COMMENTS ON THE PROPOSED BIOSAFETY REGULATORY REGIME OF THE REPUBLIC OF MOZAMBIQUE, (COMPRISING A COMPONENT OF THE DRAFT NATIONAL BIOSAFETY FRAMEWORK, MARCH 2005)

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The African Centre for Biosafety has been approached by a coalition of non-governmental groups in Mozambique, to provide comments on their country's draft Biosafety Regulation, with a view to contributing to its improvement. We have also been in touch with Mr Paulino Munisse, from the Mozambican National Biosafety Co-ordinating Committee and National Institute of Agriculture Research, who also, similarly expressed his gratitude to receive these comments.

Our comments are thus proffered in the spirit of friendship, in the interests of protecting the health of the people of Mozambique, their cultural and environmental heritage, and agricultural systems from the risks posed by genetic engineering and genetically modified organisms (GMOs).

INTRODUCTION AND SUMMARY

The proposed biosafety regulatory regime (hereafter referred to as the “draft biosafety law” or “biosafety law”) of the Republic of Mozambique consists of a draft Decree of Council of Ministers, containing the biosafety regulation and 2 draft technical guidelines for risk evaluation as well as public awareness and participation in biosafety and biotechnology related issues.

The biosafety regulation itself consists of a preamble, 27 articles, organised in 9 chapters and 6 annexes, and a glossary of terms.

The draft biosafety law is typically a permitting system, based on a step-by-step, case-by-case risk assessment, evaluation and decision-making that adopt a risk management approach to genetic engineering in food agriculture and medicine. By this we mean that Mozambique views genetic engineering as having a role to play in agriculture, food security and human health care, but that the risks have to be managed by the creation of an enabling legislative environment, to this end. In other words, Mozambique will follow the route taken by South Africa and permit the entry of GMOs into its agriculture systems, after a desk- top evaluation of the risk assessment data provide by an applicant.

Currently, Mozambique’s seed law prohibits the import and planting of GM seed. However, Mozambique accepts genetically modified (GM) food aid, including and especially from the United States. According to the United States Agency for International Development (USAID), the US government has allocated nearly $12.6 million in humanitarian assistance to Mozambique for 2006. USAID’s Food for Progress (FFP) has provided 15.500 MT of P.L480 Title II emergency food assistance valued at %11.6 million to Mozambique through the World Food Programme. (USAID, Southern Africa-Food Insecurity, February 3 2006).

Whilst we do not wish to dwell on the politics of huger and food aid, we point out that the opening or maintaning of markets is a key objective of Public Law 480 (PL 480). PL 480 clearly asserts that the purpose of US food aid

programmes is to 'develop and expand export markets for United States agricultural commodities'.[1] A position repeatedly pronounced by government officials: 'The opening of new markets is immensely important for the future of U.S. agriculture.'[2] Moroever, US agribusiness such as Cargill and Arthur Daniel Midlands (ADM), which control US maize exports, have been the main beneficiaries of US food aid Programmes.

After careful consideration of the various provisions and annexes of the Biosafety law, we respectfully make the following recommendations:

1. Our most serious concerns are those related to the provisions in the biosafety law dealing with GM food aid. We are extremely concerned that Article 8(1) makes the acceptance of GM food aid compulsory once an emergency has been authorised. It futhermore appears to accept the fallacious argument that only GM food aid can serve as an alternative solution to emergencies in a timely manner. It is highly undesirable that Article 8 be allowed to be part of the Biosafety regime of Mozambique because these provisions will enslave Mozambique to the US in perpetuity;
2. Furthermore, we expressly point out that Mozambique should take care to ensure that it will not be used as a conduit to push GM food aid into the rest of Africa. The creation of specific provisions in biosafety regulation on the acceptance of GM food aid is extremely worrying as these will have reaching implications, affecting all countries in the region.
3. **We believe that Articles 12 and 13 of the Biosafety law should be deleted and every effort should be made towards ensuring a Southern African region that is not dependent on food aid, least of all, GM food aid;**
4. Explicit reference should be made to the Precautionary Principle, in accordance with the Biosafety Protocol;

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[1] United States Department of Agriculture, US Food Aid Programs Description: Public Law 480, Food For Progress And Section 416(B) http://www.fas.usda.gov/excredits/pl480/pl480brief.html

