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# Comments on the National Biotechnology Safety Bill of Uganda

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# Introduction

We have in the past, commented on several drafts of Uganda's biosafety law and will not repeat the issues canvassed therein regarding the role and influence of the United States. We have been requested by civil society groups to comment on the National Biotechnology Safety Bill, 2008, approved by Uganda's Cabinet during April 2008.

Uganda has steadily been drawn into the GM debate over the past years. In June 2008, two short months after the cabinet approved the 2008 Bill, news broke that the first ever field trials involving GMOs in Uganda had failed dismally. The GMOs in question were GM bananas developed by the National Agricultural Research Organization (NARO) in collaboration with the Katholic University of Leuven (KUL/Belguim) from genes isolated from rice, to increase resistance to black Sigatoka disease. The trials were supported by the United States Agency for International Development (USAID).

Indeed, USAID has been extremely active in Uganda over the years, aggressively promoting the adoption of GM technology in that country. It has trained several Ugandan scientists, supplied state-of-the-art equipment and installed a level-two Biosafety Greenhouse at Kawanda.[i] USAID is also funding GM cotton trials, and although field trials have been approved, these have not yet commenced.[ii]

GM banana research, however, continues to be a priority for Uganda – the world's second largest banana producer after India. Research regarding GM nutritionally enhanced bananas has attracted funding from the Gates Foundation,[iii] for the development and field testing of GM Cavendish bananas, utilising local cultivars modified to express either increased pro-vitamin A, vitamin E, or iron.

Uganda is also part of the Water Efficient Maize for Africa (WEMA)[iv] a five-year research programme to develop GM drought tolerant maize, under the auspices of industry backed African Agricultural Technology Foundation (AATF). WEMA is funded by the Bill & Melinda Gates Foundation, which has committed funding of $42 million[v] to the programme.

Money from USAID, the Monsanto Fund and the Gates Foundation is also paying for virus resistant greenhouse experiments involving GM cassava in Uganda.[vi]

Uganda, along with Kenya, are both poised to be testing grounds for various GMOs in the ensuing years. The Biosafety Bill will be an important tool to ensure that these activities take place. We offer our comments pro bono, to civil society in Uganda as a guide to pin pointing and highlighting the key problems with the Bill so that these may contribute to their further work in this regard.

## Key Findings

We have recently commented on the Biosafety Bill of Kenya approved by the Kenyan Parliament and it is our respectful view that the Uganda Bill is, in many respects, similar to its Kenyan counterpart, as if it was drafted by the same person/s. It bears little or no resemblance to the African Union's Model Law on Biosafety.

The Biosafety Bill establishes a typical administrative permitting system for the regulation of GMOs in Uganda. It is also an enabling statute in respect of which, secondary legislation will have to be passed to bring the legislation into force. As it currently stands, it is not legally operational. Field trials and the importation of GM food aid into Uganda will continue to take place in a legal vacuum.

The Bill introduces strange and confusing unscientific concepts for research and development involving GMOs. This appears to have been done with the intention of creating the impression that open field trials are undertaken in confined conditions where no adverse impacts to human health and the environment may occur. The Bill designates the country's National Council for Science and Technology as the competent authority in charge of GMOs in Uganda, including receiving GM applications and granting approvals. It has wide ranging powers set out in no less than 14 different provisions. Whilst written authorisations are required for GMO activities, and risk assessments for these activities must be conducted, any activity or GMO may be exempt from authorisation provisions or be subject to fast track procedures. Uganda is clearly in a hurry to introduce GMOs into its environment. Convoluted, cumbersome and contradictory provisions have been created in regard to cessation orders, access to information and confidential business information. The public will be hard pressed to understand the legal import of these provisions. Attempts have been made to ensure public participation, but these provisions may be of little comfort to Ugandan civil society if exemptions and fast track procedures are applicable for GMOs released into the environment or imported into Uganda for food, feed and processing. Duty of care provisions have been crafted as well as administrative measures for damage to the environment, restoration of the environment and so forth. However, these are not sufficient to deal with the complexities that underpin a comprehensive liability and redress regime. Labelling of GM foodstuff is another area requiring urgent and further work.

## Overview of the Biotechnology Safety Bill

### Definitions: Strange and confusing unscientific concepts

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. We have come to this conclusion because the definition anticipates that transportation of GMOs within physical barriers, usually in a greenhouse for example,

is a contained use activity. This is a far cry from level I-IV contained use facilities under laboratory conditions.

