AFRICAN CENTRE FOR BIOSAFETY

SUBMISSIONS ON SOUTH AFRICA'S GENETICALLY MODIFIED ORGANISMS AMENDMENT BILL PUBLISHED 8 OCTOBER 2004

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TABLE OF CONTENTS

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Prepared 23 October 2004

INTRODUCTION

South Africa's Genetically Modified Organisms Act (Act No. 15 of 1997) ("GMO Act"), which came into effect on the 1 December 1999, has opened the floodgates for the extensive experimentation in open field trials of a large variety of GM crop plants, the commercial growing of GM maize, soya and cotton, the import into South Africa of millions of tons of GM maize from Argentina, and the export of GM seeds to Indonesia, the Philippines and Colombia. Much of the experimentation with GM maize and cotton crops takes place in South Africa by multinational agrochemical companies seeking nurseries in the Southern hemisphere for the production of seeds, which they export to the United States for further cultivation there. The data generated in South Africa during these trials are important to these companies to support permit applications in the European Union and elsewhere.

The GMO Act is riddled with fundamental flaws and requires an extensive overhaul, before it can approach a biosafety regime, based on the precautionary principle with the principal objective of protecting our society, food and environment from the risks posed by GMOs.

After several years of sustained pressure by civil society groups in South Africa, an inter-departmental Parliamentary Conference was held in Stellenbosch in Cape Town during April 2003, on GM crops and food with a focus on the GMO Act. Government officials and members of Parliament made promises to ensure that the GMO Act would be revised. The chairperson of the Portfolio Committee on Land and Agriculture, Mr Neo Masithela said that he hoped that South Africa would become "guiding light" on biosafety for Africa.[1]

On the 8 October 2004, the Minister of Land Affairs and Agriculture published the draft Genetically Modified Organisms Amendment Bill (Notice 2166 of 2004) for public comment.

This submission presents a critical analysis of the proposed amendments both as a response to the invitation by the Minister and to place the same in the public domain. This submission is structured as follows: A summary of the proposed amendments is first provided, followed by a detailed explanation, analysis and comment of the

[1] Parliamentary Conference promises to improve the GMO Act.
Biowatch SA Press Release - 16 April 2003

amendments. An overview is also provided of the key biosafety issues that the amendments have failed to address in its entirety. These are accompanied by recommendations.

SUMMARY OF PROPOSED AMENDMENTS

In short, the proposed amendments are dismally disappointing. They do not fully implement the Biosafety Protocol, perpetuate the lack of transparency, will expedite the trade in GMOs, make it easier and more cost effective for the biotechnology industry to conduct field trials, and appear to open up a hitherto closed door to human gene therapy. The amendments have thus utterly failed to address key biosafety issues, including:

- Post commercialisation monitoring of GMOs on human and animal health;
- Socio-economic and food security impacts;
- Application of the Precautionary Principle in decision-making;
- Risk Assessment;
- Spillage of GMOs during transport;
- Fair administrative justice and public participation;
- Access to information;
- Liability and redress; and
- Identify preservation system and documentation requirements of Article 18 of the Biosafety Protocol

The proposed amendments may be summarised as follows:

1. Definitions.

Several new definitions have been introduced which have been drafted in a shoddy and confusing manner. Some of the proposed definitions perpetuate the flawed and scientifically untenable definitions of the GMO Act and fail to give effect to the Biosafety Protocol.

2. Human Gene Therapy

The proposed amendments appear to open a hitherto closed do to human gene therapy. If this is so, then the NDA intends to sneak human gene therapy into the GMO Act, whereas it should have formed part of the national debate when the National Health Bill was being drafted. Human gene therapy is a simplistic and reductionist solution to complex diseases that must be understood in terms of the human being as a whole in his or her social, ecological environment. Billions of dollars have been invested, and hundreds of clinical trials carried out since 1990, mostly in the United States, but there has not been a single documented case of the miracle cure that was promised. It took the death of a healthy teenager Gelsinger in an early phase clinical trial in September 1999 to alert the public to the hazards of gene therapy. The US Food and Drug Administration (FDA) and the National Institutes of Health (NIH) responded to widespread concern. Clinical trials were suspended. A public enquiry turned up 652 cases of serious adverse events that went unreported, along with seven other deaths.

We strenuously oppose the proposed amendment.

3. Fast track permits to ensure expeditious and unrestricted trade and releases

- It has been proposed that the Registrar be given powers to issue fast track permits and for imports and exports of GMOs and allow field trials to take place without public participation and biosafety oversight by the Executive Committee.

- It is proposed that the Minister will make regulations regarding only the time period within which fast track permits are to be granted. Thus the process regarding the granting of fast track permits will remain secret.

It is extremely worrying that these amendments should place so much emphasis on the issue of extension/fast track permits when it has failed to set out any procedures for fast track permits.

4. Socio-economic issues and public input to be considered for only certain GM applications

The amendments do not address public participation at all. The current provisions in the GMO Regulations dealing with public reaction to advertisements in the area where a release is to take place, are not consistent with the public participation requirements of sections 3 and 4 of the Promotion of Administration of Justice Act (PAJA) and Chapter 2 of Regulations promulgated in terms of PAJA (Government Gazette Vol. 446. No 23710, 31 July 2002.)

The proposed amendments have opted to refer to an undefined concept 'public input' and in this regard, it is proposed that consideration of public input and the potential socio-economic impact take place within a regulatory framework that has already instructed the EC to approve applications. This will also only occur in respect to applications for environmental releases and the use of facilities. These amendments have thus not addressed the current deficiencies in the GMO Act, which do not require public participation in respect of applications for the use of facilities for the development and production of GMOs, including the production of GM plants to produce pharmaceuticals for humans and animals.

5. Entering of bilateral, regional and multilateral agreements or arrangements: failure to give effect to Biosafety Protocol

The proposed amendments dealing with bilateral, regional or multilateral agreements and arrangements do not comply with the Biosafety Protocol, as it has not honestly reflected the provisions of Article 14(1) of the Protocol and allows for agreements and arrangements to be concluded that may undermine the Biosafety Protocol. Compliance with Article 14 of the Protocol will ensure that such agreements and arrangements do not pre-empt or undermine on going negotiations under the Protocol regarding issues of liability and redress and Article 18 of the Protocol. Furthermore, it will mean that such arrangements and agreements will have to be notified to the Biosafety Clearing House and crucially, they can be monitored and enforced.

