COMMENTS ON THE NATIONAL BIOSAFETY GUIDELINES FOR TANZANIA, THIRD DRAFT, JUNE 2004

FOR: PELUM, TANZANIA

By Mariam Mayet
March 2005

"Whether we like it or not, in future we will be compelled to adopt this [GM] technology" Charles Keenja, Tanzanian Minister of agriculture and food security, May 2004[1]

"Tanzania cannot afford to be left behind by technologies that increase crop yields, reduce farm costs and increase profits" Wilfred Ngirwa, Permanent Secretary, Tanzanian Ministry of agriculture and food security, February 2005 [2]

"I am so glad we will be able to produce cotton. Technology is likely to be our liberator." Member of Parliament, Songwe constituency[3], February 2005

[1] Tanzania looks abroad for GM advice SciDev.Net, 6 May 2004 http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=

[2] Permanent Secretary for the Ministry of Agriculture and Food Security GM Crop Tests Get Green Light in Tanzania SciDiv. Net 28 February 2005 http://www.scidev.net/News/index.cfm?fuseaction=readnews&itemid=1952&language=1

[3] GM Crop Tests Get Green Light in Tanzania SciDiv. Net 28 February 2005 http://www.scidev.net/News/index.cfm?fuseaction=readnews&itemid=1952&language=1

TABLE OF CONTENTS

BACKGROUND

On the 7 February 2005, the Permanent Secretary for the Ministry of Agriculture of the United Republic of Tanzania announced that Tanzania would begin its first field trials of Genetically Modified (GM) crops, in particular Bt cotton.[4] The trials, expected to commence "before October," 2005, are to be supervised by researchers from Sokoine University of Agriculture, Morogoro. Apparently, the field trials would take place in the regions of Mbeya, Rukwa and Iringa in Tanzania's Southern highlands where cotton production had been suspended in 1968 "in an effort to stop the bollworm spreading to the rest of the country."[5] It must be noted, however, that at least one field trial has already taken place in Tanzania involving a pharmaceutical-genetically engineered low-nicotine tobacco in the South of Tanzania. The trial apparently took place during 2002, authorised by the Ministry of Agriculture.[6]

Tanzania is a Party to the Convention on Biological Diversity and has ratified the Cartagena Protocol on Biosafety (Biosafety Protocol). Tanzania is a participant in the USAID funded Association to Strengthen Agricultural Research in East and Central Africa (ASARECA). ASARECA facilitates collaborative research between those countries linked to ASARECA (e.g. Uganda, Kenya, Ethiopia, Eritrea), US public and private sectors and international agricultural research centres.

Tanzania is also part of the East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Development (BIO-EARN). BIO-EARN is a programme designed to build policy and research capacity in agricultural biotechnology in Kenya, Uganda, Ethiopia and Tanzania, funded by the Swedish Development Agency (SIDA) with policy development funded by IBS/International Service for National Agricultural Research (ISNAR).

No doubt, its involvement in the ASARECA and BIO-EARN projects have served to pave the political path for the introduction of GMOs into Tanzania.

Tanzania is also one of the participating countries of the UNEP-GEF Biosafety Capacity Building projects and as such, receives funding and some capacity, to put together its National Biosafety Framework. *The National Biosafety Guidelines for Tanzania* Third Draft, June 2004, ("Biosafety Guidelines) is a part of the NBF.

However, the UNEP-GEF Biosafety Capacity Building project is seen by many NGOs as being structurally flawed inasmuch as it is designed primarily to coax governments to establish merely a permitting that will say yes to GMOs, rather than an effective biosafety regulatory system based on the precautionary principle. UNEP-GEF biosafety capacity building workshops have been criticised for their preoccupation with administrative processes, not paying enough attention to biosafety details and for focussing principally

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[4] GM Crop Tests Get Green Light in Tanzania SciDiv. Net 28 February 2005 http://www.scidev.net/News/index.cfm?fuseaction=readnews&itemid=1952&language=1

[5] GM Crop Tests Get Green Light in Tanzania SciDiv. Net 28 February 2005 http://www.scidev.net/News/index.cfm?fuseaction=readnews&itemid=1952&language=1

[6] Personal Communication, Muffy Koch , 15 November 2004. This information has also been confirmed by Tanzanian government officials.

on the implementation of the Biosafety Protocol, whereas biosafety regulatory frameworks must of necessity be comprehensive and holistic.[7]

THE NATIONAL BIOSAFETY GUIDELINES FOR TANZANIA

According to the Minister of State in the Vice President's office-Environment, the Honourable Mr Ntagazwa, the Biosafety Guidelines are meant to "facilitate the importation and use of GMOs and their products in Tanzania" (p. 3). Indeed, the Guidelines, which pay a great deal of attention to scientific details, establish a non-legally binding, voluntary framework for the introduction of GMOs into Tanzania. This framework is meant to compliment and mutually support national policies and legislation (p.8). The Guidelines also appear to be of a temporary nature in that one of its primary objectives is to "encourage and assist the establishment of an appropriate national regulatory framework" (E(i), p.8). It is unknown why the Tanzanian government has not chosen to draft legally binding regulations instead of opting for non-binding guidelines.

