of certain GMOs that have been found to be very toxic.
- A sub-clause be added to clause 30 to require the Authority or applicant to inform the general public of such an accident including measures to be taken so as to safeguard human health and the environment through the media of wide coverage. Such accidents may be hazardous and should not be concealed between the applicant and the authority alone.

**REASON 4: Weak and uncoordinated institutional framework to handle the regulation of Modern Biotechnology**

**A. Analysis Note**
A number of institutions are established under the Bill for the Management of Biotechnology and Bio-safety in Uganda.

1. **Ministry Responsible for Environment (National Focal Point)**
The Bill provides under clause 4 and 5 that the Ministry Responsible for Environment will act as the National Focal Point. It will also coordinate exchange of information between relevant ministries and departments of government and approve research, testing and general release of GMOs.

2. **Competent Authority**
The competent Authority\(^1\), along with other bodies is responsible for the implementation of the Act and specifically with governing and making decisions relating to the application procedure for anyone looking to develop, produce, use or application of genetically modified organisms in Uganda. The Competent Authority is the Uganda National Council for Science and Technology (UNCST) under clause 6 and 7. Its core function is to give information to the Ministry in charge of Agriculture, set standards and issue

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\(^1\) Clause 6 and 7
guidelines on safety, research and testing including taking all necessary measures to avoid the adverse effects on the environment, biological diversity, human health and on socio economic conditions arising from GMO.


The National Bio–safety Committees (NBCs) is established under clause 9. The committee consists of eleven members to be appointed from various government and nongovernmental sectors. They are mandated to review applications for testing and general release, advise Competent Authority on fees, new scientific information, comments received from the public, advise Competent Authority on implementation of Act (cl. 9,10), recommend mitigation measures in biotechnology use.

4. The Institutional Bio–safety Committees

The Institutional Bio–safety Committees (IBC) are established under clause 14. It’s envisaged that every institution registered under the Act must have a bio–safety committee comprising of not less than five persons with at least three of them having knowledge in bio–safety. They are mandated to; approve laboratory and contained testing, Review, monitor and supervise laboratory experiments, contained and confined testing, Recommend applications for confined testing and general release to Competent Authority.

Clause 15 provides for the approval of research and development of biotechnology. The different stages of research include; laboratory experiment and testing. Before one conducts a laboratory experiment, he/she should be approved by the Institutional Bio–safety committee within 21 days of the committee notifying the competent Authority. The clause is silent on the role of the Competent Authority at this stage.

The provision is loose without enough restrictions in relation to what approval is and who approves under the Act. It can be open to abuse since approval under the Act is at different stages. The prohibition is restricted to only ‘research and general release’, of GMO yet there are other wide range of activities that can also impact negatively on health and environment yet not provided for.

Clause 29 provides for a prominent role by the IBC as almost similar to that of C.A in assessing risks. The Bill makes no distinction and blurs accountability lines when it grants approval and evaluation of risk powers.

15 Clause 19 (1), (3) and (4)
to the IBC. This can raise conflict of interests since the IBC is an interested party in any GMO related activity.

The exact role of the Component Authority (CA) is not clearly spelt out. How does it treat the risk assessment report provided by the applicant? The Bill is not instructive on how the information provides should be treated by the CA? And as to whether the CA can carry out its independent assessment. Generally, the bill is silent on the criterion that will be followed by the CA to determine the status of application.

A. Proposal

- The competent authority should be mandated to prepare risk assessment for each application for release of GMOs under the Act. It should take into account risks posed by the release including any risks to the health of people or risks to the environment. In so doing, the competent authority should be supported by other subsidiary bodies established under the Act.

- Farmers groups should have more representation since they will be more affected in the event of release of GMOs.

- The Bill should have a provision to the effect that decisions shall place significant emphasis on whether the deliberate release represents a benefit to the community and a contribution to sustainable development and that that a product may only be approved for release when there is no risk of detrimental effects on health or the environment.

- There needs to be set guidelines to direct the work of the committees, criteria for appointment so as to avoid bias and compromise.

- Proposal for amendment of Clause 15 relating to research and general release of GMOs to Provide for who approves and in what mode (Authority should approve and in written form) and provide for prohibition of engaging in ‘any activity’ concerning GMO so that every potential activity there under is captured.