The NDA must be honest when dealing with its obligations under the Biosafety Protocol.

6. Failure to give effect to Biosafety Protocol regarding information to Biosafety Clearing House

Articles 17 and 20(3) of the Biosafety Protocol places obligations on South Africa to make available to the BCH specific categories of information that goes far beyond that which the proposed amendment contemplates. As a Party to the Protocol, South Africa is expected to **fully** and not partially implement its obligations under the Protocol. It is clear that the NDA is extremely reluctant to make information available, even when required to do so under international law.

7. Proposed secrecy of Guidelines

It is proposed that the NDA no longer has the obligation of publishing guidelines but that it merely makes these 'available'. The Guidelines contemplated, set out the notification requirements for permit applications including fast track permits, issues pertaining to risk assessment and protocols used by the Advisory Committee and Executive Council to assess GMO applications.

The proposed amendment seeks to impose yet further veils of secrecy around the regulatory process regarding GMOs. These Guidelines should be placed within the public domain, unconditionally, so that they are easily accessible and freely available for public scrutiny and should be independently peer reviewed.

8. Public sector participation on Advisory Committee

It is proposed that the membership of the Advisory Committee be extended to include two persons from the public sector who have knowledge in ecological matters and have a non-prejudicial position, with regard to GMOs.

It is unknown why only these members should have a non-prejudicial position with regard to GMOs, whereas the other 8 members of the Advisory Committee hailing from the scientific community should be allowed to have a biased position with regard to GMOs. It is a well- established fact that several scientists who are members of the Advisory Committee are also members of the industry lobby group.

The proposed amendments have thus done nothing to remedy the current situation of conflict of interests.

9. Liability and redress

It is proposed that the current provisions of the GMO Act be amended to acknowledge the process underway in terms of Article 27 of the Biosafety Protocol, to negotiate a liability and redress regime. However, in the interim, the current liability provisions will remain the same. Liability for environmental damage will continue to be borne by the user, which includes farmers and local communities who may be involved in the growing of GMOs in field trials and for commercial purposes.

10. Access to Information

It is proposed that in the future, the public have access to (a) the general description (as opposed to a description) of the GMO and (b) a summary of the risk assessment of the

impact on the environment and human health. These amendments have been introduced to come in line with the merest minimum standards set out in Article 21 of the Biosafety Protocol dealing with confidential information

These proposed amendments will not assist civil society groups in South Africa to gain access to information concerning permit applications in order to meaningfully assess the same. Even summaries of risk assessments will contain sections that have been deleted because the applicants have decided, that it is confidential business information (CBI). Civil society groups have experienced this first hand, and have come to the conclusion that the NDA and the applicants (biotechnology companies) have obstructed us from conducting any meaningful assessment of permit applications. Indeed, it has become self-evident that the NDA gives the applicants *carte blanche* to exercise an arbitrary decision regarding the information that has been withheld from us, on the grounds that such information is considered by the Applicant to be confidential business information.

11. Proposed insubstantial amendments to appeal provisions

Insubstantial amendments have been proposed for the appeal provisions of the GMO Act. Biowatch South Africa has recently appealed against the commercial growing and marketing of Syngenta's Bt 11 maize, and will be making comprehensive submissions.

DETAILED ANALYSIS AND COMMENTS ON PROPOSED AMENDMENTS

Section 1, Definitions

Proposed Amendment to definition of "accident"

"accident" means any incident involving an unintended general release of genetically modified organisms, including any unintentional transboundary movement, which would have an immediate or delayed impact on the environment.

The inclusion of 'unintentional transboundary movement' in the definition of 'accident' recognises that where there is a general release of GMOs within South Africa, these GMOs may spread across national boundaries, posing potential risks to biodiversity and human health within the jurisdiction of other states, particularly its neighbours (and hence resulting in an unintentional transboundary movement). The motivation behind this inclusion is Article 17 of the Biosafety Protocol, which deals with unintentional transboundary movements and emergency measures. However, whereas Article 17 of the Biosafety Protocol envisages that an unintentional transboundary movement can result from **a release, including field trials**, the definition of 'accident' requires that an unintended transboundary movement result from a general release. 'General release' is defined in the GMO Act to include the introduction of GMOs into the environment by whatever means, where the organisms are no longer contained by any system of barriers and no longer under person's control, so that the organism is likely to survive and be disseminated.

The Biosafety Protocol does not define "unintentional transboundary movement." However, an intentional introduction of a GMO into the environment of a Party (i.e. a

deliberate release) may in certain circumstances give rise to an unintentional transboundary movement of that GMO into another state.

Field trials conducted in South Africa involving in particular, GM cotton can result in an unintentional transboundary movement to the environment of South Africa's neighbours in Southern Africa, and thereby, contaminating wild relatives of cotton in these countries. Three species of *Gossypium* occur in Southern Africa, namely, in northern Namibia, Northern Botswana, Northern Province, Mpumulanga, Swaziland and KwaZulu-Natal. These three species of *Gossypium* are *Gossypium anomalum* subsp. *anomalum* which occurs in Namibia, *Gossypium herbaceum* subsp *africanum* which occurs in Namibia, Botswana, Limpopo, Mocambique, Swaziland and KwaZulu-Natal and *Gossypium triphyllum* which occurs in Namibia and Botswana.

This definition needs more careful attention redrafting to give full effect to the Biosafety Protocol and the realities of South and Southern Africa.

Proposed Amendment, new definition for activities

A new definition for 'activities' has been created, and provides as follows "activities" mean any act with regard to, but not limited to, the importation, exportation, development, production, use, distribution, storage, and application of GMOs.

This new definition is intended to be more comprehensive regarding the regulation of GMOs, as well as to extend the powers of the Executive Council (see below). However, this definition, perhaps owing to shoddy drafting, does not include the release of GMOs into the environment. The concept 'use' is not defined in the GMO Act, or in the GMO Regulations. In this respect, it is assumed that 'activity' will have a corresponding meaning? This is important because the term 'activity' is already defined in the GMO Regulations, which means " work undertaken with regard to the development, production, use and application of genetically modified organisms.'

