www.biosafetyafrica.net
Suite 3, 12 Clamart Road Richmond 2190
Johannesburg, South Africa
Tel + 27 (0) 11 646 0699
Fax + 27 (0) 866 707 997

COMMENTS ON NATIONAL BIOTECHNOLOGY BILL, 2005 OF ZIMBABWE

By Mariam Mayet
African Centre for Biosafety
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COMMENTS ON ZIMBABWE'S NATIONAL BIOTECHNOLOGY AUTHORITY BILL, 2005

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"Has Zimbabwe set its eyes on the production of GM food/oil crops for biofuels in large scale plantations? Why else would the Authority be given the following powers: "approve the large scale use of products of biotechnology in industrial production and application….assist in the clearance of applications for setting up industries based on the use of products of biotechnology…?"

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INTRODUCTION

Christian Care, based in Zimbabwe, has approached the African Centre for Biosafety to provide comments on the National Biotechnology Authority Bill, 2005. These comments are provided *pro bono* in the public interest.

The Zimbabwean Parliament passed the National Biotechnology Authority Bill ("NBA") during October 2006. Although the ostensible objectives of the Bill are to establish the National Biotechnology Authority to regulate the development and use of *all* biotechnology applications and products, in essence, the Bill will be used to deal with transgenic techniques used in the production, experimentation and use of genetically modified organisms ("GMOs") in food and agriculture and perhaps at some stage, in gene therapy applications in the field of medicine. The NBA will also be used to deal with emerging technologies such as nanotechnology. As a Party to the Cartagena Protocol on Biosafety, the NBA will thus be utilised as Zimbabwe's primary "Biosafety" instrument, to implement Zimbabwe's obligations under the Biosafety Protocol.

It is not clear why Zimbabwe has chosen to use a single legal instrument to deal with *all* biotechnology processes, products and applications, when the orientation of the entire piece of legislation is clearly bent towards the regulation of modern biotechnology and products of biotechnology, namely, GMOs. Indeed, not all biotechnology processes, products and applications require the same level of regulation or biosafety oversight as the NBA provides.

Whilst we welcome Zimbabwe's efforts to craft a law to regulate modern biotechnology, its products (GMOs) and various activities associated with the use of GMOs, we are taken aback by the failure of the NBA to fully implement Zimbabwe's obligations under the Biosafety Protocol. The NBA does not deal with transboundary movements (import and export) and has merely crafted enabling provisions in this regard. This is particularly strange in the light that Zimbabwe receives bulk shipments of cereals and oil seeds as food aid/trade from GMO producing countries. This means that the important debate about food safety has been sidelined.

The main preoccupation of the NBA seems to open Zimbabwe up, to wholesale GE experimentation. Thus, one is left with the distinct impression that the NBA will be used as the legal mechanism to turn Zimbabwe into a massive Genetic Engineering (GE) experimental farm. Indeed, the Memorandum to the NBA says as much about the functioning of the National Biotechnology Fund "Central to the objectives of the Fund is to promote the marketing and production of, stimulate demand for, research into modern biotechnology."

SUMMARY

- It appears as if the entry point of GE into Zimbabwe, will be via public/private research projects, leading to large scale GE agricultural production and processes, which could include any GE crop plant, including the production of GE food and oil crops for biofuels;

- The NBA cannot be implemented until "guidelines and standard procedures" have been drafted to deal with critically important biosafety issues such as the import, export, general and trial release of biotechnology products, risk assessments, environmental impact assessments and so forth;
- The NBA does not address important biosafety issues, such as socio-economic and food security impacts; application of the Precautionary Principle in decision-making; principles, parameters, methodology and content of risk assessments; fair administrative justice and public participation; access to information; liability and redress; Identity preservation system and documentation requirements of Article 18 of the Biosafety Protocol and labelling and consumer right issues.

DETAILED COMMENTS

1. **Interpretation**

The concept, "potentially harmful research or undertaking" needs to be scientifically and carefully defined.

In the definition of "user" does not include the grower of GMOs commercially. Why not?

2. **Application of Act (section 3)**

The scope of the NBA is extremely wide, applying to *all* activities involving biotechnology processes, whereas, in reality, the legislation has been drafted specifically (although not exclusively) to deal with genetic engineering and genetically modified organisms and gene therapy (transgenic techniques). Having said, this, we welcome the *notion* that the legislation also applies to new and emerging technologies, and to technologies that are declared to constitute potentially harmful research or undertakings. It is thus advisable and indeed desirable that discrete secondary Regulations are drafted to deal

with distinct biotechnologies separately. We are taken aback by the failure of the NBA to mention the need for biodiversity conservation, taking into account that Zimbabwe is both a Party to the Convention on Biological Diversity and the Protocol on Biosafety.