The Guidelines are made up of 105 pages, comprising of a bundle of measures: non-binding "regulatory" type measures that typify a permitting system for GMOs; extensive measures under the heading "Risk Management" dealing with different types of "containment procedures"; and ten annexes. The document is thus not only voluminous but may be quite intimidating to farmers and ordinary citizens in need of information.

It is beyond the scope of these comments to deliver a line-by-line analysis of the Guidelines. Indeed, such an enterprise will be extremely time consuming. Rather, the emphasis in this document will be on highlighting key issues with a view to providing a critical yet constructive analysis of such key issues. In doing so, the following striking features of the Guidelines have been identified:

- Its non-binding legal status and hence, its lacking the force of law for compliance and enforcement purposes. It therefore is sorely lacking "teeth" and is an extremely poor substitute for a legally binding biosafety regime;
- Its commitment to a public-private partnership for the introduction of GMOs into Tanzania;
- Its emphasis on field trials, yet its neglect of adequate biosafety regulation for commercial releases and imports of GMOs as food, including food aid, feed and processing;
- Its neglect of explicit reference to the precautionary principle in regard to decision-making ostensibly because it has already decided that it is prepared to live with certain levels of risks especially in respect of commercial growing and imports of GMOs and GMOs imported as food aid; and
- Its commitment to public consultation in order to neutralise opposition and win support for GMOs through "consensus building." In fact, no effort has been spared in the Guidelines to ally the fears of the public by committing to an open and transparent process.

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[7] Letter by African Centre for Biosafety to Charles Gbedemah, Regional Co-ordinator for Africa UNEF-GEF Biosafety Capacity Unit, titled Comments And Concerns: Unep-Gef Biosafety Capacity Building Workshop For Anglophone Africa, 2nd April 2004.

KEY ISSUES

Scope and "restrictions" on GMOs

The Scope of the Biosafety Guidelines is sufficiently broad to apply to all the relevant activities related to GMOs (import, export, contained experimentation, field trials, general releases etc) and to all GMOs irrespective of its intended use (p.7).

The Guidelines also contemplate restricting certain GMOs that have been set aside as those that "should not be introduced in Tanzania" (Annex II, page.76). These are grouped under Level of Safety Concern 5 (Level 5) and include "**organisms whose ecological attribute indicate that they may cause adverse effects on human health or on managed natural ecosystems, the consequences of which are predicatably high, and that no feasible types of confinement will allow safe conduct of research outside contained facilities**. Six categories of Level 5 GMOs are set out, including " history of adverse effects; ability to survive and proliferate; non-indigenous status; high frequency of exchange of genetic information with native populations, lack of techniques to minimise escape from research sites and recapture when adverse effects occur "etc.

It is indeed strange that what is required is that the "ecological attributes" of GMOs should be a factor in anticipating adverse effects, whereas the emphasis should be on the genetic construct of the GMO in question and its impact on the host plant, receiving environment and the inter-action between all of these elements over a given period of time. More curiously, it is also unknown why a GMO's "ecological attribute" should be an indicator for adverse impacts on human health! There also appears to be no good reason why adverse effects on the environment should be restricted only to "managed natural ecosystems." These exclusions also appear to apply mainly to GMOs to be imported into Tanzania for the purposes of field trials only, and does therefore not include GMOs that may be imported as food, feed and processing. It is thus an open question whether these restrictions also apply to commercial releases.

Finally, it can also be said that the approach being taken regarding the restrictions to be imposed on GMOs is not consistent with the precautionary approach as called for by the Biosafety Protocol (Article1), but is one that tends to seek **proof** of adverse effects on the environment and biodiversity, before the restrictions may be imposed.

It is highly recommended that Annex II (p.76) be redrafted in its entirety.

Private sector involvement

The Biosafety Guidelines set out a proposed structure for the institutional arrangements that will be responsible for the implementation of the NBF (p.9). It establishes the National Biosafety Committee (NBC), an advisory body to the relevant Ministers and competent authorities.