The introduction of the new definition 'activities' creates a great deal of confusion. It appears as if the drafters have forgotten about the existence of the GMO Regulations.

Proposed Amendment, new definition for commodity clearance

A new definition has been inserted 'commodity clearance' to denote authorisations for use of a GMO as food, feed and during processing.

Proposed Amendment, amendment to definition of contained use

The definition of 'contained use' has been amended to include the words "and their impact on the external environment"

The additional wording is an attempt to bring the current definition of 'contained use' of the GMO Act in line with the corresponding definition of the Biosafety Protocol. The amended definition now requires that physical barriers or a combination of physical barriers together with chemical barriers used for the experimentation and growing of GMOs need not only to limit the contact of such GMOs with the environment as was previously the case, but also to limit their **impact on the external** environment.

However, the rationale for the definition of contained use, namely, the 'limiting of contact… and impact on the external environment' perpetuates the shortcomings of the definition of contained use of the Protocol, which is in fact not scientifically tenable, inasmuch as this definition in fact allows for several kinds of deliberate releases to take place, including the following:

- Caged transgenic fish or other aquatic GMOs in open ponds, lakes and marine environments;
- Vaccinations with transgenic viruses and naked nucleic acid vaccines
- All forms of gene therapy
- Xenotransplantation using transgenic animal organs
- Open field trials with fencing or other physical barriers (including green house experiments);
- Transgenic organisms enclosed in cages or other containers and destined for deliberate release;
- Liquid and solid wastes of transgenic livestock contained in the laboratory;
- Liquid and solid wastes of laboratories creating transgenic organisms destined for deliberate releases.

It must be noted that scientifically, the concept of "contained use" *per se*, is not controversial generally speaking. Scientists understand this to mean "strictly under laboratory conditions" However, the concept of "contained use" became extremely controversial during the Biosafety Protocol negotiations, when the biotechnology industry tried very hard to do 2 things: (a) water down the definition of contained use to ensure that it was broad enough to include experiments that would take place outside of the laboratory e.g. greenhouse experiments; ponds etc, and (b) ensure that GMOs that are being moved around the world (transboundary movements) would not be subject to strict regulation, i.e. that the Advanced Informed Agreement (AIA) procedure of the Protocol. In other words, the AIA would not apply to the transboundary movement of GMOs that are destined for contained use. They had succeeded on both counts.

It is also unacceptable that the extraordinarily wide definition of contained use of the GMO Act includes activities such as the storage and transport of GMOs. The storage of GMOs for example at silos and the transport of GMOs are not activities that qualify as contained use. These activities must be separately regulated to avoid spillage, dissemination and contamination.

It is recommended that the definition of contained use be revised in its entirely to come in line with that used in the African Model Law on Safety in Biotechnology (African Model Law). "Contained use" is defined in the African Model Law as "any operation in which genetically modified organisms are produced, grown, stored, destroyed or used in some other way in a close system not exceeding ….cm (to be filled in) in volume in which physical barriers are employed, either alone or together with chemical and/or biological barriers, to effectively **prevent their contact with, and their impact on, humans and the external environment."** (own emphasis).

Proposed Amendment, new terminology for fast track permits

A new concept has been created called 'extension permit' which means a permit issued for activities relating to GMOs for which a permit had previously been issued, to supersede the concept of 'fast track permits' in accordance with the discussions of the

Executive Council.[2]This has ostensibly done to give the concept a more palatable name.

Proposed amendment, new definition for transboundary movement

A new definition for transboundary movement has been created and means the movement of a GMO from one Party to another Party, including movement between Parties and non-Parties. Although the word 'Party' is not defined, reference is here being made to a Party to the Biosafety Protocol. The inclusion of non-Party in this definition is to ensure that the import and export of the technology and GM seed and bulk shipments of GM grain between South Africa and non-Parties to the Biosafety Protocol such as the United States and Argentina is not impeded.

It must be noted that Article 24 of the Biosafety Protocol requires that the transboundary movement of GMOs between South Africa, a Party to the Protocol and non-Parties such as Argentina and the United States be consistent with the objective of the Biosafety Protocol. South Africa is obliged to ensure that it does not allow the transboundary movement of GMOs from non-Parties to undermine the Biosafety Protocol, i.e. adherence to biosafety standards considerably lower than those required by the Biosafety Protocol. Furthermore, Article 24(2) of the Protocol requires South Africa to encourage non-Parties to adhere to the Protocol and contribute appropriate information to the Biosafety Clearing House on GMOs released in, or moved into or out of areas within their national jurisdiction. We would like to see some commitment from South Africa to this effect.

Proposed Amendment of section 2 of GMO Act, exclusion of germline modification, inclusion of human gene therapy

An amendment has been proposed to exclude germline modification from the purview of the GMO Act and in so doing, it appears as if human gene therapy which has previously been excluded from the Act is now included.

A definition for germline modification has not been included in the proposed amendments. Germline modification entails the alteration of the genetic code in sperm cells, ova and fertilized ova to prevent disease or to induce desired traits, e.g. designer babies. The term is broad enough to include germline modification in humans. This is a good development.

However, scientifically, human germline modification does not include human gene therapy; these entailing 2 different genetic engineering applications.

The removal of the words "human gene therapy" from section 2(a) means that human gene therapy will fall within the purview of the GMO Act, in terms of section 2(1) c) of the GMO Act. [3].

Human gene therapy is the use of normal genes or genetic material to replace or cancel out the "bad" or defective genes in a person's body that scientists believe are responsible

[2] Extract of the Meeting of the Executive Council in terms of the GMO Act, 25th August 2004, Roof Garden, furnished to the African Centre for Biosafety by the Registrar: Genetically Modified Organisms Act, on the 23 September 2004.

[3] Section 2(1)c) provides "This Act shall apply to the use of gene therapy.

for a disease or medical problem. The "good" genes find their way to the right spot in the body and begin to do the work required. For example, a person with the disease cystic fibrosis (CF) has a faulty gene for handling lung development, which results in excess mucous in the lungs, leading to chronic coughing, choking and serious respiratory infections.[4]

We are extremely concerned about the use of gene therapy and oppose the amendment.