[2] Hembree Brandon, 'Veneman says more farm aid likely', Southwest Farm Press, Jun 21, 2001 http://southwestfarmpress.com/ar/farming_veneman_says_farm/

5. Care must be taken to avoid creating a situation where trade legislation will triumph over the biosafety regulation;
6. It is important to confer powers to refuse permits based on a risk assessment, environmental assessment and socio economic assessment. It is also equally important to confer clear powers to ban GMOs or the use of GMOs for a particular purposes. **It is not appropriate that biosafety regulation create the impression that it is set up only to grant authorisations**;
7. The Annexes need to be reviewed and redrafted by the National Biosafety Committee and until such time as a comprehensive framework for risk evaluation (which also includes a set of criteria for post release monitoring and socio-economic impacts) is in place, the current ban in Mozambique on the import of GM seeds should not be lifted;
8. We are extremely concerned about various provisions that compell the granting of authorisations. Decision-makers must be given enough leeway in legislation to reject appliations, even where the applicant complies with the requirements of the biosafety law;
9. Certain provisions dealing with field trials allows for the possible circumvention of the step-wise approach to GMO regulation and should be amended;
10. The provisions dealing with confidential information appears to be inherenly unfair and undemocratic and needs to be redrafted to ensure a balance between the public's right to access to information and the protection of the genuine business interests of the applicant;
11. The provisions dealing with liabilty and redress and accidents should be separated from each other and further work is needed in order to come in line with the debates and the provisions under the Biosafety Protocol on both subjects;
12. Although extensive guidelines have been drafted for public participationa and consulation, these will lack the force of law. Thus Article 19 dealing with public awareness, education and participtation does not create any rights for the public to be consulted or to participate in GM applications.

DETAILED COMMENTS

CHAPTER I

Article 1: Objectives

It is essential that at the very outset, in the objectives, that explicit reference be made to both the Precautionary Approach and Precautionary Principle, especially since these have already been captured on page 4 of the Draft National Biosafety Framework. This will provide the necessary context for the regulations as a whole and will accord better with both the objectives and provisions of the Biosafety Protocol to which Mozambique is a Party. In this regard, it will be sufficient to make reference to Article 15 of the Rio Declaration on Environment and Development as well as Articles 10(6) and 11(8) of the Biosafety Protocol.

Article 2: Scope

Article 2(1)

The phrase "…..without prejudice to the regime as set out by the Decree 56/97 of November 11 that regulates the operations of international trade to and from Mozambique and other applicable legislation.." needs to be more carefully considered because it appears to convey the notion that the trade provisions will take precedence over all the provisions of the biosafety law. Whilst it is highly desirable that legislation passed later (in time), must not contradict legislation promulgated earlier, care must be taken to avoid creating a situation where trade legislation will triumph over the biosafety regulation. It must be borne in mind that the relationship between the Biosafety Protocol and the WTO agreements is not addressed by the substantive provisions of the Protocol. The Preamble of the Biosafety Protocol emphasises on the one hand that the Protocol shall not be interpreted as implying a change in the rights and obligations of a Party existing under

existing international agreements, and on the other, it states that this is not intended to subordinate the Protocol to other international agreements. The Preamble also states that trade and multilateral environmental agreements should be mutually supportive. Thus, how the implementation of the provisions of the Biosafety Protocol relates to the WTO agreements is an open question but at the very least, mutual supportiveness between biosafety regulation and trade should be aimed for. Indeed, the door is left wide open for countries that are both Parties to the Protocol and members of the WTO, to use the ambiguities in the Biosafety Protocol to ensure that Biosafety legislation is not subordinated to trade related measures at the domestic level.

