



REVIEW OF THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL 2012

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A. INTRODUCTION

This policy memo aims to contribute to the ongoing public debate on the National Biotechnology and Biosafety Bill which is before Parliament. The bill is intended to provide a regulatory framework for the safe development and application of biotechnology in the country. The advancement of modern biotechnology has been popularized as a powerful tool in alleviating poverty and enhancing food security. However it presents a wide range of socio-economic concerns and biosafety risks that require an effective legal regime. While the proposed bill is an important milestone in the quest for a functional and effective regulatory regime for modern biotechnology, it contains a number of contentious clauses that need to be reconsidered before passed into law.

B. KEY CONCERNS ON THE PROPOSED NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL.

B1. Application and scope of the bill

The bill is restrictive; it only applies to research and general release of genetically modified organisms (GMOs) and does not mention the full range of Genetically Modified Organisms (GMO) activities that require regulation. Cartagena Protocol to which Uganda is a party² mandates parties to ensure an

adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from biotechnology. The Cartagena Protocol is clear in Article 4 which specifies that the protocol should apply transboundary movement, transit, handling and use of GMOs and must consider risks to human health.³ The bill should explicitly regulate the full range of activities involved which include research, contained use, confined field trials, import, export and the general release of a GMO.

Policy Recommendation

In accordance with article 4 of the Cartagena Protocol, there is a sequential mode of regulation of any GMO from contained use to field trials and the general release of a GMO putting into consideration risks to human health and the environment. This provision does not comply with international obligations and needs to be reconsidered to ensure an adequate level of protection from the risks associated with GMOs.

B2. Critique of the Objectives of the Bill

Analyzing section 2 (a)-(h) of the bill, it is clear that the spirit of the bill is intended to promote the development of GMOs in the country and not regulate them. The first objective states that the bill will be used to facilitate and not regulate the introduction of GMOs in the country. This means that the bill will be used to create an enabling policy environment to ensure that GMOs are promoted in the country. The Cartagena Protocol stipulates that the precautionary approach should be used to ensure an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from biotechnology taking into account

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² Cartagena Protocol on Biosafety is a legally binding protocol to the Convention on Biological Diversity. The Protocol seeks to protect biological diversity from potential risks posed by genetically modified organisms resulting from modern biotechnology.

³ Article 4 of Cartagena protocol states that it shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity taking into account risks to human health.

risks to human health.⁴

The proposed bill facilitates the promotion of GMOs in the country without proper safeguards. For instance the bill does not mention the precautionary principle in the bill which is a fundamental aspect of biosafety legislation. This is a violation of the precautionary principle, a fundamental aspect of the Cartagena Protocol to which Uganda is a signatory. The Cartagena Protocol mandates parties to ensure an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from biotechnology. Generally, the provisions of the bill do not comply with international obligations and need to be reconsidered to ensure an adequate level of protection from the risks associated with GMOs.

Abandoning the precautionary principle reduces the liability of large multinational seed companies with regard to harm caused to small holder farmers and the environment. The mere fact that the bill does not mention the precautionary principle defeats the purpose of any biosafety legislation because it is important to be cautious of these emerging technologies.

In the other objectives 2(f-g), the bill promises more than it offers for example in objective 2(f); building strong institutional relationships among biotechnology stakeholders and objective (g); promote technology transfer and benefit sharing in the use of modern biotechnology. These objectives are not clearly articulated in the body of the bill and there are no specific strategies to achieve them .

Policy Recommendations:

- The main objective of the bill must be to provide a regulatory framework in accordance with the precautionary approach as enshrined in Article 1 of the Cartagena Protocol.
- The bill should state in its objectives that purpose of the bill is to minimize and manage risks that may be posed by genetically modified organisms to the environment and human health.
- Strategies should be developed to operationalize objectives 2 (f-g) in the bill.

B3. Critique of Proposed Institutional Arrangements

The bill establishes four institutions in sections 7, 9 and 14. The institutions are; Competent Authority; The National Biosafety Committee; The National Focal Point; and Institutional Biosafety Committee whose roles are prescribed

⁴ Article 1 of the Cartagena Protocol states that in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration, the objective of the protocol is to contribute to ensuring an adequate level of protection in the field of 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 biodiversity taking into account risks to human health and specifically focusing on transboundary movements.

in the aforementioned sections. The Uganda National Council for Science and Technology is designated as the competent authority in charge of granting approvals for the testing of GMOs. This includes ensuring safety of biotechnology to human health and the environment during the development and testing and use of a GMO among other duties.

The bill also establishes the National Biosafety Committee in Section 9 a multidisciplinary committee to advise the competent authority. While the multidisciplinary membership solicited from the different sectors should be applauded, we believe that farmer representation is not adequate. Since this bill is targeting farmers who are the greatest beneficiaries of these technologies, they need to sufficiently understand the impact of GMOs to make an informed assessment of the benefits and risks and chose whether to adopt or reject them. Involving farmers makes it easy to associate themselves rather than impose decisions on them and make them mere recipients.

Institutional Biosafety Committees (IBC) is mandated to regulate, supervise laboratory experiments as well as contained and confined testing. The IBC is also required to approve laboratory experiments and contained testing which should be conducted within the confines of guidelines set by the competent authority.

The bill further states that the IBC will be comprised of three members knowledgeable on biosafety. However, the bill does not stipulate the composition of the committee and also does not provide for public input into the decision making process.