It should be noted that one of the functions the NBC is required to perform is curiously, "to facilitate socio-economic impacts" (1.2(d), p.10). **It is recommended that this provision be redrafted.**

The NBC is to be comprised of *inter alia*, governmental, and non-governmental organisations, and the private sector that are relevant to the issues of biotechnology and biosafety (pp10-11). It is indeed contrary to sound biosafety practise that the private sector, which will include the biotechnology companies or their agents responsible for the development of GMOs, should also be included in a forum of this nature. This is particularly pertinent since a National Biosafety Scientific Advisory Sub-Committee is required to be answerable to the NBC (p. 11). It is a concern that the NBC may be used by the biotechnology industry as important political and scientific leverage to ensure that the political, legal and scientific climate in Tanzania remains favourable to GMOs.

It is imperative that the entire biosafety regulatory system distance itself from the very industry it is meant to regulate. Failure to do so, will result in the public having scant public confidence in the regulatory system.

Permits

Permits are required *inter alia* for GMOs that may be imported into Tanzania as well as for field trials. (pp 12, 15). "Permit" is strangely defined as "a written document issued by the appropriate authority for the introduction of a GMO under conditions **that it will not present a risk of pest introduction/movement**" (p.6) own emphasis. It is unknown why the issuance of a permit of GMOs should be contingent upon the likelihood that GMOs may be accompanied by pest introduction or movement. The introduction and movement of pests are not the most important or relevant biosafety concerns that should be addressed when a permit is being issued especially in regard to environmental releases.

It is recommended that a simple definition of permit be drafted that does not deal with the risks posed by GMOs. A standard definition should be used.

Interestingly, applications for permits are to be made by the "applicant" who must either be a permanent resistant of Tanzania or in the case of a non-resident, a designated agent. In the case of a corporation, it would have to be a company incorporated in Tanzania. In other words, these provisions attempt to include local scientific institutions as far as possible in the experimentation of GMOs. It also serves as an incentive for foreign biotechnology companies to establish subsidiaries in Tanzania. It is thus likely that a high percentage of applications will be lodged by Tanzanian research institutions. It can also be inferred from these provisions that Tanzania has committed itself to a private-public partnership between its research institutions and the developers of the technology.

Field trials, general releases, risk assessment, and risk management

GMOs imported into Tanzania for the purposes of release into the environment are dealt with in accordance with the Advanced Informed Agreement (AIA) procedure of the Biosafety Protocol, except that whereas the Biosafety Protocol allows decision-making to take place in accordance with the precautionary principle (Article 10(6)), the Guidelines are silent on the precautionary principle (2.1, p 12). Although provision is made for the possibility that an application for the import of a GMO for field trials may be rejected (2.2 (c), p15), it is essential that decision-making in the first place, take place within a precautionary context as sanctioned by the Biosafety Protocol. Explicit reference

to the precautionary principle will go a long way to guiding decision-makers and inspiring confidence in the regulatory system.

"Release into the environment" is defined as "the use of a GMO outside the physical confinement found in a laboratory, a contained greenhouse, a fomenter or other contained structure." However, the Guidelines further distinguishes release into the environment is dealt with as "field trial" and "general release." Yet, the emphasis in the Guidelines appears to be biased in favour of field trials and not sufficient attention has been paid to the regulatory issues pertaining to general releases.

For the purposes of field trials, the entire Annex III of the Biosafety Protocol has been duplicated and incorporated as the risk assessment required for the purposes of the field trial of GMOs (3.1-3.4, pp 16-17). However, it is conceded that effort has been made to provide for risk assessment parameters that go beyond the minimum requirements of the Biosafety Protocol (pp. 85-88), as it should! This is welcome.

It appears as if social, economic, cultural and ethical impacts of GMOs may only be assessed when GMOs are to be commercially grown and not during the field trial stage. According to the Guidelines, these considerations are viewed as "covering a wide range of safety concerns, relevant for general release of GMOs (refer to **Annex VI** G)" (p. 17) At the same time, however, **Annex VI** deal with " Risk Assessment Parameters" that apply to both field trials and general releases. Thus, this apparent confusion or vagueness as to when exactly socio-economic impacts are to be taken into account should be cleared up.