Article 2(2) GM Pharmaceuticals for humans

The phrase "…that are subject to other specific legislation from other treaties and international agreements" needs to be carefully considered, re-evaluated and reformulated in the light of the following:

The Biosafety Protocol does not exclude GMOs that are pharmaceuticals for humans, from the scope of the Protocol. The Protocol merely excludes the Advanced Informed Agreement (AIA) procedure and Article 12 dealing with review of decisions from applying to those genetically modified pharmaceuticals for humans that are addressed by relevant international agreements and organizations, such as the World Health Organisation (WHO).[3] Furthermore, it is unclear to what extent such relevant agreements and organizations need to 'address' GMOs that are pharmaceuticals in order for the AIA and Article 12 of the Protocol not to apply to such GMOs. The view has been expressed that information available so far shows that no pharmaceutical for humans are covered by any other agreement or

[3] See further, IUCN and FIELD 'An Explanatory Guide to the Cartagena Protocol on Biosafety. Draft' April 2002.

organization in their condition as a GMO and are therefore covered by the Protocol.[4]

In any event, genetically modified plants and animals used to produce pharmaceuticals are not exempt from the provisions of the AIA procedure of the Protocol. According to the rules of the WHO and its member states, it is highly unlikely that the actual genetically modified plant or animal will ever receive approval as a pharmaceutical as such. More so as further processing to achieve a standardized, reliable pharmaceutical will in any event be necessary. Furthermore, the exemption of the Protocol does not apply to genetically modified pharmaceuticals that are not dealt with by relevant international agreements or organizations nor where such agreements or organizations do not directly address the environmental and biodiversity impacts of a GMO. The exemption will also not apply to genetically modified pharmaceuticals that are intended for veterinary purposes. Additionally, an importing Party has the sovereign right to require a risk assessment prior to the import of any GMO for any use.

Article 3: National Biosafety Competent Authority

Article 3(2)(a)

It is recommended that in the English translation, the word “re-expedite” be changed to “repatriated to the country of export”, for the sake of clarity and legal certainty.

Article 3(2)(b)

It would be good to include the term “manipulation”, alternatively, clarify the distinction between manipulation and activities concerning GMOs under contained use, to ensure that the powers of inspection and control extend to the activities in laboratories, greenhouses and other research facilities.

[4] Institute for Sustainable Development and Third World Network. ‘The Convention on Biological Diversity With Some Explanatory Notes From A Third World Perspective’ May 2000.

*****Article 3(2)(d)

Whilst it is important to confer powers to grant permits, it is equally important to confer powers to refuse permits based on a risk assessment, environmental assessment and socio economic assessment. It is also equally important to confer clear powers to ban GMOs or the use of GMOs for a particular purpose, as well as the use of certain types of dangerous technologies or outdated technologies, for instance like the use of antibiotic resistant gene markers, which have been banned in the European Union, Norway etc, as well as risky constructs such as the cauliflower mosaic viral promoter.

It is not appropriate that biosafety regulation create the impression that it is set up to only grant permits.

Article 4: National Biosafety Committee (NBC)

Additional specific powers for NBC

1. The current lack of information and understanding of the environmental risks of GM crops has a number of potential consequences. These range from serious environmental damage, reversion to intense chemical control measures in the event of pest resistance developing etc. The National Biosafety Committee's role is an extremely important one and care should be taken to ensure that sufficient powers are given to it, to develop a comprehensive Ecological Risk Assessment (ERA) 'toolkit' as being currently been done in South Africa belatedly, after more than a decade of environmental releases. Such a toolkit should serve as the most important decision-making tool and basis for environmental releases, prior to any approval being given for an environmental release. Such 'toolkit' for ecological risk assessment for pre-environmental release must be developed by independent scientists, for the Mozambican context, taking into account the unique biodiversity, climate and ecology of Mozambique.

2. It is anticipated that the ERA that is drafted in South Africa, will be a comprehensive framework that develops a set of criteria also for post release monitoring as well as methodologies and criteria for a full environmental impact assessment.

We have taken note of Annex III and IV, which we deal with more fully below, when we deal with the provisions concerning field trials and commercial releases. However, we are of the respectful opinion that until such time as the National Biosafety Committee has fully developed the proposed ERA, the current ban in Mozambique on the import of GM seeds (and hence by implication the planting of GM seeds) should be retained.

3. Furthermore, the NBC should specifically be tasked to develop criteria for socio-economic assessments to be conducted. There is a dearth of independent, peer reviewed studies, that investigate in a comprehensive manner, the medium to long-term socio-economic impacts, particularly concerning resource poor farmers. Comprehensive studies are lacking that address issues concerning the high price of GM seeds, the impacts of patents which make it illegal for farmers to propagate their own planting material – a common practice resource poor farmers in Africa cannot survive without.