The Bill also creates a definition called ‘confined use’ which refers to a ‘field trial’ as opposed to a ‘confined field trial.’ This notion of field trials is one that envisages exposure of GMOs in the open environment yet with barriers to ‘effectively limit their contact with or impact on humans and the external environment.’ Limiting contact with the external environment is markedly different to avoiding contact with the external environment. No separate definition has been created for field trials as is commonly understood, and this is included as a release within the definition of ‘Introduction into the environment.’ The impression created by the term ‘confined field trial’ is that there will be no environmental impacts because the trial is ‘confined’-which is rather disingenuous.

## Scope

The scope of the legislation is broad and does not exclude any activity or category of GMOs from the purview of the law. It applies to all GMOs, and the full range of activities involved. It is curious that the term ‘making’ in relation to a GMO, as opposed to ‘development’ is used. Nevertheless, exemptions from approval requirements are contemplated, as discussed later in the paper.

## Objectives

The objectives of the Bill make it crystal clear that it is to be used as an instrument to facilitate research and development involving GMOs. In other words: the imperatives driving the legislation are to create the enabling policy environment for the roll out of untold GM experiments in greenhouses and in the open Ugandan environment. The Bill also recognises that GMOs present risks to human health and the environment and that these risks are to be tolerated through risk minimisation and management measures. There is no mention of the precautionary approach set out in the objectives of the Cartagena Protocol on Biosafety, to which Uganda is a Party.

## Institutional arrangements

The Bill designates the country’s National Council for Science and Technology as the competent authority in charge of GMOs in Uganda, including receiving GM applications and granting approvals. It has wide ranging powers set out in no less than 14 different provisions. A Biosafety Committee (BC) is also established, consisting of a group of technical experts, to render advice to the Competent Authority (CA). It is also the BC who will provide policy direction to the CA. The BC is meant to play a pivotal role in GMO decision-making as it is obliged to receive, consider and make recommendations on applications forwarded to it by the CA. Membership to the Biosafety Committee will be solicited from both the public and private sectors in 15 different categories.

The Ministry responsible for the environment is the National Focal point who will be the spokesperson in Uganda on behalf of the government on international issues concerning GMOs, including matters related to the Biosafety Protocol. Similar to the approach adopted in the Kenyan Biosafety law, the concept of regulatory agencies has been created to denote the various government departments that are involved in some or other way, with the regulation of GMOs.

## Conflict of interest

Since the Biosafety Committee is set to play a key role in GMO decision-making, the provisions in section 10 dealing with 'declaration and conflict of interest' should be robustly enforced.

## Conducting activities requires written authorisation

All the activities concerning GMOs that fall within the scope of the law require written authorisation from the CA. The Bill sets out the information in the schedules that will be required to accompany applications. This is a standard approach adopted in most biosafety regimes in Africa. Environmental releases will require an environmental impact report in accordance with the regulations under the NEMA Act.

## Risk Assessment

Section 31(1) creates an obligation on the applicant to carry out a risk assessment of any risks associated with a GMO in accordance with the principles and rules of the sixth schedule to the Bill. This provision does not make it obligatory for the applicant to ensure that every single application for contained use, field trials, general release, placing on the market, export and import is accompanied by a risk assessment report. Nevertheless, section 31(2) prohibits the CA from making any decision on any application to develop, import, use in contained or confined use, transit, release or placing on the market of a GMO, without an assessment of the risks to the environment, biodiversity, human health and socio economic conditions. The inclusion of socio-economic conditions is welcome.

Section 31(3) further requires the CA to ensure that the applicant's risk assessment report is evaluated and considered before any decision is made. Where the evaluation of the assessment shows that the GMO or activity poses unacceptable risks to the environment, biodiversity or health, the CA may refuse the application. In other words rather dire risks must be foreseen before action can be taken, which is not consistent with the precautionary principle.

## Risk Management

Section 32 creates a general duty on the CA to impose risk management measures to manage and control adverse effects on the environment, biodiversity, human health and socio economic conditions.

## Exemptions and simplified procedures

Section 21 (1) confers a discretion on the Competent Authority to exempt from the authorisation procedures, or apply simplified procedures, GMOs and categories of use that it determines are not likely to have adverse effects on human health and the environment. It is not known how the Competent Authority will come to such a decision if it does not scrutinise the risk assessment and other relevant biosafety data relating to such GMO or category of use and solicit also the expert opinions of members of the Biosafety Commitee.