3. Functions and powers of Authority

The NBA has allocated the powers and functions to the Authority concerning commercial releases, and to the Board, for applications for contained use and field trials.

It is noteworthy that one of the functions of the Authority is to actively promote biotechnology research, development and application in Zimbabwe. This translates also into "actively promoting genetic engineering applications." This is extremely worrying since the Authority is also empowered to approve deliberate releases and large- scale use of GMOs. This appears to be contrary to the dictates of sound biosafety regulation that the very institution tasked with approving GMO uses and releases, should also be mandated to promote GE.

Another main function of the Authority is to review project proposals concerning *high-risk category organisms* and *controlled experimental trials* and to exercise decision-making powers over such proposals. It thus appears as if the entry point of GE into Zimbabwe will be via project proposals to conduct research. But, the NBA has not stopped there because the Authority is also mandated to ensure that GMOs are applied in large -scale agricultural production and processes. Has Zimbabwe set its eyes on the production of GM cereals and oil crops for biofuels in large -scale plantations? Why else would the Authority be given the following powers: "approve the large scale use of products of biotechnology in industrial production and application… .assist in the clearance of applications for setting up industries based on the use of products of biotechnology…"

The “operations” of the Authority are to be directed and controlled by a Board appointed by the Minister, however, none of the members of the Board are required to have any expertise/experience in biosafety. The NBA does also not prohibit the private sector or those having a commercial interest in biotechnology from serving on the Board.

4. Guidelines and Standards of Practise and Procedure

The main regulatory mechanisms of the NBA, necessary to implement the NBA itself have yet to be drafted. These will be contained in ”guidelines and standards of practise and procedure” which are meant to be binding. These appear to be separate from the Regulations that the Minister is empowered and mandated to make, in terms of section 59 of the NBA. These guidelines will pertain to such important biosafety issues such as: the content of risk assessments and environmental impact assessments, the requirements for general release and trial release of biotechnology products (which specifically includes GMOs); requirements and procedures for the import and export of biotechnology products and so forth.

Thus, it appears that until the guidelines and standards have been drafted, the NBA cannot be implemented.

5. Application for and grant or refusal of registration of permission (contained use and field trials, section 25)

In this section (section 25), permission has to be sought for the development, production, use and application for **contained use or trial release** of biotechnology products or of potentially harmful research (yet to be defined). For such applications, two requirements must first be met: the submission of an assessment of the risk and an assessment of the impact on the environment. It is not clear whether the assessment of the risk includes an assessment of the risks as they relate to: human health, the environment, socio- economic harm. This needs to be clarified in the Guidelines, whenever these are eventually drafted. It must be borne in mind that in terms of section

3 (2)(d) dealing with the scope of the NBA, specific mention is made of the impact on national security, human health, animals, plants and the environment. This needs to be factored into the Guidelines and Regulations made in terms of the NBA in the future.

The NBA does not set out any further information that needs to be provided, and thus it is not possible for us to meaningfully comment on this aspect. At the very ***minimum***, and in accordance with the Biosafety Protocol, attention should be given to the principles, parameters and requirements for the risk and environmental impact assessment.

The risk evaluation is to be done with reference to guidelines and standards that still have to be drafted and thus, we are unable to comment meaningfully on this aspect at this stage.

It is anticipated that inspections will be done, as part of the risk evaluation. More attention should be given to these provisions, as they need to be linked up concretely with the inspection of facilities where contained use experiments are being conducted as well as inspections that should take place, during the course of any field trials. Special mechanisms should be drafted to deal with the keeping of records for commercial releases for the purposes of post-commercialisation monitoring. Indeed, the Guidelines should contain detailed risk management measures for all environmental releases.

It remains to be seen to what extent, there will be meaningful continuity and co-ordination between the Authority and the Board relating to permission for different activities relating to the same GMO. The concern is that decision-making, based on the highest biosafety standards may not be possible, unless the Authority will simply act as an additional “filter”?

We are extremely disappointed that decision making either on the part of the Authority or the Board concerning contained use, trial releases and commercial releases are not based on the precautionary principle. This principle is set out clearly in the Biosafety Protocol and represents one of the

hard fought victories for Africa as a result of the efforts of the African Group within the highly contested negotiations under the Biosafety Protocol.

6. Import and Export

We could find no special provisions in the NBA that specifically regulates the import and export of GMOs generally, or within the context of Zimbabwe's obligations in terms of the Biosafety Protocol although it is clear that the NBA does apply to imports and exports of GMOs, specifically.