4. Finally, provisions should be drafted to prohibit a person to serve on the NBC in circumstanes where there is a conflict of interests.

CHAPTER II

Article 5 Import of GMOs for food, feed and processing

It is a great pity that the Biosafety law has chosen to follow the artificial distinction made by the Biosafety Protocol, between seed and food. All GMOs that enter the food supply and the environment, should be treated the same as the risks they pose do not diminish or change because the use for which they have been imported, differs.

Nevertheless:

1. In respect to Article 5(1), "...interested parties" should be replaced by "the applicant" because it is the applicant who must submit the requisite information including the certification of the absence of risk.
2. The information to be supplied in the Application form should also include details of regulatory status in other countries including bans and restrictions as well as information on how the applicant will comply with the identification requirements as outlined in the decision finally taken in Curitiba, Brazil at COP MOP3, concerning Article 18(2)(a) of the Biosafety Protocol, dealing with the identification of GMOs imported for the purposes of food, feed and processing. Special attention must be paid to contamination by unapproved GMOs, and the linkages between correct identification, labelling, traceability and issues of liabiltiy and redress in the event of a mix up, product recall and so forth.
3. We are **extremely concerned** about the way in which Article 5(3) has been drafted **which compells** (see the use of the terms ..."shall issue an authorisation..." the MINAG to issue an authorisation within a period of 90 days. This is not appropriate in biosafety legislation because decision-makers must be given the opportunity to also reject an application, even if the applicant complies with the law, especially in circumstances where (a) the applicant has not been truthful about the absence of risks; (b) the applicant is not aware of the presence of risks; (c) new information comes to light about the presence of risks/unacceptable risks prior to decision-making.
4. We also caution against the issuance of authorisations for a period of one year, because this may lead to dependence by Mozambique on imports or displace domestic markets. It is best that new authorisations are required every four months, subject to the monitoring fo the socio-economic and other impacts of the imports.
5. In relation to Annex II, the utmost care should be taken to ensure that the Annex is as comprehensive as possible to enable biosafety decision-making on the basis of all the scientific issues. The information requested in Annex II is rather superficial in our view, and

will not place the regulators in Mozambique in a position to make sound biosafety decisions. Important biosafety concerns need to be more thoroughly interrogated particular in the context of the allergenicity. In this regard, we refer the regulators to our work on assessing Syngenta's application for a food safety clearance for its GM maize event 604 Mir at http:/www.bioasfetyafrica.net

Article 6 Contained use and field trials

1. In regard to Article 6(2), we caution against the phrase "…except in the cases where the applicant produces documents that certify that similar scientific experiments have been carried out in other countries by recognised scientists." This allows for circumvention of the step-wise, approach to GMO regulation, as well as the case-by-case assessment approach articulated in the NBF. Many of the risk assessment data that served as a basis for decision-making in the US and South Africa is old and dated and cannot and should not serve as a basis for Mozambique to simply leap into field trials without the NBC having sight of the application and having an opportunity to interrogate it. Furthermore, who will qualify as a "recognised scientist?"
2. The information requested of an applicant as set out in Annex III needs to be carefully reviewed in the light of the following:

    - Transgenic (or genetically modified) crops are associated with potentially significant environmental risks;At present our knowledge and understanding of the ecological impacts of transgenic crops is inadequate.
    - It is widely acknowledged that more, scientifically rigorous ecological research on the environmental risks of transgenics is critical.
    - There is an imbalance in the speed at which the technology has been adopted versus the rate at which research is being commissioned to investigate environmental risk.