Our grave concerns regarding human gene therapy can be summarised as follows[5]:

(1) Human gene therapy is a simplistic, reductionist solution to complex diseases that must be understood in terms of the human being as a whole in his or her social, ecological environment.
(2) Billions have been invested, and hundreds of clinical trials carried out since 1990, mostly in the United States, but there has not been a single documented case of the miracle cure that was promised;
(3) It took the death of a healthy teenager Gelsinger in an early phase clinical trial in September 1999 to alert the public to the hazards of gene therapy. The US Food and Drug Administration (FDA) and the National Institutes of Health (NIH) responded to widespread concern. Clinical trials were suspended. A public enquiry turned up 652 cases of serious adverse events that went unreported, along with seven other deaths.
(4) In gene therapy, an artificial construct – consisting, in the minimum, of a promoter driving the expression of a gene, and the gene itself - is delivered, either by viral vectors, or as naked DNA into cells. One of the major technical hurdles for delivering foreign genes is the form in which the constructs are delivered. Although naked DNA is widely used for modifying germ cells, this does not work as well for somatic cells therapy, for which viral vectors are routinely used;
(5) Random integration of viral vectors into genomes give rise to unintended effects known collectively as position effects. These affect both the inserted gene and the host genes in its vicinity.
(6) The expression of the introduced gene is not the only, nor the main problem, its regulated expression within the body is the key to normal functioning. Unfortunately, most foreign genes are introduced with aggressive viral promoters that simply make them over-express in an unregulated way. The underlying assumption is that the single gene product is necessary and sufficient to provide a cure. But this does not even work for so-called single gene disorders. The cell, and ultimately the entire organism functions as a whole, so practically every part of it will have changed when even a single gene is mutated. Consequently, restoring that gene is unlikely to put things right, and may even result in the gene product being targeted by the body's immune defence.
(7) The simplistic gene-centred approach has failed because it is fundamentally at odds with the complex reality of the organic whole. In contrast, indigenous cultures all over the world never lost touch with the organic reality that encompasses an entire way of life.

It is thus recommended that:

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[4] http://www.fda.gov/cber/infosheets/genezn.htm
[5] This summary is taken from a paper written by Dr Mae Wan Ho and Professor Joe Cummins *Genetically Modified Humans: For What and for Whom?* http://www.isis.org

- A definition be provided for germline modification that is both scientifically and legally precise and which includes human gene therapy; and
- The GMO Act continues to unequivocally exclude human gene therapy from its purview.

Proposed Amendment of Section 3 of GMO Act, composition, nomination and expertise of Executive Council

It is proposed that the number of members on the Executive Council be increased from 8 to 10 members. This has been done for 2 reasons: to accommodate the splitting of the Department of Arts, Culture, Science and Technology into 2 departments and to formally include the Department of Water Affairs and Forestry. It is also proposed that these members be nominated by their respective departments.

It is also proposed that the members from the 10 National government departments that will serve on the Executive Council have knowledge of the implications of GMOs with regard to the sector represented by his or her department, **including any existing legislation applicable within the sector.** This amendment appears to be motivated by the enactment of legislation such as the National Environmental Management Biodiversity Act, (NEMBA) which is administered by the Department of Environmental Affairs and Tourism, which contains several provisions directly relevant to GMOs.

Currently, section 3(2)(c) of the GMO Act does provide for the inclusion of "any other person" on the Executive Council. This post does not appear to have been filled, and the Minister of Agriculture should be called upon to appoint an independent biosafety expert to monitor the proceedings of the Executive Council, particularly since there is scant public confidence in the regulatory system.

Proposed amendment, section 4 of GMO Act, new objectives for Executive Council

It is proposed that the current section 4 of the GMO Act[6] be replaced with a new section 4, which provides 'The Council shall advise the Minister on all aspects concerning all activities relating to genetically modified organisms, and to ensure that such activities are performed in accordance with the provisions of this Act."

The purpose of this amendment is to ensure that the EC has powers in respect of "activities" in relation to GMOs. As noted earlier, "activities' does not specifically include 'release.'

Proposed amendments to section 5(a), requirements for extension permits

The amendments proposed relate to requiring an applicant who wishes to obtain an extension permit, also to submit a risk assessment. However, the risk assessment need only assess the impact on the environment of the activity in question (e.g. a field trial). No mention is made of human and animal health, and socio-economic impacts. Thus,

[6] Section 4 of the GMO Act currently provides "The Council shall advise the Minister on all aspects concerning the development, production, use, application and release of genetically modified organisms, and to ensure that all activities with regard to the development, production, use, application and release of genetically modified organisms are performed in accordance with the provisions of this Act."

the flaws in section 5(a) of the GMO Act have not been addressed by the proposed amendment.

Proposed amendments to section 5(g), the glossing over of biased provisions

It is proposed that section 5(g) be amended so as to try and give a semblance of regulatory acceptability to an otherwise fundamentally flawed and biased provision. It is proposed that the Executive Council also take into account risk management, public impact and the potential socio-economic impact **before it approves** an application for the release of GMOs into the environment.

The central issue is that section 5(g) has been drafted within a context of approval as opposed to precautionary decision-making, as required by environmental policy in South Africa, the National Environmental Management Act (NEMA) and the Biosafety Protocol. It is not acceptable that biosafety legislation be drafted with the specific purpose of approving applications regarding GMOs. The entire section 5(g) should be redrafted to reflect commonly accepted biosafety regulation and decision-making based on the precautionary principle.

It is not acceptable to us, that the consideration of public input and the potential socio-economic impact take place within a regulatory framework that has already instructed the EC to approve applications.

It is interesting to note that both section 5(1)(g) of the GMO Act and the proposed amendment only refers to approvals with regard to the use of facilities and the release of GMOs into the environment. There is no reference to transboundary movements of GMOs especially commodity clearance permits. In other words, it is envisaged that the EC is bound to take into account public input and socio-economic impacts only in respect to applications for environmental releases and the use of facilities. In any event, no provision is made in the GMO Act nor its Regulations for public input in respect of applications for the use of facilities for the development and production of GMOs, including the production of GM plants to produce pharmaceuticals for humans and animals.