- The Competent Authority should have the power and capacity to audit the reports of the IBC. The IBC has been given emerge powers which can be abused hence the need for checks.
1. There should be a technical back up team over and above the members of the Competent Authority.

2. The Competent Authority should constitute a representative from all the institutions handling GMOs and the Public.

   1. Restrict and ring fence risk evaluation powers and approval rights to the CA to act as an oversight body over IBCs.
   2. Provide for the CA carrying out an assessment of its own and 'audit' the risk assessment report submitted by the applicant and not necessarily to be taken as gospel truth since the applicant has a vested interest in providing 'good report' to facilitate the approval.
   3. Provide for its findings report for the assessment to be the basis of its decision–wherein other critical issues can be dealt with including indicating any measures to be taken to ensure the safe use of a genetically modified organism.
   4. Provide for the authority liaising closely with the regulatory authority or IBC to come up with appropriate measures to manage and control risks identified during the risks assessment process.
   5. Provide for criterion of determining an application to include among others socio–economic considerations arising from the impact of the genetically modified organism on the environment, any relevant representations submitted by members of the public among others.

**REASON 5: Inadequate provisions for proper and clear risk management systems**

**A. Analysis Note 1**
Given that the goal of GMO technology is to create novel organisms, many of the risks associated with such activities will be complex, indefinable and difficult to anticipate with any degree of precision. It is therefore important to acknowledge uncertainty and deal with it using the precautionary principle. It denotes that when you are going to use a certain portion then you must conduct an impact assessment. There is need to conduct risk assessment covering both human health and environmental safety.
Under Clause 22 (3), the Bill provides for the publication of the application for the general release of the GMO in a Gazette and official website of the Authority as a notice of the application. The application shall contain among others the name and identity of the GMO, intended date of release, intended use, suggested method of safe handling, storage and transportation. The competent authority then notifies all ministries and agencies with functions relevant to the application, publish the same in the gazette for comments. The Clause also creates an obligation for the public (any person or ministry) who may have a concern in relation to the application to forward it to the Authority within 30 days of receipt of the notice. The choice of means of communication limits the number of people who can access this information.

B. Proposal

- Amendment of Clause 22 to provide for the mode of publication of the notice general release in addition to the Gazette, the official website of the Authority; include at least two newspapers with nationwide circulation, and in an appropriate electronic media such as Facebook. This is vital for information purposes to the public and in tandem with the notion of access to information and also a participatory approach to GMO issues.

- In addition to gazetting, consultations should be sought from the general public who have interest in the application. The public needs to know and understand the processes that will affect their socio-economic lives.

- The Clause should further provide for the extended and mandatory obligation of the Authority to respond to the concerns raised by any person on the application for release. This should be included as a proviso concluding Clause 22(4).

A. Analysis Note 2

Clause 23 on Application for import, transit or export of a GMO. The application for importation provides for pre-determined information by the law that should be forwarded to the Authority together with the application. The application for import among others should contain approvals from the country of origin of the GMO and any other country.

The Clause is not flexible enough to allow the Authority to request for any other information that may come to its knowledge before or during
the processing of the application. The proviso relating to transit subjects the applicant to a low standard of just ‘describing the method for safe transportation of the GMO’, the bar should be raised to demand an obligation for the applicant to secure proper package of the product so as to avoid cases of spillage in Uganda which maybe harmful to human and the environment.

In relation to importation, the Bill is based on the presumption that the GMO will be accepted in Uganda as the destination country. Whereas it’s good to get clearance from the country from which a GMO is being imported what is most important is to ensure that the product being imported is safe to the human, environmental health of Ugandans. A product which may have worked well in one country or been accepted in one may not be of good use in Uganda’s context depending on variances in ecosystem, environment, physical features and the terrain of the country.

A. Proposal

Amend Clause 23 to;

1. Include a proviso allowing the Authority to ‘request for any such other information that the applicant or the Authority may consider necessary for the assessment of the potential risk or benefits of importation of the particular genetically modified organism.’

2. Provide for ‘ensuring that the genetically modified organisms being transported are properly packaged and transported in accordance with such regulations as may be prescribed and any applicable international standards.’