According to the position of the Ecological Society of America (Snow et al. Genetically engineered organisms and the environment: current status and recommendations. Ecol. Appl. 15, 377-404, 2005)

- Some GMO's could play a positive role
- GMO's could have negative effects under certain circumstances
- GMO's that present novel traits will need special scrutiny
- More extensive studies of benefits and risks are needed
- Release should be prevented if scientific knowledge about possible risks is clearly inadequate
- Post-release monitoring will be needed in some cases to identify, manage and mitigate risk
- Science-based regulation should incorporate a cautious approach, recognizing the context-dependence of risks
- Ecologists, agricultural scientists and molecular biologists need wider collaboration and broader training

We therefore reiterate our recommendation that the NBC develop comprehensive tools for the assessment of GMOs prior to their release into the environment, and in this regard, they deal extensively with the following:

- Detrimental effects on non-target organisms
- Gene flow to wild relatives or non-transgenic varieties;
- Development of weediness
- Development of resistance or tolerance
- Production of novel toxins
- Recombination of bacteria or viruses to produce new pathogens
- Impacts of changes in agricultural management practices on biodiversity
- Loss of crop genetic diversity
- Cumulative, synergistic, compound and scaling effects
- Unanticipated consequences

3. We once again, point out that it is not acceptable that the MINAC is compelled to issue an authorization. The discretion to refuse the application, is something that biosafety should not take away. This is a fundamental issue. Moreover, the length of time and the circumstances under which authorization is granted for field trials should be left up to the discretion of the decision-maker, and not be stipulated in the regulations.
4. We recommend that explicit reference be made to the Precautionary Principle as enshrined in Article 11(8) of the Biosafety Protocol.

Article 7 Deliberate Release into the Environment

1.Unfortunately, Annex V does not relate to Article 7(1) of the Biosafety Bill, as Annex V does not deal with the species that is to be permitted for deliberate release but seems to be a table dealing with administrative costs. We are thus unable to comment on this meaningfully.

2. In relation to Article 7(1)(b), the drafters need to pay much more attention to language because "…field trials…were conducted in other locations by recognised scientists" is extremely worrying, taking into account that on the basis of the results of field trials, decisions will be made for the commercial approval for sale and planting, of GM seeds, animals and so forth. The field trial results will have to be in compliance with permit conditions and fully set out, the biosafety testing. Thus, the ERA or toolkit we have been referring to above, must be used for the purposes of evaluating the results of the field trials in order to make a decision regarding deliberate release.

3. Similarly, in Article 7(1)(f), more attention needs to be paid to "…monitoring measures of the life cycle" because this could entail monitoring measures dealing with issues concerning efficacy of the crop plant for instance, and not biosafety issues like impacts on non-target organisms etc.

4. Article 7(1)(g) should be amended to reflect the outcome of the decisions taken by the second Meeting of the Parties in Curitiba, Brazil concerning identification of GMOs imported for direct release into the environment.

5. At the risk of repeating ourselves, we point out that the imperative "the authorisation, shall be issued by MINMAG." really should be amended.

6. In relation to Annex IV, we point out that deliberate release of transgenic organisms mean that they are released not only into the environment for growing/propagation but also for consumption by humans and animals. Thus, a thorough food safety evaluation must be conducted and in this regard, the applicant must submit sufficient information concerning food safety. Moreover, a comprehensive and independent monitoring programme will be required that also monitors compliance with permit conditions. Ideally, such monitoring should be situated within medium to long term spatial planning for risks associated with increase in scale of GMO plantings/adoption.

Article 8 Food Aid

The acceptance of GM food aid has been extremely contentious in Southern Africa, precipitated by Zambia's refusal in 2002, to accept GM food aid from the US and many other countries in Southern Africa, requesting that the GM food aid be milled. It is true that food security strategies in Southern Africa are weak-due to a complex set of factors that go beyond the scope of our work on the biosafety bill. What we have learnt from food aid, is the following:

GM food aid is presented as the only solution to African countries and this is an argument strongly advanced by the US, which is aggressively promoting GM crops in developing countries. The US food aid systems works as a parallel market for surpluses produced by US farmers. US Food aid Programmes since its creation, were linked to the well-being of US farmers, and still today, surplus disposal is one of the major objectives of the biggest US Food aid Programme, the Public Law 480. PL 480 clearly asserts that the purpose of US food aid programmes is to 'develop and expand export markets for US agricultural commodities'. This not only includes markets for domestic agricultural surpluses but also, crucially, facilitates the penetration of GM food. USAID has made it quite clear that it sees to " integrate biotech into local food systems" and "spread agricultural technology through regions of Africa."