The scope of the NBA as set out in section 3(2)(a) applies to all activities aimed at the importation and use of biotechnology processes, alas, "biotechnology processes" is not defined. Whilst the Authority is empowered in terms of section 5(1)(l) to approve the safety aspects of the import and export of biotechnology products, and to advise custom authorities on the import and export of biologically active material and products of biotechnology (section 5(1)(m), no provisions have been specially crafted to deal with the ship loads of grains and oil seeds coming into Zimbabwe that may be genetically modified or containing some GE content. It is really important that the Regulations deal with the multitude of obligations, and rights created by the Biosafety Protocol, including the critical Article 18(2)(a) of the Protocol.

7. General/commercial Releases

We are unable to find any explicit, direct provisions dealing with the regulation of GMOs (within the context of the definition of products of biotechnology) dealing with the process that an Applicant will be subject to, before permission is granted for a commercial release. Provisions do not exist specifically linking field trials with a commercial release in the context of a step- wise (step-by-step) biosafety assessment process. Instead, section 27(2) requires only, that a user notify the Authority in advance of any general release, whereupon approval will be required. This type of approval thus appears to be a rubber-stamping exercise, and the obligation placed on the Applicant, merely a formality.

8. Microbial or biological agents or toxins

Section 24(1)(d) contains an interesting provision that totally disallows the - transfer of any microbial or biological agents or toxins. We welcome this provision and look forward to more detailed Regulations to also cover the development and use of such agents or toxins. Arguably, this could be done within the scope of “transfer” for the purposes of development, experimentation and other uses in Zimbabwe.

9. Duty of Care (section 26)

We welcome these provisions in general. However, we do believe that specific references must be made to biodiversity, ecosystems, genetic diversity, human and animal health, risks to society and so forth, in order to properly capture the risks posed especially by GMOs. It may be necessary for Regulations to set out what the “appropriate measures” entail. Usually, general environmental principles already exist in general environmental legislation that underpins the “duty of care.” Where such principles exist in such environmental laws in Zimbabwe, cross-references should clearly be made in the Guidelines and Regulations.

These "duty of care" provisions are linked to issues relating to liability for damage arising (in the case of GMOs), from either the GMO itself or the use of the GMO. Usually, when obligations regarding the duty of care are breached, the spectre of civil liability arises, where damage is suffered, and not necessarily, criminal sanctions as contemplated in section 26(2) of the NBA.

10. Notification of releases and accidents (section 27)

It is important to note that in terms of the Biosafety Protocol, Zimbabwe has an obligation under international law, to discharge its obligations with regard to unintentional releases. These obligations should be fully complied with.

In the event of an unintentional transboundary movement occurring, Article 17(1) of the Biosafety Protocol requires Parties to send the notification to:

- Any affected or potentially affected States;
- The Biosafety Clearing-House; and
- Where appropriate, relevant international organisations

Additionally, the most likely "accidental" releases that may take place may relate to contamination arising from environmental releases, as well as contamination in bulk shipments of grain entering Zimbabwe. Issues relating to testing, product recall, liability and redress become very important in this context.

Additionally, Article 17(3) requires that the notification contain specific information, such as:

(a) available relevant information on the estimated quantities and relevant characteristics and/or traits of the GMO;
(b) information on the circumstances and estimated date of the release, and on the use of the GMO in the originating Party;
(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, as well as available information about possible risk management measures;
(d) Any other relevant information; and
(e) A point of contact for further information.

11. Returns to be furnished by registered users (section 28)

We no not understand the term "returns" and cannot comment meaningfully on this section.

12. Biosafety Committees (section 30)

It is extremely odd that provisions dealing with the establishment of **Biosafety Commitees** that no explicit requirement exists for the appointment of an **expert or experts** knowledgeable on **biosafety**!! Indeed, specific references are made to biotechnology expertise on the part of no less than three persons.

13. Inspections (section 33)

This section contains typically “search and seizure” provisions found in legislation. Whilst these may have relevancy with regard to biotechnology applications taking place under contained use conditions-in the laboratory. However, specially tailored provisions will be required for trade/aid shipments of bulk grain/oil seeds; the type of inspections that need to be take place with regard to field trials to ascertain compliance with permit conditions for instance, testing for contamination, spot checks on supermarket shelves of imported products for illegal contamination and so forth. These provisions will then have to be linked to product recalls, impounding and repatriation of shipments, liability and redress and so forth.

14. Funding Issues (sections 34, 43, 46, 49)

The Authority will be funded by monies appropriated to it by Parliament as well as loans, donations and grants, subject to the approval of Minister. This means that funds for the functioning of the Authority from the biotechnology industry, foreign government agencies such as USAID who are bent on the promotion of GE in Africa, are possible and perhaps even desirable?