3. Provide for proof of advance written consent granted by a relevant authority of the country to which the genetically modified organism is destined, to the effect that such relevant authority has no objection to the intended exportation. This is good practice necessary in maintaining standards.

4. Additionally, in as far as possible, every GMO importation, transportation or exportation should be handled on a case to case basis since no case of GMO from one particular country can ever be the same in view of the fact that there is a clear difference in ecological systems of each country.
A. Analysis Note 3
Under clause 24, the competent authority upon receipt of all the applications above, shall refer the matter to the NBC for consideration within ninety working days, two hundred and seventy working days and eighty working days for confined testing, general release and export, transit or import respectively.

However, clause 25 (a) allows the competent authority to expedite the application of research or general release of a GMO where a Competent Authority of another country has previously approved the same and such a country is in a comparable ecosystem. It may also expedite the process where a competent authority in another country has established that the GMO poses minimal risk to human health or environment\(^\text{16}\). Also where the conference of parties\(^\text{17}\) has exempted the GMO from the advance informed agreement procedures, or where there is a confirmed emergency or where it has previously been considered by the competent authority.

B. Proposal
Clause 25 (a, b, c) should be struck out because there are no two eco systems that are similar and undermines the ethos of the Cartagena Protocol. The Cartagena Protocol on Bio–safety requires that risk assessment should be carried out on a case to case basis.\(^\text{18}\) The required information may vary in nature and level of detail from case to case depending on the living modified organism concerned and its intended use and potential of the receiving environment. The provision defeats the purpose of the bio–safety legislation and does not use a precautionary approach because all GMOs must be subject to risk assessment.

A. Analysis Note 4
There is need to publicize widely the revocation of an approval. Clause 26 provides for conditional approval of a research or release of a GMO but subject to measures imposed to manage and control adverse effects on

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\(^\text{16}\) Clause 25 (b)

\(^\text{17}\) The Conference of the Parties established under the Convention on Biological Diversity is the governing body of the Convention, and advances implementation of the Convention through the decisions it takes at its periodic meetings. Accessed from: https://www.cbd.int/cop/

\(^\text{18}\) Annex III of the Cartagena Protocol states risk assessment should be carried out on a case to case basis. The required information may vary in nature and level of detail from case to case depending on the living modified organism concerned and its intended use and the likely potential receiving environment.
the environment, biological diversity, human health, and socio-economic conditions arising from a GMO. A conditional approval need not be upscale (should only be limited to laboratory tests or pilot schemes) to avoid the risk of averting the dangers that may arise.

An approval may be revoked or suspended under clause 27. The reasons include contravention of the conditions of approval, and such a suspension or revocation shall be published in the gazette and at least one newspaper of wide circulation. A party who is affected by this decision is however given an opportunity to be heard.19

B. Proposal
Such revocation should be published in at least two newspapers of wide circulation, including local languages and blacklisting of such an organization or product/activities involved so that the general public who do not access the gazette are informed of such revocation.

A. Analysis

Note 5
Clause 28 is to the effect that the competent authority may stop a person from researching, releasing or involving any GMO activity from continuing where its apparent that the activity will compromise the human or environmental safety or where one is conducting the activity without approval or where more information relating to the adverse effect of the GMO has been discovered.

A. Proposal
■ The clause should be mandatory and directive and use ‘shall’ instead of “may”.

■ Insert a new provision relating to GMO Free Zone. Taking into account the provisions of Article 26 of the Cartagena Protocol on Biosafety and the provisions of the Convention on Biological Diversity relating to conservation and sustainable utilization of biological diversity, the competent authority shall develop policies that protect the rights of communities to declare GMO free zones where the release of any GMO is prohibited.

19 Clause 27 (1) –(4)
**REASON 6: The Bill has gaps relating to access to justice by complainants**

**A. Analysis Note**

Clause 31 caters for restoration orders and provides to the effect that a restoration order may be issued in circumstances where an activity has been conducted without approval of the authority, damage caused and an order for stoppage of research has been given. A person so ordered above is mandated to restore the conditions as near as possible to the state in which it were before the release of the GMO. Such restoration order may carry a charge to the person on whom it is charged for restoration of the environment. The restoration to be performed by the applicant must be to the satisfaction to the authority that the applicant has undertaken all necessary measures to restore. Where damage has been caused, this should be factored in the fee to be levied.