It is a reflection of plain shoddy drafting that an applicant is meant to apply for a permit in respect of 'activities' which is newly defined, which excludes environmental releases and the proposed section 5(g) should empower the Executive Council to approve environmental releases and the use of GMOs in facilities and no more than that.

Proposed amendments, new section 5(1)(h), communication of approvals to Biosafety Clearing House

It is proposed that a new paragraph be introduced to require the Registrar to communicate a decision taken regarding the approvals for use of GMOs at facilities and environmental releases to the Biosafety Clearing House (BCH).

Article 20 of the Biosafety Protocol deals with information Sharing and the Biosafety Clearing House. The Biosafety Clearing House is an information exchange mechanism to assist Parties to implement the Protocol. It is also a means by which information can be accessed by the public.

Article 20(3) places an obligation on South Africa to make available to the BCH specific categories of information that goes way beyond that which goes way beyond what the proposed amendment contemplates.

Article 20(3)(a) 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.

As a Party to the Biosafety Protocol, South Africa is expected to fully comply with its obligations under Article 20(3). It is thus unacceptable to us, that the proposed amendment should be confined only to compelling the Registrar to communicate a decision taken in respect of certain approvals.

Proposed amendment to section 5(i), to deal with SA's obligations under BSP in the event of an accident occurring

It is proposed that the existing sub-paragraph 5(1)(i) be amended to oblige the Executive Council to inform any other country of any accident directly or though the Biosafety Clearing House, that may have an impact on that country's environment.

Recall, a new definition has been created for "accidents' which include unintentional transboundary movements. As mentioned earlier, Article 17 of the Biosafety Protocol deals with unintentional transboundary movements and emergency measures. Article 17 compliments the general duty on states under international law to prevent or minimise transboundary harm. In the framework of the Protocol, Parties are required to prevent or minimise the risks of unintentional transboundary movements of GMOs.

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

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

The drafters should ensure that they give full effect to the provisions of the Biosafety Protocol and not provide for half-measures. The relevant international organisations are not identified in the Biosafety Protocol but depending on the circumstances of the release may include organisations with appropriate expertise.

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.

Article 17(3) merely describes the minimum information that any notification to affected or potentially affected States should contain. The amendments have not even tried to give effect to these minimum requirements.

Finally, Article 17(4) refers to the obligation on South Africa as a Party to the Protocol to hold immediate consultation to mimimize any significant adverse effects on biodiversity and human health. Thus, mere notification to the affected states is not enough. The obligations of prevention and co-operation require States to offer any assistance to mimimize any significant adverse effects to biodiversity and human health and to request immediate consultation to agree upon any applicable emergency measures.

South Africa must fully comply with the provisions of the Biosafety Protocol.

Proposed amendments, amendment to co-operation agreements

It is proposed that the current subsection 5(k) be amended to ensure that the Executive Council enters into co-operate or enter into agreements with any other person or institution upon such conditions as the Council and the person or institution concerned

may agree upon, **provided that such agreements do not result in a lower level of protection of the environment that that provided in the Act.**

However, where such agreements are entered into in order to implement the Biosafety Protocol, then they need to provide either the same of higher levels of protection as provided by the Biosafety Protocol. It is also important for the stated purpose of such co-operation and agreements to be included in the legislation.

Proposed amendments, insertion of new paragraph 5(1)(l), advice on bilateral, regional, and multilateral agreements and arrangements

It is proposed that the Executive Council be given new powers to advise on South Africa's entering into any bilateral, regional and multilateral agreements and arrangements with any other Party of the Protocol, provided that such agreements and arrangements **do not result in a lower level of protection of the environment that that provided for in the Act.**

Article 14 (1) of the Biosafety Protocol allows South Africa to enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of GMOs, consistent with the objective of the Protocol, and provided that such agreements and arrangements **do not result in a lower level of protection than that provided for by the Protocol.**

It is of paramount importance for this sub-paragraph to comply with this double requirement for separate agreements or arrangements regarding the transboundary movement of GMOs amongst Parties. Already, Mexico, the United States and Canada entered into an agreement to implement Article 18(2) of the Protocol to deal with the documentation requirements for GMOs imported by Mexico for the purposes of food, feed and processing.[7] The motivation for this agreement was because exporting countries[8]had difficulty in agreeing on whether adventitious presence, for example, an intended presence of an unauthorised GMO in the country of import may trigger the same documentation requirements. It was thus decided that this issue would be dealt with in the specifics of any bilateral or multilateral arrangements.

The Trilateral agreement set a threshold level of 5% for triggering identification, when none has been discussed in the meetings of the Protocol. In other words, that the "may contain" requirements of the Biosafety Protocol would not be triggered where an exporter or importer may have contractually defined, in accordance with the regulatory requirements of the importing country, that a shipment of 95% non-GMO content is "non-GMO shipment".

South Africa is both an importer and exporter of GMOs. South Africa imports GMOs from the US and Argentina, and whereas the US cannot become a Party to the Biosafety

[7] "Proposed Framework for Bilateral Arrangements" and "Model Bilateral Arrangements to Implement Article 18.2(a) of the Cartagena Protocol on Biosafety"

[8] At the initiative of the US, Canada and Argentina, 2 meetings of exporting countries were held in March and June 2003, to seek agreement on documentation requirements for GMOs for food, feed and processing, which is dealt with in Article 18(2)(a) of the Biosafety Protocol on handling, packaging and identification of GM commodities. *Trilateral Agreement A Pre-emptive Strike by Exporting Countries* Third World Network Biosafety Information Service, 13 March 2004 http://www.twnside.org.sg/title2/service99.htm

Protocol, Argentina has still not ratified the Protocol, but may do so in the future. As an exporter of maize to the Southern African region in particular, South Africa probably exports GMOs or shipments of maize containing GM maize. It is possible that South Africa may intend to conclude agreements with its neighbours who are Parties to the Protocol, especially from the Southern African Development Community (SADC) regarding such exports.

It is of paramount importance that any bilateral, regional or multinational agreement concluded by South Africa and any Party to the Protocol is subject to the objectives of the Protocol and no not result in a lower level of protection than that provided for by the Protocol. This will ensure that such agreements do not pre-empt or undermine on going negotiations under the Protocol regarding issues of liability and redress and Article 18 of the Protocol. Furthermore, it will mean that such arrangements and agreements will have to be notified to the Biosafety Clearing House and crucially, they can be monitored and enforced.