We are thus extremely concerned that Article 8(1) makes the acceptance of GM food aid compulsory once an emergency has been authorised. It furthermore appears to accept the fallacious argument that only GM food can serve as an alternative solution to emergencies in a timely manner. We dispute this, with respect. We are of the view that a much more appropriate system of food aid is where cash is donated for the purchase of food locally or regionally, since this also contributes to the development of local markets, reduces costs, and improves timing for food delivery.

We also point out that valuable lessons have been learnt during the 2002/3 Southern African food crisis. Alternatives were found to exist to GM food aid, even under circumstances of extreme emergency. In October 2002 Zambia faced overwhelming pressure to accept GM food aid. At that time, 2.4million people were estimated to have been at risk of starvation. Zambia was presented with a scenario of no choice – GM food aid was said by USAID and the WFP to have been the only alternative to prevent starvation. However, Zambia overcame its food crisis without GM food aid. Crucially, in 2003, Zambia produced bumper harvests of GM free maize. Ironically, the WFP has since 2003, purchased 100,000 tonnes of food from Zambia, which it sent to Zimbabwe, Angola, the Democratic Republic of the Congo, and Namibia.

We are of the respectful view that the Biosafety regulation should not sanction the acceptance of food aid, and that sincere efforts rather be made to deal more concretely, with Mozambique's food insecurity, and strategies towards self- reliance and food sovereignty. It is highly undesirable that Article 8 be allowed to be part of the Biosafety regime of the Republic of Mozambique because these provisions will enslave Mozambique in perpetuity?, to the US and continue to allow US agribusiness to profit from the poverty in Africa.

CHAPTER IV EXPORT OF GMOS AND PRODUCTS

It is our respectful submission that more thought needs to be put into provisions dealing with the export of GMOs from Mozambique. Mozambique is strategically situated in Africa and cargo comes into and out of Mozambique by ship especially. Thus the possibility of GMOs being transhipped through Mozambique into the rest of Africa is highly likely. In any event, Mozambique should draft careful provisions dealing with export that goes beyond merely complying with the legislation of the country of import. In this regard, we propose that the consideration is given to provisions dealing:

- with the outcome of COP MOP 1 and 2, dealing with identification of GMOs in terms of Article 18(2)(a)(b) and (c);
- shipments of GM food aid
- liability and redress

Article 11

Taking into account the comments made immediately above relating to Article 10, we recommend that Article 11 also be amended to include compliance with the new provisions concerning documentation, food aid, liability and redress etc.

Chapter V Transit

Article 12

The transit of GMOs through the territory of Mozambique brings with it, certain obligations and risks, particularly concerning issues of identification, contamination, and liability. The issue of transit will be discussed also in some detail at the next COP MOP4 and in the interim period, Parties will be invited to submit comments to the Secretariat regarding their experience. We anticipate that one of the key issues will be the responsibility of a transit state vis-à-vis, implementation of the documentation requirements pursuant to

Article 18(2)(a). We urge Mozambique to actively participate in this endeavour. South Africa has drafted a transit policy for GMOs, and this can be found on our website on http:/www.biosafetyafrica.net

Article 13 Transit of food aid destined to countries in the Region

We expressly point out, that Mozambique should take care to ensure that it would not be used as a conduit to push GM food aid into the rest of Africa. The creation of specific provisions in biosafety regulation on the acceptance of GM food aid is extremely worrying as these will have far reaching implications, affecting all countries in the region. We believe that Articles 12 and 13 should be deleted. We believe that every effort should be made towards ensuring a Southern African region that is not dependent on food aid, least of all, GM food aid.

CHAPTER VI

COMMON PROVISIONS (Articles 14-19)

1. We have already dealt with Annexes I, II and III in some detail above. We impress upon the regulators, scientists and civil society in Mozambique, to ensure that these Annexes are substantially revised and redrafted in the light of our discussions above.

2. In regard to Article 14(2), we believe that it is important to distinguish between risk assessment, which is what the applicant is required to do, and risk evaluation, which the NBC will co-ordinate, for the sake of clarity.

3. In regard to the labelling provisions in Article 15, regard must be had also to the possibility that food products can and should be labelled as "GM Free." It is also important to clarify who will bear the responsibility for producing the 'contain' label in the different circumstances/food

products, GM containers and so forth. A provision should be created for false and misleading information and failure to label.