The bill is silent on the nature of the activity and does not specifically address where the damage will occur for instance environment or human health. The liability and redress system has been vaguely defined. For example under these provisions 30–31 if a farmer’s crop was contaminated by GMO seeds then the farmer would have to prove that the person introducing the GMO was at fault and that they failed to follow the safety measures.

**B. Proposal**

- The restoration order should include compensation to the affected parties including an award for damages in instances where a farmer is unable to use his/her land for cultivation due to the effect of contamination by GMO.

- The Bill should have a strict liability provision where the applicant is held liable unless he/she can prove that it is not his product that caused the harm as envisaged under Model law. The Bill should provide for liability

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20 Clause 31 (2) (b)
21 A person who carries out a genetic modification activity is strictly liable for any harm caused by such a GMO under Article 14(1) of the model law. The capacity to sue has been extended to any person, group of persons, or any private or State organization. These may bring a claim or seek redress for the breach or threatened breach of any provision relating to damage to the environment, biological diversity, to human health or to socioeconomic conditions. The Model Law also calls in Article 11 for the labeling of all GMOs and products of GMOs for the purposes of traceability.
for damages by the person responsible for an activity pursuant to Bill regardless of any fault on his part when the activity causes damage, inconvenience or loss by deliberate release or emission of GMOs into the environment.

**Reason 7: Inadequate investigations and unclear complaint process**

**A. Analysis Note**
Part IV of the Bill provides for investigations and complaints. Clauses 33 to 36 provides for complaints handling mechanisms. These include investigations, appointment of inspectors by way of notice in the gazette. The inspector so appointed has powers to enter and inspect premises where he/she has reasonable grounds to believe that a document, information or article needs to be examined or where there is belief that there is a likelihood of an activity causing an adverse effect to the environment and human health. In so doing the inspector may seize, stop or quarantine the sale of a GMO that was released or imported illegally.

However, clause 35 (4) prohibits the inspector from entering a dwelling house without the consent of the occupants save for exigent circumstances. Whereas cognizance is given to the right to privacy under clause 35 (4) and (5) the entire part VI is not directive enough to the inspector. It does not mandate the inspector to carry out his work, the language used throughout is discretionary “the inspector may… instead of “shall”

**A. Proposal:**
The clause should be mandatory and directive and use “shall” instead of “may”.

**REASON 8: Lack of provisions relating to access and property rights**

**A. Analysis Note**
Another key conflict over GM technology that needs to be addressed by the Bill relates to ownership and accessibility to local farmers. Access to GM plant and animal materials is a function of diverse factors such political, economic standing of the person seeking access, ownership and control.

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22 Clause 35 (1) (a & b)
The grant of intellectual property rights for instance may have implications for access to plant and animal materials. S.8 of the Patents Act Cap 216 aligns Uganda’s Industrial law to TRIPS’ Provisions which makes modern biotechnology patentable. The provision of the Patents Act is to the effect that ‘An invention is patentable if it is new, involves an inventive step and is industrially applicable’.

It is important to note that an owner of GMO plants can restrict access to seeds by farmers. Provisions for biotechnology patents is seen as disadvantage foreign biotechnology firms and putting resource poor farmers at their mercy hence endangering the right to food and food security. This law should provide for the protection of farmers’ and community rights and in particular guarantee the farmers’ right to save, sow, reuse and freely exchange seed.

B. Proposal
Clear restrictions on patent licences in Uganda regarding seeds should be incorporated in the Bill with a cross reference to The Patents Act to provide protection to local Farmers.

Reason 9: The Bill is marred with broad interpretation, non–precision and confusion in definition of various terms used

A. Analysis Note 1
It is important from the onset to understand the distinction between biotechnology and genetic engineering. Biotechnology is any application of biological science that uses biological systems and living organisms to make or modify products or processes, while genetic engineering is more specifically an advanced form of biotechnology that involves the transfer of genes within and between species. Genetic engineering involves, for example, the insertion of a foreign gene into a plant and while this can mean that the plant now has a useful characteristic—such as being resistant to an insect or disease—the claims made that such changes bring only benefits are unfounded.