Funding of biosafety regulation is a contentious issue. Whereas some hold the view that those that benefit from GE should pay for its regulation and that society should not have to bear the costs for a dangerous technology, others believe that the state should pay for these costs out of the state coffers and that a special fund should be created for industry contributions for biosafety monitoring and enforcement purposes only.

Indeed, a Fund is established in terms of section 43 of the NBA, which is not designed to promote biosafety research, but to promote biotechnology research and expedite biotechnology products coming to the market. The Fund will also be used to fund the Authority. Money will be paid into the Fund from levies, from Parliament and donations, loans and other financial assistance. Levies are to be imposed on producers, processors and buyers of biotechnology products. Whilst we welcome the levying of taxes on those that profit, we are perturbed by the purposes for which the money in the Fund will be utilised, particularly, when the bulk of the money may come from the private sector/foreign government assistance programmes. Care should be taken that the institutions set up, do not just become a conduit for the flows of money into and out of the biotechnology/agro-processing industries.

Regulations regarding the functioning of the levy system have still to be promulgated and thus, we cannot provide any further meaningful comment at this stage.

15. Conflicts of interest (section 55)

We welcome these provisions that deal with a conflict of interest but regret that these are limited only to the matters and projects before the Board, and to conflicts of interests involving relatives and family. It is important that the principle of no conflict of interest should pervade the legislation as a whole and applies to all decision-making bodies, and be extended beyond relatives and family but to also those that have a direct or indirect commercial interest in any matter before any decision-making body.

16. Confidentiality (section 56)

The provisions dealing with the public's right to access to information are extremely problematic. The information that the public has access to, is limited only to that which has been provided to the Authority for the purposes of an application made in terms of section 25. Section 25 deals with applications for contained use and field trials only. What about access to

information concerning imports, exports and commercial releases and other forms of biotechnology applications of a potentially harmful nature?

Furthermore, the information is quite limited and will not contain the non-confidential business information (non CBI) parts of the application itself and the risk assessment. These documents are the most important documents that the public should have access to. The most perturbing provisions are those contained in the proviso to section 56(2)(c) which provides that the Authority may withhold any information at the request of the applicant where the applicant is in the process of registering any intellectual property right in relation to any product of biotechnology. What this means is that information can be withheld indefinitely, because the applicant can argue that it is "in the process of registering a biotechnology patent." The only saving grace may be that the Authority has discretionary powers ("may") whether or not to invoke these provisions, and this may require some form of investigation on its part to verify claims made by the Applicant; a rather unnecessary set of responsibilities for the Authority to assume. Nevertheless, the proviso is draconian and mitigates against the tenets of fair administrative justice.

17. Transparency and access to information

The Biosafety Protocol is underpinned by information sharing in an open and transparent manner. Numerous provisions of the Biosafety Protocol are devoted to access to information especially via the Biosafety Clearing House. More attention should be given to these provisions and these should be captured in the Regulations. Access by the public, and other Parties to the Protocol are assured to certain information and this cannot be wished away.

In regard to information sharing with the Biosafety Clearing House, regard should be had to Article 20(3)(a) of the Biosafety Protocol, which refers to information required by Parties for the Advanced Informed Agreement procedure, some of which is expressly required to be submitted to the BCH, which includes:

- Notification of intended export from the Party of export or the exporter;
- Information required under Annex I of the Protocol;
- Acknowledgement of the notification of intended export from the Party of import;
- Decision by the Party of import on whether to approve, prohibit or restrict the import and any relevant reasons for that decision;
- Where relevant, information on the domestic regulatory framework governing the import of GMOs from the Party of import;
- Additional information from the Party of export;
- Information on risk assessment;
- Information on review of decision;
- Information on simplified procedures.

In addition, Parties are also required to submit to the BCH:

- Decisions by a Party regarding transit of specific GMOs through its territory;
- Written notices of decisions approving, prohibiting or restricting the first intentional transboundary movement of GMOs for intentional introduction into the environment;
- Final decisions regarding the domestic use of GMOS to be traded for direct use for food, feed and processing;
- Notice of reviews of decisions regarding intentional transboundary movement;
- Notice of simplified procedures regarding intentional transboundary movement and GMOs exempt from the AIA procedure;
- Notice of bilateral, regional and multinational agreements and arrangements with other Parties regarding intentional transboundary movements of GMOs;
- Notice of unintentional transboundary movement of GMOs;
- Points of contact for notification of unintentional transboundary movement;
- Information on illegal transboundary movements.

The Biosafety Protocol also places obligations on the government of Zimbabwe with regard to Public Awareness and Participation, which must be complied with.

18. PUBLIC PARTICIPATION

The NBA does not deal with public participation at all.

19. SOCIO ECONOMIC ISSUES

The NBA does not deal with socio-economic impacts all.