Additionally, a new paragraph should be created for public consultation and input into any bilateral, regional or multinational arrangement or agreements concerning GMOs and that the process is transparent and accountable.

Finally, as part of its duties on prevention, Parties may wish to develop bilateral or regional contingency plans concerning the unintentional transboundary movements. The Convention on Biological Diversity (CBD) encourages the development of joint contingency plans. (Article 15(1)(e) of the CBD).

Proposed amendment, making guidelines available as opposed to publishing

It is proposed that the previous provision relating to the need for publishing guidelines be changed to require only the making available of such guidelines. The National Department of Agriculture has issued guidelines recently, http://www.nda.agric.za/docs/geneticresources/geneticcontrol.htm which form an integral part of the regulatory process concerning GMOs. These Guidelines have since been removed from the website but contain a great deal of information relating to the notification requirements under the Biosafety Protocol and issues pertaining to risk assessment and the protocols used by the Advisory Committee and Executive Council to assess GMO applications.

It is unacceptable and the NDA should seek to impose yet further veils of secrecy around the regulatory process regarding GMOs. These Guidelines should be made placed within the public domain, unconditionally.

Proposed amendment of section 9, creation of additional powers for Registrar to issue fast track/extension permits (general power)

It has been proposed that the Registrar be given powers to issue an extension or fast track permit. This amendment is motivated by the challenge lodged by the African Centre for Biosafety regarding the *ultra vires* nature of fast track permits issued by the Registrar, when he has no powers to do so.

On the 2nd June 2004, the ACB advised the Registrar that several fast track permits for the release of GMOs into the environment had been granted by the previous Registrar,

Shadrack Moepuli, in terms of section 5(12) of the Regulations made under the GMO Act. The ACB contends that it is apparent that the fast track permits issued in terms of the Regulations to the GMO Act, Regulation 5(12) are *ultra vires* for several reasons including the fact that Regulation 5(12) is not in conformity with section 9 of the Act and accrues greater powers to the Registrar under the said Regulations than is provided for under the Act.

The NDA advised the ACB that they were in the process of soliciting a legal opinion on the matter and that the Minister of Agriculture would respond to the ACB on this issue. However, to date, no further communication has been received from the Minister of the NDA.

It appears those permits that were previously issued prior to the GMO Act coming into effect and then later, were brought within the purview of the Act when it came into effect in December 1999, by the Shadrack Moepuli, as fast track permits, when he did not have the power to do so.

Proposed amendment, increased powers to Registrar to issue extension/fast track permits for imports and exports of GMOs and extend time periods for field trials

The following new paragraph is proposed to give the Registrar additionally powers which he may exercise at his own discretion without having to wait for the Executive Council to meet and authorise him/her to do so. In other words, time and biosafety constraints have been done away with, in order to expedite the issue of permits to ensure the unimpeded, continued and smooth flowing of trade in and release of GMOs into the environment.

" Notwithstanding the provisions of subsection (1)(a) to (g), the registrar may issue an extension permit for importation and exportation of genetically modified organisms, and for extending the time period to complete activities relating to genetically modified organisms, for which a permit had previously been issued"

Thus, the Registrar may in the future, ensure that fast track permits are issued for second and subsequent transboundary movements of GMOs whether for direct introduction into the environment or for use as food, feed or processing. This may take place without the Registrar having to receive any instructions of and conditions laid down by the Executive Council. This provision thus serves two additional purposes: it takes full advantage of the weaknesses inherent in the Biosafety Protocol and cures the defects in the current GMO Act and the Regulations dealing with the ultra vires nature of the powers of the Registrar to issue fast track or extension permits. It is strange that these amendments should place so much emphasis on the issue of extension/fast track permits when it has failed to set out any procedures for fast track permits.

> It is true that Biosafety Protocol's central operational provisions, the Advanced Informed Agreement (AIA) procedure does not apply to second and subsequent transboundary movements of GMOs intended for direct introduction into the environment, and does not apply at all to GMOs traded for direct use as food, feed and processing. However, the Biosafety Protocol does not and cannot restrict the sovereign rights of countries to require notifications, prior informed consent and risk assessments for all GMOs and its uses, irrespective of whether the Biosafety Protocol requires the AIA procedure to apply to such GMO and associated uses.

Article 2(4) of the Biosafety Protocol expressly provides as follows:

'nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's obligations under international law".

According to the IUCN[9], this paragraph establishes that the rules contained in the Biosafety Protocol are a "floor" rather than a "ceiling"-i.e. they are *minimum standards* for achieving the objective of the Protocol, that the countries were able to agree to, when they negotiated the Protocol. According to the IUCN, when countries draft their national biosafety frameworks, article 2(4) expressly reserves the right to adopt protective measures that go beyond the agreed minimum. The only proviso is that in taking such measures, Parties must ensure that these measures are not in conflict with its obligations under other international agreements, such as those under the World Trade Organisation (WTO). Trade-related biosafety measures can in fact be compatible with the relevant agreements under the WTO as long as these are justified by a rational policy purpose such as, for example, the protection of human life or health. Trade-related measures that are relevant to biosafety fall within the purview of three agreements of the WTO, namely, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the Agreement on Technical Barriers to Trade (TBT) and the General Agreement on Tariffs and Trade (GATT) 1994. These agreements allow biosafety measures to be taken, including import bans, use restrictions such as risk assessments and risk management measures, and traceability, identification and labelling requirements.

There is thus no need, for biosafety to be sacrificed for the need to expedite the trade in and release of GMOs into the environment.

This amendment also allows for the Registrar to extend the period of time to complete activities relating to genetically modified organisms, for which a permit had previously been issued. What does 'extend the period of time to complete activities relating to GMOs' mean? What is obviously intended here, is to do away with the requirement that new applications for field trials of the same GMO should be lodged and in so doing, doing away with a number of democratic tenets including:

(a) public participation;
(b) assessment by Advisory Committee and the Executive Council, especially of the results of previous field trials.