Section 21(2) sets out six grounds for applying simplified information requirements and/or review procedures. These grounds, to a large extent, deal with previous approvals by other

countries and scientific information or knowledge existing there about the risks posed. The impression created by these provisions is that the whole notion of case-by-case biosafety assessments for field trials and environmental releases will be dispensed with especially for those GMOs that have been in commercial use for some time. These provisions are not scientific, contradict the Biosafety Protocol and will place the Ugandan environment in severe jeopardy. It is unscientific and not good biosafety practise to extrapolate decisions made in one country about the safety of a GMO in that country's receiving environment, to the Ugandan situation. An interesting provision for the application of simplified procedures is to be found in sub-section (d), to the effect that if sufficient information is available that any capacity of a GMO to spread in the environment and invade other unrelated ecosystems and capacity to transfer genetic material to other organisms will not result in adverse effects this will justify an exemption or simplified procedures. Does this mean data generated by industry or industry backed scientists about the behaviour of GMOs in other countries will justify short cuts being taken in Uganda?

These provisions also appear to contradict Committee is set to play a key role in GMO decision-making, the provisions in section 10 dealing with 'declaration and conflict of interest' should be robustly enforced.  the requirements for an EIA for environmental releases. It is also worrying that there is no provision for the Competent Authority to consult with the Biosafety Committee - where arguably the independent biosafety expertise will reside- before invoking these provisions.

## Review of decision

A regulatory agency or an applicant may request the Competent Authority to review its decision (approval) where there is a change in circumstances that may have a material effect on the outcome of the risk assessment upon which the decision was made, or additional scientific or technical information has become available that may have a material effect on the decision's conditions etc. The CA has the power to review its decision if it is satisfied that the change is warranted, and if so, it must substitute its earlier decision with another that takes the changed circumstances into account. It has 120 days to make up its mind to review its decision and come to a new decision. It must then give the applicant notice of the change of decision giving reasons therefore, and provide the applicant with a reasonable period of time to implement the new measures, where these have been imposed.

## Appeals

Anyone who is aggrieved by a decision of the CA has the right to, within 60 days, lodge an appeal against such decision with the Minister who is then obliged to establish an appeals board.

## Suspension, revocation and cessation orders

The Competent Authority can suspend or revoke any approval where there is contravention of the Act or a condition imposed consequent upon written approval being granted.
This provision can, however, only be come into play if the state is diligent in monitoring compliance. The Authority is required to give notice before suspending or revoking an approval, and allow the person thirty days to give reasons why the approval should not be suspended or revoked.

Where an approval is suspended or revoked, the Authority is required to publish the suspension or revocation in the Gazette and at least two newspapers with nationwide circulation.

Cessation orders may also be issued by the CA to a 'person' (arguably, the applicant) who is in noncompliance. The cessation order does not mean that the activity in question must cease, but provides the 'person' an opportunity to demonstrate compliance, within a reasonable period of time. This appears to be a claw back clause from the preceding provision dealing with suspension and revocation of approvals, although it is not clear whether these provisions are linked. The cessation order may be withdrawn by the CA once it determines that sufficient information exists to allow the activity to resume – without risk management measures – if there is no significant risk to human health and the environment. This appears to give the impression that an applicant is guaranteed minimum interference with its activities once it has been given approval. What is **significant** risk? In the earlier discussion, we pointed out that approvals will not be granted if a GMO poses unacceptable risks. An additional provision has been created in section 27(4), to the effect that where the CA has knowledge that an activity poses a threat to biosafety, it shall immediately take action to put necessary safety measures in place.

It is not clear why they have crafted the provisions dealing with cessation orders as these appear to duplicate those dealing with suspension and revocation.

Additional provisions dealing with cessation of activities are also provided for in section 32 dealing with risk management. Section 32(2)(c) provides that the CA in consultation with the relevant regulatory agency may order the cessation of any activity involving GMOs that are **proven** to cause risks to the environment biodiversity and human health or order the cessation of any activity which is being undertaken in violation of the Act or any decision made.

Section 39 also deals with cessation orders. Subsection (1) gives the CA the discretion, in consultation with the relevant regulatory agency, to issue a cessation order for the immediate cessation of an approved activity or for the immediate imposition of additional risk management measures. This can, however only be done IF the CA in consultation with the regulatory agency determines that there is an imminent danger posed to the conservation and sustainable use of biodiversity, also taking also into account the risks to human health on the basis of one or more tests conducted and evaluated in a manner consistent with acceptable scientific procedures; or in the event of non-compliance with the provisions of the Act or regulations. These provisions are very similar to those contained in the Kenyan Biosafety Bill which we have recently commented on. We repeat what we said in those comments that the grounds for issuing the cessation orders are severely constrained even in the face of imminent danger because scientific tests would first have to be conducted!! These provisions are highly irregular!

Taken together, the numerous provisions dealing with cessation orders are highly cumbersome and contradictory, as if drafted by several different people holding divergent views on the issues, giving the legislation a distinct schizophrenic orientation.