GMOs stands for Genetically Modified Organisms—also called genetically engineered seeds or foods. Biotechnology is defined as a means of any technique that uses living organisms or substances from living organisms to make or modify a product, improve plant or animal breeds or microorganisms for specific purposes.

A. Proposal
The distinction between the two should clearly be brought out. The GMOs are in different classes which should be reflected in the Bill to help in accessing risk and give guidance on the category of permits that will be issued.

B. Analysis Note 2
Clause 3 defines ‘general release’ to mean the deliberate introduction of a GMO. It defines biosafety restrictively to mean the safe development, transfer, application and utilization of biotechnology and its products. The definition of Biosafety should be extended to the prevention of large-scale loss of biological integrity, focusing both on ecology and human health. The Bill introduces various seemingly unscientific concepts for experimentation with GMOs. The first is the concept of ‘confined field trials, which the Bill tells us, is also the same as ‘contained use.’ However, this definition has been crafted in such broad terms so as to exclude the standard scientific definition of contained use that would typically refer to laboratory conditions. It appears as if no definition exists for the traditional scientific concept of contained use for the development and propagation of GMOs in secure laboratory conditions.

A. Proposal
Whereas the definition of Modern Biotechnology under the interpretation clause might be understood by scientists it should be simplified for the general public.

REASON 10: The Bill contains provisions with dual criminal liability

A. Analysis Note:
Clause 37 provides for offences and penalties of persons who engage in unlawful releases, research; fail to disclose false information among others. However clause 38 provides for dual liability where an offence committed a
body corporate is visited upon the directors of the company. Such a provision is an absurdity and does not comply with company law principles where a company is separated from its members save for where the directors can be held personally liable. The provision has personal liability, for directors or members, in respect of the offences, rather than corporate liability.

A. Proposal
Clear rules as to criminal liability should not be flouted. There is always room to lift the veil in cases where members of the company can be help accountable in company law, which rules should not be flouted. This provision should there be amended to deal away with issues of dual liability.

OTHER CONCERNS

1. Need for Oversight over Institutions handling Modern Biotechnology
The Competent Authority should appear and lay reports before parliament like other government institutions like the Uganda Human Rights Commission. The bill is silent on the independence of the institutions. They might be subjected to control, directions and autonomy of companies with vested interest hence the need for oversight mechanisms.

2. Assessing the Socio-economic impact
The bill is silent on the socio-economic considerations arising from the impact of living modified organisms on the conservation of sustainable use of biological diversity especially with regard to biological diversity to indigenous communities.

Corporate control by multinationals has increased over seed and agro-chemical markets at the expense of poor farmers. The products of biotechnology, such as GM seeds, are often protected under patent and monopoly production as the proprietary technology of the corporation who manufactured them. This may mean that farmers who have planted these seeds cannot replant the seeds from the harvested crop in order to grow the next season’s crop. Some activists have argued that this is a violation of the right to save seeds, while corporations argue that charging a fee for the use of the seed is necessary for them to be able to pay for their research and development costs.
Another concern is that GM crops are introduced faster than the development of the regulatory capacity in developing countries. Important to note is whether the Competent Authority technical expertise to audit applications for use of GMOs, in case of spillage and quick response to avert risks arising from GMOs.

There will always be voices on the need to exhaust conventional means (farming system without the application of alternative methods or genetic engineering). The question is whether Ugandans have fully exhausted conventional means before we debate on whether we need to introduce GMOs. If we are still using the hoe we cannot rule out that we have not fully exhausted the potential of conventional farming to address issues of food shortages and food security.