As already pointed out, the Biosafety Guidelines deal extensively with risk management. The Guidelines define the objective of risk management " to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment regarding the use, handling, introduction and field release of GMOs" (4.0, p.17). The impression thus being given is that risk management measures are not meant to apply to general release of GMOs. The Biosafety Guidelines appear to give the following explanation therefore: " In current agricultural research development practices, conventionally modified organisms are generally extensively tested prior to commercialisation" and hence 'evaluations and data collection at each incremental stage… -Greenhouse, limited scale controlled field plots and large-scale multiple field plots-are conducted both to ascertain efficacy and to eliminate any organism or application resulting in unwanted environmental effects" (pp17-18.) The approach thus taken assumes that the data collected during field- testing will be sufficient to ascertain the absence or presence of risk and where it is determined that there is no risk, then no monitoring will be required once the GMO is commercially grown. In other words, the GMOs will be regarded as being "risk free." This approach is not consistent with the views expressed by scientists the world over that adverse environmental impacts, may only become apparent in the long term. A further question is, what about the monitoring of impacts on human health? Will this also fall to the wayside once the GMO has been authorised for commercial import and/or growing?

Post release monitoring

The above interpretation is supported by the provisions of the Guidelines dealing with post- release monitoring, which is required only where the risk assessment **determines that the continuous presence of the released GMO presents risk of harm** (p. 64).

The more ominous implications of the provisions of the Guidelines (5.2.4 p.64) are that even if risks to the environment are identified, the release will be allowed subject to the conditions that post release monitoring take place. Again, this approach is not consistent with the precautionary approach articulated by the Biosafety Protocol.

Tanzania is in advance, already deciding that it will accept certain levels of risk even before it has consulted with its populace, especially farmers as to the levels of risk they are prepared to live with, if any!

GMOs imported as food (aid), feed and processing

Special provisions have been drafted for food aid (6.3 p.67) and in this regard, all that is required is that the donor of the genetically modified food and feed comply with the prior informed consent principle and the notification requirements in accordance with Article 8 of the Biosafety Protocol dealing with "Notification" requirements read together with Annex IV of the Guidelines (p. 83.) Although this Annex makes reference to a risk assessment report, there is nothing in the Guidelines that suggest that this will be taken into account or that it may influence decision-making regarding the acceptance of GM food aid.

Additionally, the Guidelines require that GM grain donated as food aid also be milled prior to distribution to beneficiary populations. These provisions are consistent with the recommendations made by the SADC Committee on Biotechnology and Biosafety, and are welcome.

No further provisions as to risk assessments and safety considerations regarding the impact of human health are made. In other words, as long as GM food aid is milled before distribution, and the national focal point is properly notifies and gives its consent, GM food aid will be able to stream into Tanzania without any further biosafety restrictions.

These provisions are, however, also meant to apply to bulk shipments of GMOs entering Tanzania as food and feed (other than food aid, as trade). Such GMOs need to be specially cleared as "commodity imports" and as such, require rigorous food safety assessments. **Special provisions must therefore be drafted for imports into Tanzania, of bulk shipments of GMOs imported and to be used in Tanzania as food, feed or processing. In sufficient attention has been given to the transboundary movement of GMOs entering Tanzania as food, feed and processing. The bulk of the trade/cross border movement of GMOs takes place in this category of GMOs. Rigours safety assessment provisions must be drafted including decision-making based on the precautionary principle.**

Placing on the market (labelling of GM products)

Placing on the market of products (dead or alive) of GMOs is dealt with in Annex V (p.84). The most interesting provisions are those contained in Section C of Annex V dealing with the labelling. In this regard, the following information concerning labelling of products would be required:

1. The words "This product contains GMOs" whenever there is evidence of the presence of GMOs in the product;

2. The words " This product may contain GMOs" where the presence of GMOs cannot be ruled out;
3. The words "This product may cause…(specify the particular reactions, allergies or other side effects)" where it is known that a particular reaction, allergy or other side effect may be caused by the product;
4. Where applicable, further as a qualification to (1) and (2) above, the words "This product contains genetic material (nucleic acids) from GMOs" or "This product is based on raw materials from GMOs."

These measure are very welcome and represent a good start for the further development of a labelling regime. However, in order to ensure adequate enforcement, products should routinely be subject to testing. However, as pointed out earlier, the Guidelines are voluntary and non-binding. Hence, enforcement of these provisions will be a challenging task for the Tanzanian authorities.

Socio economic impacts

Socio-economic considerations are dealt with in Annex VI (Risk Assessment parameters, p.88). It is required that parallel to and simultaneous with the scientific risk assessment, an evaluation of the socio-economic risks should be undertaken by the relevant Ministries. The parameters for such enquiry is established (6 extremely relevant and well thought out socio-economic enquiries are set out all of which go well beyond the provisions of the Biosafety Protocol as set out in Article 26 of the Protocol. These provisions are welcome.

