ADDRESSING PUBLIC CONCERNS ON THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL 2012

7. Does this Bill provide for regulation of Agricultural Chemicals and Seed Systems in Uganda?

- The Agricultural Chemicals (Control) Act 2007 explicitly regulates the production, distribution, importation, importation, and all dealings with agricultural chemicals including pesticides in the country.
- The Seeds and Plant Act (2006) provides for the promotion, regulation and control of release, processing, marketing, importing and quality assurance of seeds and other planting materials in the country.
- The proposed biosafety law is meant to ensure that any products of modern biotechnology, including GMOs - regardless of their purpose- do not cause adverse effects to human health, animal health, and the environment.

8. How deterrent should a penalty be?

- A penalty should be as deterrent as the effects of the offence committed. If the offence is of a grave nature, with dire consequences, then a penalty should be as deterrent as possible.
- Penalties should never be created based on emotions and perceptions.
- The Bill adequately provides for sufficient penalties, with respect to each offence. Each month of imprisonment is rated at two currency points. The proposed penalties are proportional to the rules under Uganda's legislations relevant to enforcement. The penalties propose imposing the value of currency points or imprisonment or both. The currency point is determined by the Ministry of Finance.

9. What should be defined in a law?

- Any new terms to country's legal system should be defined. But terms that are natural or already existing in the Penal or Civil Procedures (e.g. damage, person). The Constitution, and other laws such as "The Interpretation Act" need not be defined.
- Terms that are pertinent to this law have been adequately defined. Any suggestions for clarity can be channelled to Parliament for possible amendment.

10. What is needed for risk/safety assessment and management of GMOs?

- Risk/safety assessments and management are provided for in the Bill under Clauses 29, and 30; Schedule 3 (Form 1, Form 2, Form 3), and Schedule 4. These provisions are directly derived from the Cartagena Protocol on Biosafety.
- Regulations providing detailed procedures for risk/safety assessments and management will be developed by the responsible Minister in consultation with experts.
- Competent persons and facilities will be assigned by the Competent Authority the role of conducting these assessments. Since 1999, the Country in collaboration with various partners including the Convention on Biological Diversity (CBD) through the UNEP-GEF has invested in building human resource and infrastructural capacity for a functional National Biosafety Framework including capacity to conduct these assessments.

11. Who can apply to conduct research and import modern biotechnology products?

- The Ugandan law clearly defines who a legal person as.
    - An applicant is an English term which means a 'person who applies'.
    - No person shall conduct any GMO work without approval under this law (Clause 15).
    - The term person also means a body corporate.

12. What is the interpretation of the "Expedited Review Process" provided by the Bill?

- Clause 25 of the Bill provides for expedited review of applications for release of GMOs.
- Expedited review refers to quick review of an application where the Competent Authority waivers the set timelines of the application review process due to the nature of the application or circumstances e.g.
    - Emergencies such as famine or war and there is sufficient information that the GM food does not cause harm to human health.
    - If the application has been approved for a similar purpose by a neighbouring country or countries with similar ecosystems and information is sufficient to show that the GMO poses no harm to human health or the environment.

ADDRESSING PUBLIC CONCERNS ON THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL 2012

1. Why should we have a broad title for the National Biotechnology and Biosafety Bill?

- The Bill was formulated to operationalize the National Biotechnology and Biosafety Policy, 2008.
- GMOs technology is just one technique among many modern biotechnology tools that have internationally been agreed to be regulated. This Bill has a wider mandate than GMOs, later upcoming techniques such as animal cloning, gene editing and synthetic biology will be regulated by this law by developing relevant regulations.
- As a key requirement of the Cartagena Protocol on Biosafety, countries must put in place legal mechanisms to regulate all Living Modified Organisms, especially as relates to trans-boundary movement.

2. How does the Bill regulate modern biotechnology and GMOs?

- The Bill explicitly provides for regulation of modern biotechnology including genetic modification (GMOs technology).
- The Bill requires all persons and entities conducting biotechnology related work to register with the competent Authority, and empowers the Minister to make any other relevant regulations as relate to biotechnology use.
- All other clauses in the Bill directly specify the process under which review, approval or denial, risk assessment and management, identification and registration etc. are conducted.

3. Which Government agencies or authorities are responsible for regulating biotech?

- Government through Cabinet decision made in 2001, decided that the UNCST was the Competent Authority on matters of Biosafety, and this was communicated to the UN's Convention on Biodiversity Secretariat,
- A government agency promoting what it regulates is not unique or new—look at the Uganda Insurance Regulatory Authority, Uganda Diary Development Authority etc. An agency with best knowledge of the sector usually has a division to regulate it.
- Due to the cross-cutting multi-sectoral nature of biotechnology, the Bill requires the UNCST to cooperate with Ministries responsible for agriculture, health, environment, trade, labour and social development, information and communications technology and other relevant agencies in carrying out its functions.

4. How will the public participate in decision making?

- The process of preparing the National Biotechnology and Biosafety Policy of 2008 and the Bill have been thoroughly consultative. The records on these consultations may be accessed at the Science and Technology Committee secretariat.
- Under the Functions of Competent Authority: Clause 7 (1) (i) to **promote awareness and education concerning the activities regulated under this Act and to coordinate public participation**.
- Clauses 10 (b), 22 (3) and (4) empower members of the public to comment to the Competent Authority on any applications received and published in the national *Gazette* and their website.

5. Does the Bill provide adequate mechanisms for labelling?

- Under **Clause 44 (2) (c)**, the Bill empowers the Minister to provide clear regulations for handling, transport, **identification**, and packaging of genetically modified organisms. Identification is synonymous with labelling. The Parliamentary Committee on Science & Technology recommends adding the word 'labelling' in this clause.
- The methods of labelling have to be elaborated in the regulations to cater for the various modern biotech products and the nature of the market systems in our country, cognisant of formal and informal trade, nature of products, etc.
- Labelling should be unambiguous to avoid mis-information. *Labels should not be used scare the public from using products proven to be safe.*

6. What happens in the event of damage as a result of a GMO?

- Clauses 31 and 32 in the Bill comprehensively cover the liability of persons whose actions cause damage to human health, the environment, society. Rewording these clauses with the words **'liability and redress'** can be done if this clarifies matters to stakeholders.
- **Our Constitution under Article 28**, guarantees every person a 'Right to a fair hearing'. Liability should and must always be channelled to the responsible person for causing damage as guaranteed by our Constitution. **Article 50** gives rights to any person to seek redress from competent courts for any infringement of their fundamental rights and freedoms and the redress may include compensation.