Policy Recommendations:

- The composition of the committee should be expanded to five members, two of which should be farmer representatives. This will ensure greater participation and general knowledge of the impact of GMO that will be released.
- The competent authority should set guidelines for the approval of laboratory experiments to be carried out.
- S.14 (2) should stipulate clearly who comprises the IBC committee and must draw technical expertise knowledgeable on biosafety. Secondly, no person should sit on the committee in respect of a subject matter in which he has any direct or indirect interest of any kind.

B4. Decision making procedures

With regards to decision making, the bill states in section 22(1) that a person who intends to engage in research or general release of a GMO must first obtain “approval” from the competent authority which is the Uganda National Council for Science and Technology. It is important to note that with regard to GMO applications approval requires written authorization not “approval” by the competent authority. Furthermore in section 22(3) after receipt of the application,

the competent authority shall publish in the gazette and official website of the authority a notice in prescribed form of the application for general release. It is imperative that the publication should also be in all local newspapers throughout the districts where the GMO is being tested in the different languages so that an ordinary person can understand what the GMO is about and the risks involved. If the application is denied, the reasons should be published in a gazette or the official website of the authority.

Policy Recommendation:

The bill should include conflict of interest provisions under the Bill. Where disclosure of conflict of interest has been made that person should not be part of the entire decision making process if he or she has an interest of any kind.

B5. Review of Applications

The bill provides a mechanism for the review of decisions due to the nature of GMOs. This is important because circumstances may change and could lead to further risks to human health and the environment. However the bill in section 25 provides for the expedited review of an application for research and general release of a GMO where a competent authority of another country or established at regional level has previously approved research or general release of the GMO in comparable eco systems. This shows that Uganda is clearly in a hurry to release GMOs into the environment without any safety procedures as stated under the objectives of the bill. This provision 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 Biosafety states risk assessment should be carried out on a case to case basis.⁵ 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 receiving environment. The provision defeats the purpose of the biosafety legislation and does not use a precautionary approach because all GMOs must be subject to risk assessment.

Policy Recommendation:

Section 25 should be deleted from the bill because it abuses the precautionary principle which is a key tenet of any biosafety regulation. The bill must explicitly require all activities go through the entire approval process.

B6. Liability and Redress

The liability and redress mechanism provided in section 31 of the bill is inadequate and requires amendment. The bill provides for the issuance of a restoration order to a person responsible for an activity that causes damage by the unintentional release of a GMO. However the clause does not specifically address to whom the liability will

⁵ 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.

be borne whether jointly or severally and does not attach liability to the developer of a GMO or product. The bill is silent on redress mechanisms does not specifically provide for compensation for harm caused to the environment and/or the costs of reinstatement, rehabilitation measures that have been incurred where applicable.

Interestingly, the bill states that a restoration order may be issued where the activity of a person has caused damage. 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 to give protection to the multinational corporations that will be promoting their technologies and to ignore the rights of farmers. For example, under these provisions section (30-31) if a farmers 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. However, the bill would make it very difficult for affected farmers to expect compensation in such circumstances.

Policy Recommendation:

Uganda should apply the 'strict liability' provision which states that whoever introduces a GMO shall be strictly liable for any damage caused. A strict liability provision would deter reckless behaviour and claims of development when marketing GMOs. Incorporating a strict liability provision would be one way of operationalization of the precautionary principle which is a key element of the Cartagena Protocol.

C. IMPORTANT ISSUES THE BILL IS SILENT ABOUT

C1. Public Participation.

The bill is devoid of an elaborate public participation mechanism to involve citizens in the decision making process of biotechnology development in the country. The bill does not specify anywhere the right for the public to participate in the decision making process. The bill in S.7 (i) only mandates the competent authority to promote awareness and does not specify the rights of the public to participate in the decision making process. The Cartagena Protocol on biosafety requires all parties to promote and facilitate public awareness, education and participation.⁶

Globally, public participation is recognized as an important tool for promoting sustainable economic growth and development.⁷ Therefore, public participation with regard

⁶ 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.

⁷ Bather Kone & Mahlet Teshome: Public Participation in African Biosafety Regulations & Policies; African Union Commission.

to biosafety is a necessity and is not a matter of choice in the development of a national biosafety law system. It is also important to note that given the concerns surrounding biotechnology, significant public involvement in biosafety legislation process is an essential strategy for building public confidence in the legal and regulatory process. Consequently ignoring the requirements of public participation would not only undermine the legislative process but will go against the spirit of the Cartagena Protocol. As noted above, public participation is an important issue which should be captured in the bill and should not be relegated to any subsidiary biosafety legislation.

C2. Labelling

A comprehensive labelling and traceability system is a key feature of a biosafety law in accordance with article 18 of the Cartagena Protocol.⁸ Labelling and identification should include relevant traits and characteristics given with sufficient detail to enable traceability and facilitate verification. The bill is silent about labelling of GMO products that will be released into the open market. The bill must have an explicit provision on labelling of GMOs so that people can exercise

⁸ 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 transboundary movement within the protocol are handled packaged and transported under conditions of safety taking into consideration relevant rules and standards.

their right to choose products free from GMOs.

C3. Socio economic concerns

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 as enshrined in article 26 of the Cartagena Protocol. As stated above, the bill does not protect the rights of farmers in case of accidental release of a GMO they cannot claim compensation.

D. CONCLUSION

Generally the National Biotechnology and Biosafety Bill in its current form establishes an administrative permitting system for the introduction of GMOs in the country without any 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. It is our sincere hope that the recommendations pointed out will be given the necessary and deserved attention as Parliament continues to deliberate on the bill.

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