Thus, neither members of the public, the Advisory Committee nor the Executive Council will be in a position to assess *inter alia*:

- The scientific design of the previous field trials;
- Whether the applicant is able to answer key questions regarding the safety of the GM events in question, particularly, ecological risks;
- The justification and data used by the applicant in obtaining the previous field trial permits;

[9] An Explanatory Guide to the Cartagena Protocol on Biosafety, at 38.

- Whether the data produced by the applicant from these previous field trials is able to support the claims of the applicant in relation to the previous and proposed field trials;
- Whether the applicant has complied with permit conditions; and
- Whether the proposed field trials will be able to provide the information necessary for the formulation of conclusions about ecological safety.

Proposed amendment to section 10, inclusion of public sector on Advisory Committee

It is proposed that the membership of the Advisory Committee be extended to include two persons from the public sector who have knowledge in ecological matters and have a non-prejudicial position, with regard to GMOs.

It is unknown why only these members should have a non-prejudicial position with regard to GMOs, whereas the other 8 members of the Advisory Committee knowledgeable in the fields of science applicable to the development and release of GMOs are allowed to have a biased position with regard to GMOs.

It is a well- established fact that several scientists who are members of the Advisory Committee are also members of the industry lobby group, Africabio, such as Muffy Koch, Jennifer Thompson, Jane Morris etc, thereby creating unacceptable conflict of interests. The GMO Act is about the regulation of the biotechnology industry and its products, something the NDA does not seem to be able to comprehend.

It thus appears as if the repeated calls by civil society to the NDA to ensure that the biosafety regulatory process in South Africa is impartial has fallen on deaf ears. The membership of the Advisory Committee needs to be urgently reconstituted to ensure that **all** its members have a non-prejudicial position with regard to GMOs!

Proposed amendments, section 17 –insubstantial changes to liability provisions

The current provisions of the GMO Act have been amended to acknowledge the process underway in terms of Article 27, to negotiate a liability and redress regime. However, in the interim, the current liability provisions will remain the same. Liability for environmental damage is still to be borne by the user, defined to include any natural or legal person or institution responsible for the use of GMOs and includes the end-user of consumer e.g. farmers and local communities who are involved in the growing of GMOs in field trials and for commercial purposes. A further amendment has also been introduced to exempt the person concerned at the time of an activity from liability if the GMO was in the possession of an inspector during the course of inspection and investigation.

Proposed amendment to confidential information, access to information

It is proposed that in the future, the public have access to (a) the general description (as opposed to a description) of the GMO and (b) a summary of the risk assessment of the impact on the environment and human health. These amendments have been introduced to come in line with the provisions of Article 21 of the Biosafety Protocol dealing with confidential information. As mentioned above, the Biosafety Protocol only sets minimum international standards, whereas South Africa's Constitution and the

Promotion of Access to Information Act govern the situation in South Africa. Biowatch South Africa has approached the High Court to clarify the ambit of the public's rights to information regarding GMOs. The ruling from this case will have to be given effect to by the NDA and it is expected that substantial revisions will have to be made to the GMO Act.

Proposed amendment to appeal provisions, changes to powers of the appeal board

Time frames have been proposed within which the Minister must appoint persons to the Appeal Board and the person who would serve as chairperson of the appeals board. It is also proposed that the powers currently provided in the GMO Act to the appeal board be qualified. Currently, the Appeal Board may make such order as it deems fit. This has been qualified, in that it may make such order as it deems fit, in order to minimise significant negative impact on the environment or human health.

Biowatch South Africa has appealed against a decision to allow the commercial growing and marketing of Syngenta's Bt 11 maize seed. Biowatch will be making detailed submissions on the extent to which the current provisions in the GMO Act should be amended in order to further the administration of justice. The African Centre for Biosafety associates itself with these submissions.

Proposed amendments to powers of Minister to make regulations

It is proposed that section 20(1) (a) be amended to empower the Minister to make regulations regarding applications and issue of permits, including the time period for such permits as well as extension permits. It is thus not contemplated that the Minister will make regulations regarding the issue of extension permits, only the time period within which such permits are to be granted. Thus the process regarding the granting of fast track permits will remain secret.

KEY BIOSAFETY ISSUES NOT ADDRESSED BY PROPOSED AMENDMENTS

1. LACK OF POST COMMERCIALISATION MONITORING OF IMPACTS OF GMOS ON HUMAN AND ANIMAL HEALTH

The Constitution implicitly obliges the State to ensure that South Africans have the right to safe food-as a critically import socio-economic right. Maize is a critically important agricultural product because it is used as a staple for millions of people not only in South Africa, but also in the Southern African region.[10] South Africa allows the growing and import of GM maize also referred to as 'yellow maize', which is used in South Africa as an ingredient in feed rations for diary, beef, poultry and egg production.[11] This maize is

[10] Trends in the Agriculture Sector 2003 National Department of Agriculture http://www.nda.agric.za/doc/Trends2003.Field_husbandry.pdf

[11] Trends in the Agriculture Sector 2003 National Department of Agriculture http://www.nda.agric.za/doc/Trends2003.Field_husbandry.pdf

also a raw material for the production of starch used in turn, in the manufacture of sweeteners, syrups, and fermentation products. Maize oil is also extracted from the germ of the kernel. Thus maize products are present in a wide range of processed food products. South Africa grows and exports GM white maize, consumed by millions within South and Southern Africa. Yet, since the time when these GMOs were approved, neither the NDA, nor the National Department of Health nor any other government agency has conducted any post commercialisation testing and monitoring for the effects of transgenic maize on animal and human health. This failure has arisen because the GMO Act does not address the issue of post commercialisation testing and monitoring adequately or at all.

Recommendations

The GMO Act must be urgently amended to include comprehensive provisions dealing with the testing and monitoring of the impacts on the environment, animal and human health of GM food, feed and plants. In regard to the testing and monitoring of GM food and feed, the following preliminary recommendations are made:

Animal Health Monitoring should include inter alia, the following:

- Growth and life span: organ development;
- Disease susceptibility: immune status, pathogenicity, infectiousness; and
- Reproductive function-these should take place over at least 4 generations.
- Short and long term monitoring of animal behaviour: health, physiology and metabolism;

Monitoring of Humans

There is a range of techniques that could be used for this purpose. These include non-invasive techniques such as testing immune responsiveness, consecutive blood sampling, hormone assays, and bacterial status etc.