## Prohibitions

Section 32(2) (b) sets out an interesting provision dealing with the powers of the CA. It may, in consultation with the relevant regulatory agencies prohibit further import, transit, contained or confined use, release or placement on the market of any GMOs if it is satisfied that the GMO contains characteristics or specific traits which pose unacceptable risks to the environment, biodiversity or human health. 'Unacceptable risks' is obviously a key concept and will need scientific exploration so as to bring about legal certainty.

## Duty of care, safety measures and recovery of costs, restoration measures

Section 32(2)(e)-(g) set out a series of administrative type measures that are more relevant to liability and redress than to risk management (where the provisions are situated). Sub-section (2)(e) requires that the CA, in consultation with the relevant regulatory agency, place a duty of care on the applicant to prevent or limit harm to the environment, biodiversity or human health or to restore the environment to its previous state as far as it is feasible. Sub section 2(f) allows the CA to undertake the safety measures itself if the applicant fails to do so, and recover the costs incurred. Sub section2(g) deals with the taking of measures by the CA in the case of an imminent and serious danger to the environment, biological diversity or human health caused by a GMO at the cost of the person responsible for causing such damage.

Section 37(1) confers a discretion on the CA to issue a restoration order in respect of any matter relating to the release of a GMO into the environment, but does not make any mention of damage to the environment. Subsection (2) allows the CA to require that the environment be restored, to as near as it may be to the state it was before the release of the GMO, or claim the costs of restoration where restoration takes place by an authorised person or organisation.

## Monitoring and reporting

Section 32(2)(h) deals with monitoring and reporting and requires the applicant to submit reports periodically in respect of the monitoring and evaluation of risks carried out after approval of the import, contained or confined use, release or placing on the market of a GMO. A great deal will depend on whether the CA itself imposes the parameters for such monitoring, as opposed to allowing self regulation on the part of the applicant.

## Confidential Business Information

Confidential business information is defined as "that information, which is novel, has economic value and the economic value is enhanced by its being secret."

It is welcome that a definition has been created for CBI, to guide decision making and provide more legal certainty to a rather contentious issue. A general obligation has been created for the CA to protect the CBI of the applicant. The CA is also obliged to allow the applicant an opportunity to identify which information is CBI and to justify this claim. Where the CA disagrees with the applicant, the Bill requires that the CA consult with the applicant to come to an agreement. Where there is no agreement, the CA appears to be allowed to disclose such information provided that it informs the applicant of its decision, gives reasons for the decision, provides an opportunity for consultation and allows the applicant

to challenge the CA's decision in a review and appeal process. So, again, a lot of attention is paid to due process to protect the rights of the applicant.

A curious provision exists in section 31(1)(d) which provides that an applicant shall not disclose confidential information (as opposed to confidential **business** information) except with the written consent of the Applicant. CI is much wider than CBI-it can be any information that the applicant deems to be confidential information and does not have to abide by the definition of CBI. This provision thus undermines the provisions dealing with CBI as discussed immediately above. The only information that the public appears to have access to - and is guaranteed by the Bill – is that information identified in the Biosafety Protocol, which includes the following: the name and address of the Applicant; a summary description of the GMO and its purpose; a summary of any risk assessment; and any methods and plans for emergency response.

Section 34(3) makes it obligatory on the CA to make available upon written request, non confidential **business** information to any person about any GMOs authorised for international introduction in Uganda. Section 34(6) provides that the CA may make available to any person details of any application that do not qualify as confidential information. (the CBI has thus fallen away).

As in the case with the provisions dealing with cessation orders, the provisions on CBI and access to information are schizophrenic and contradictory.

Access to Information, public awareness, participation and consultation [sub-heading]

Section 7 dealing with the functions of the Competent Authority includes the function to maintain and make a data base on GMOs available to the public. (section 7(4)).

Section 7 dealing with the functions of the Competent Authority includes the function to promote public awareness and education (section 7(6)). Public comments will be received by the Biosafety Committee who must provide recommendations thereon to the Competent Authority.

When an application for release into the environment or placing on the market is made, the Competent Authority is obliged to publish this fact in the Gazette and in at least 2 newspapers with nationwide circulation. Anyone who has concerns about the application may, within 30 days from publication, submit their concerns to the Competent Authority who is obliged to address the concerns.

Section 34 deals with public awareness and participation and subsection (1) creates a general duty on the CA to co-operate 'as appropriate' with civil society. Subsection (2) is not entirely clear but appears to create the possibility for such co-operation to be set out in a document which civil society is able to comment upon within sixty days. The CA is also required to put mechanisms in place to respond to all reasonable questions and provide relevant documents related to the authorization requirements. The CA is also obliged to give notice in the Gazette of all decisions made regarding applications for general release or placing on the market. It is not clear when the CA must perform this function.

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