As already pointed out earlier, there appears to be some confusion about when exactly the socio-economic assessment is to take place. It is recommended that already during the field trial stage, socio-economic considerations be taken into account because by the time it gets to the stage where the GMO is to be commercially approved, it may be too late for the Tanzanian authorities to day no, even if adverse socio-economic impacts are identified.

Liability and redress

The Guidelines contain good provisions on liability and redress, inspired no less in this regard, by the African Model Law on Safety in Biotechnology (African Model Law). The problem of course, is that the Guidelines are just that-Guidelines. They are voluntary in nature, and as such lack the force of law and are not enforceable in a court of law.

As such, these provisions will not serve the desired purpose, namely, to act as a deterrent against the introduction of risky GMOs into Tanzania.

Public Participation

The Guidelines reflect a commitment by the government to involve a wide range of stakeholders through a consultative process in order to promote and facilitate public awareness and public participation as stipulated in Article 23 of the Biosafety Protocol (8.1 p.69). This commitment is well taken, but it exists within a paradigm of acceptance of the inevitability of GMOs to be released into the Tanzanian environment and food supply, as opposed to one that seeks prior consultation with the public, before GMOs

are introduced. Hence, public acceptance is thus being sought for the technology in the sense that the public's support is being enlisted to implement biosafety measures (8.1.1 p.69) and to this end, public awareness and participation is seen as important for consensus-building and to build a sense of ownership and collective responsibility etc. (8.1.1. a-g, p69).

Public awareness and participation is to apply at all stages of the biosafety decision-making process. The Guidelines also ensures that notice would be given to the public though the media in a language understood by the public in a timely and effective manner (8.3 p. 71) and adequate and reasonable time frames for public participation are assured. Public consultation is aimed at securing wide input into decisions and are to include public hearings in certain cases, particularly where there is public concern about the proposed measures. These consultations are meant to encourage exchanges of information between applicants and the public before the application is acted upon. "Dialogue and consensus building among all stakeholders should be encouraged"(pp. 70-71)

Every effort will thus be made to ensure that the public is brought and "bought" into the process and where there is opposition, that such opposition is neutralised through "consensus building."

Access to Information

The Guidelines commit the government to respect the right of the public and relevant stakeholders to information about applications for research, development, field trials etc. The National Biosafety Focal point is instructed to *endeavour* to make certain information available to the public, including, information on all GMOs which have been authorised or refused authorisation, risk assessment reports and evaluation reports of the outcome of the risk assessment (p70.) These provisions are not sufficiently strong to guarantee the right of the public to access relevant information that it may need, to interrogate risk assessments and risk evaluations. However, arguably, since these provisions exist as they do only in non-legally binding Guidelines, there may well be other existing legislation in place in Tanzania at the moment that the public could use to access information. Although access to certain information is guaranteed, such as the name of the applicant, the general description of the GMO, a summary of the risk assessment and emergency measures, this is merely a duplication of the provisions in the Biosafety Protocol.

The saving grace though is that access to information on biosafety decisions (approvals and denial) appears to be guaranteed. This information is to include: a summary of the application, results of the scientific risk assessment and the evaluation of socio-economic risks; the public participation process followed and the basis for the approval or denial of the application (p. 71).

Although the protection of confidential business information (CBI) is also a requirement, interestingly, information will be regarded as CBI if there is a declaration that the information specified is a trade secret, or "any other information that has a commercial or other value that could be destroyed or diminished if the information were disclosed; or other information that concerns the lawful financial and commercial affairs of a legal or physical person that if it were disclosed it would reasonably affect that person". (pp 70-71). These provisions demonstrate that the Tanzanian government has given thought to the tensions between the public's right to know, and the need to protect the genuine

CBI of the developer of the technology, as opposed to hiding information from the public.

Additionally, the Guidelines contemplate a situation where even CBI may be disclosed if it is in the public interest. These provisions are welcome.

Conclusion

A legally binding biosafety regime is indispensable and indeed, irreplaceable. It is highly recommended that every effort should be made to put in place such a regime. Guidelines that lack the force of law are a poor substitute and should be discouraged.

The comments highlighted here have been made with the intention of contributing to a process that is designed to put in place a sound biosafety regime, based on the precautionary principle and the African Model law. It is evident from the limitations inherent in the Biosafety Guidelines that much work needs to be done towards this aim.

Nevertheless, every effort should be made towards its achievement. Having said that, several provisions contained in the Guidelines are good and represent sincere efforts towards fostering good governance.