African Delegates to the FAO Extraordinary Session of the Commission on Genetic Resources had this to put forward;

“We strongly object that the image of the poor and hungry from our countries is being used by giant multinational corporations to push a technology that is neither known to be safe, environmentally friendly, nor economically beneficial to us. We do not believe that such companies or gene technologies will help our farmers to produce the food that is needed in the 21st century. On the contrary we think it will destroy the diversity, the local knowledge and the sustainable agricultural systems that our farmers have developed for millennia and that it will undermine our capacity to feed ourselves.” – 24 African Delegates to the FAO Extraordinary Session of the Commission on Genetic Resources, June 1998

It is quite important to understand and appreciate that there are a number of profit companies behind the GMOs campaigns whose main aim is to make profits. As we debate the National Biotechnology and Biosafety Bill it is very important not to ignore the economic debate underlying GMOs.24

3. **Separate legislation strictly targeting Genetic Modification Technology.**

Given that the goal of Genetic Modification technology is to create novel organisms, many of the risks associated with such activities will be complex,

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indefinable and difficult to anticipate with any degree of precision. The uncertainty around the effects on human health and environment will call for a separate law targeting this type of technology. A separate legislation will help us draft a more specific legislation to maximize the benefits of modern biotechnology without compromising human health and the environment. A number of countries have adopted specific legislation on Genetic engineering. For example, the Norwegian Gene Technology Act has been hailed for being a progressive piece of legislation in relation to protecting people’s interests. It is therefore important to acknowledge uncertainty and deal with it using strong legislation regime. Clarity around GM technology will help Uganda appreciate the benefits that comes with genetic engineering in addressing food shortage. Ugandans should be able to decide the best option available in addressing issues of food security.

CONCLUSION

Generally the National Biotechnology and Biosafety Bill in its current form establish an administrative permitting system for the introduction of GMOs in the country without adequate safe guards to human health and the environment. The bill contemptuously disregards biosafety in most of the provisions and fails to adhere to the key tenets of the Cartagena Protocol which establishes minimum standards on biosafety which are of paramount importance. In light of the foregoing, there is need to establish a strong legal framework to regulate GMOs in conformity with human health and environment of Ugandan farmers and consumers rather than promote GMOs as an agricultural advancement.

The Bill though envisaged as a solution to food insecurity in Uganda is lacking in several provisions. It does not cater for the adequate participation of Ugandans in decision-making concerning the development, transportation or importation of Genetically Modified Organisms. It has no provisions relating to labelling of GMO products so that Ugandans are able to know and choose whether they want to consume GMOs or organic products.

Given that the goal of GMO technology is to create novel organisms, many of the risks associated with such activities will be complex, indefinable and difficult to anticipate with any degree of precision. It is therefore important to acknowledge uncertainty and deal with it using the precautionary principle under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity to which Uganda is party to.

Particular emphasis should be put on the right to information, right of citizens to participate in various processes, right to health, the right to food and right to clean environment through clear and proper risk assessment mechanisms while debating this Bill before the floor of Parliament. The Bill should be subjected to the Human Rights Compliance Checklist.26

26 Launched by the Speaker of Parliament in 2013
About Human Rights Network Uganda (HURINET–U)

Human Rights Network Uganda (HURINET – U) is a national umbrella civil society organization which was established in 1993 by a group of eight human rights organizations and formally registered as an independent, non-partisan and not for profit organization in 1994. The identity of HURINET–U lies with its diverse membership of 53 NGOs drawn from organizations that are committed to a wide range of human rights issues which are complementary in terms of areas of focus including; economic social and cultural rights, civil and political rights, child rights, gender and women’s issues, peace building and conflict resolution, prisoners' rights. Members range from purely Ugandan NGOs to international organizations.

HURINET–U has remained a reputable institution and a member of regional and international campaigns. It hosts a number of national civil society campaigns and coalitions including; Coalition on Economic Social and Cultural Rights, Coalition on Freedom of Information, Uganda Coalition on the International Criminal Court,; Coalition on Police Accountability and Reform among others.

The institutional vision is to work towards "A society free from human rights abuse" with a mission of fostering the promotion, protection and respect of human rights in Uganda through linking and strengthening the capacity of member organizations at national, regional and international levels.

HURINET–U’s work is guided by the following objectives:

1. To promote and protect human rights as provided for in the regional and international instruments that Uganda is party to and as provided in the constitution of Uganda
2. To encourage close collaboration and networking among human rights organizations in Uganda;
3. To encourage optimum sharing of information and resources both human and material among human rights organizations in Uganda
4. To continually assess a collective impact in the Ugandan society occasioned by several programs of human rights organizations in Uganda among others