4. In regard to the packaging, it is important to specify who will be responsible for the packaging, that packaging is required to ensure that there is no leakage or the possibility of the GMOs escaping.

5. In regard to confidential information, we believe that Article 17, should take care to deal only with confidential **business** information and not to all information, since it is really only trade secrets and so forth that needs to be protected. Whilst Article 17(1) appears to create the possibility of the public having a right to access to information, which we welcome, this notion is immediately undermined by Article 17(2). Article 17(2) disallows the use of the information unless the applicant says its okay to do so. This is inherently unfair, undemocratic – bordering on despotic. Clear criterion is required for the determination of what is genuinely, confidential business information that requires protection under the law and information the public has the right of access to, in order to enforce their rights under the Mozambican constitution. We urge the redrafting of this clause. We also point out that provisions must be drafted regarding the discharge of the obligations on Mozambique, as a Party to the Biosafety Protocol regarding the rights of the public to information, also, via the Biosafety Clearing House.

6. In regard to liability and redress, we believe that Article 18 does not do justice to the rich legal debate currently underway, in terms of the Biosafety Protocol's Article 27. This discussion goes way beyond liability arising in the case of accidents, as is the case with Article 18 of the Mozambican biosafety law. We urge the drafters to take note of the debate under Article 27 of the Biosafety Protocol, see http:/www.biodiv.org/biosafety and take notice of the positions taken by the African Group as well as the legal submissions made by South African civil society. Furthermore, we also urge that issues pertaining to

accidents be dealt with separately, and that the provisions of the Biosafety Protocol, dealing with accidents and emergency measures be fully implemented. In this regard, we point out that these are related issues but are distinct and require separate treatment.

7. In regard to public participation, we note the document 'Annex C: Draft Guidelines On Public Awareness and Participation in matters related to Biosafety and Biotechnology' as representing a sincere effort towards transparency, public participation, awareness and consultation. This is indeed laudable, however, these are merely guidelines and lack the force of the law, and as such are not legally enforceable and binding. Thus, we have to rely on Article 19, which deals with public awareness, education and participation and all that this Article provides is an obligation on MINAG to co-ordinate in collaboration with the NBC activities on public awareness, education and participation in decision-making processes. Thus, no rights have been created for the public with regard to public consultation and participation. Furthermore, the last part of Article 19 dealing with access to information is already curtailed/contradicted by Article 17(2) of the Biosafety bill.

CHAPTER VII (Articles 20-23)
Inspection, Monitoring And Enforcement

1. We note the provisions of Article 20, but caution that the monitoring of GMOs on the environment, human and animal health, and socio-economic impacts will require the mobilisation of considerable resources-both capital and human resources. The costs involved outweigh any perceived benefits that may be gained from the introduction of GMOs into the Mozambican environment or food supply.
2. The provisions dealing with inspection should be amended to apply specifically to the implementation of the outcome of the negotiations in Curitiba, Brazil (COP MOP2) with respect to Articles 18(2)(a)(b)and (c).
3. We welcome the provisions of Article 23 dealing with Refusal of Entry.

CHAPTER VII (Articles 24, 24a, 25)
Fees and Penalties

1. We believe that the possibility of penalties that go beyond mere fines may be appropriate, in the case where GMOs have been introduced into Mozambique under illegal circumstances e.g. corruption and bribery as this has already occurred involving a Monsanto employee in Indonesia. Imprisonment may be appropriate in cases also of repeated offenders. Generally speaking, the punishment must fit the crime and must serve as a deterrent.

CHAPTER VIII Article 26

Doubts

We are of the respectful view that more attention should be paid to the resolution of disputes concerning GM applications, where the dispute occurs between biosafety regulators and members of the Mozambican public. In this regard, cost effective mechanisms must be put into place that serve the interests of justice. These must thus be accessible, cheap, and provide speedy resolution of the issues by biosafety experts from multidisciplinary sectors of the debate.

Glossary of Terms

1. **Applicant**-include “manipulate”
2. **Biosafety**-redraft to include specific reference to the precautionary principle
3. **Create definition for containment conditions**
4. **Risk assessment**-needs to apply also to GMOs for food, feed and processing. Display on the market is not used in Article 5.