Invasive techniques could include gastric biopsies, tumour histology, and pathology testing. Testing and monitoring can also take place by using human volunteer studies and in this regard, new microbes (viruses, bacteria) containing GM vector elements should be monitored. Particular attention must be paid to the identification and monitoring and invasion of bacteria with antibiotic resistant genes.

2. SOCIO-ECONOMIC/FOOD SECURITY IMPACTS

The GMO Act has allowed for the flourishing trade in GM maize between Argentina and South Africa. However, the Act pays no attention to the detrimental impacts of cheap GM maize imports on the production and sale of maize in South Africa. Over the past 4 years, hundreds of thousands of metric tons of such GM maize are being imported into South Africa from Argentina by the animal feed industry because it is cheaper than if they were to purchase maize produced locally and thereby displacing and placing at risk thousand of jobs in the agricultural sector and related industries.

Recommendation

A mandatory requirements must be created in the GMO Act for an urgent assessment of the socio and economic impacts of the importation of GM maize in the hundreds of thousands of metric tons by the animal feed industry in South Africa, from Argentina

and the United States, including impacts on the production of maize in South Africa, the distortions in the market place caused by the sale of such maize and indeed, the long-term food security and food sovereignty impacts for South and Southern Africa, the predatory pricing policies of grain exporters and the huge subsidy regimes available to them by their governments that assist in attaining those objectives of market domination and displacement of local producers**.**

3. APPLICATION OF THE PRECAUTIONARY PRINCIPLE

Genetic modification by the application of recombinant DNA technology is characterised by scientific uncertainty. This stems from several factors including the inherent imprecision of currently employed recombinant DNA techniques, the use of powerful promoter sequences in genetic constructs and the generation, as a result of genetic modification, of novel proteins to which humans and animals have never previously been exposed. Uncertainty is a key element of the Biosafety Protocol (Cartagena Protocol on Biosafety to the Convention on Biological Diversity[12]. The lack of sufficient relevant scientific information and knowledge regarding the extent of potential adverse effects allows the Precautionary Principle referenced in the Biosafety Protocol to be triggered. The GMOs currently being grow and imported into South Africa pose potentially dangerous risks to human health and the environment.

Recommendation

The GMO Act must be substantially amended to reflect the precautionary principle as set out in Articles 10 and 11 of the Biosafety Protocol. The current formation of the Precautionary Principle in the Regulations to the GMO Act comes from Annex III of the Biosafety Protocol dealing with risk assessment and not decision-making. The South African government must ensure that it adopts a rigorous scientific and democratic approach to decision-making. Crucially, it must also seek and consider sustainable alternatives to GMOs.

4. RISK ASSESSMENT

Article 15 of the Biosafety Protocol requires that Risk Assessments must be carried out in a scientifically sound manner, in accordance with Annex III, taking into account recognised risk assessment techniques. The GMO Act continues to be silent on the question of the scope, parameters, principles and requirements for risk assessments. It is not acceptable that these be reflected in a set of non-binding guidelines sitting on some government official's desk.

Recommendation

South Africa must comply with the requirements of the Biosafety Protocol and ensure that it does so, but implementing its obligations through the GMO Act, and not a set of non-binding guidelines. In any event, we strongly recommend that these guidelines be independently peer reviewed.

[12] Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Adopted in Montreal on September 11, 2003. http://www.biodiv.org/biosafety/protocol.asp

5. DEFICIENCIES IN THE GMO ACT REGARDING SPILLAGE OF GMOS DURING TRANSPORT

We are extremely concerned about the negative environmental impacts that may arise from the spillage of whole GM maize grains during transportation and the milling process itself. We note with alarm that the transportation of GMOs as well as the mills to be used in the processing of GMOs is captured by the extraordinarily wide definition of contained use in section 1 the GMO Act.

We strenuously dispute this definition, because the transportation of GMOs and indeed, the milling thereof, is in fact a release, requiring appropriate and adequate biosafety measures (which do not in any event exist in terms of the GMO Act) that are designed to prevent ecological harm. This is particularly pertinent given that the GMO Act exercises regulatory functions in respect only of those facilities where actual genetic modifications are conducted. Only academic and research institutions and bodies involved in genetic modifications under contained use, may be required to be registered.[13]

We are aware that the government too, is cognisant of these regulatory deficiencies, and in this regard, Dr Julian Jaftha, the registrar of the GMO Act, has recently proposed five measures regarding the importation of genetically modified corn that have only commodity clearance in South Africa. According to the June 2004 issue of the Animal Feed Manufacturers' Association (AFMA) publication.

(Source: Crop biotech update 23 July 2004)

Recommendation

The definition of 'contained use' must urgently be redrafted, as discussed elsewhere. The measures proposed by the Registrar are welcome, but must, however, be given effect to in the Regulations under the GMO Act, for enforcement and compliance purposes. We also point out, that we are not convinced that any or any proper monitoring has or will take place, to ensure that GMOs imported for food and feed does not cause harm to the environment as a result of spillage during import, transport and processing phases. In fact, we are not aware of any measures being taken by either the NDA or the Department of Environmental Affairs and Tourism of such monitoring**.**

6. FAIR ADMINISTRATIVE JUSTICE AND PUBLIC PARTICIPATION

It is our belief that administrative decision-making on the part of the EC established under the GMO Act concerning GMOs fall within the purview especially of section 4(1)(a) and (b) of Promotion of Administrative Justice Act No 3 of 2000 ("PAJA"). In terms of section 4(1) of PAJA, the EC must, in order to give effect to the right to procedurally fair administrative action, decide whether-

> " (a) to hold a public enquiry;
> (b) to follow a notice and comment procedure in terms of subsection (3);
> (c) to follow the procedures in both subsections (2) and (3);
> (d) where the administrator is empowered by an empowering provision to follow a procedure which is fair but different, to follow that procedure; or

[13] Section 4(1) of the Regulations to the GMO Act.

(e) to follow another appropriate procedure which gives effect to section 3."

We strenuously dispute the view held by the NDA that regulation 6 of the GMO Act Regulations (per letter from the Registrar to the ACB dated 1 December 1999), is a fair procedure, as contemplated by the objections and provisions of section 3(5) the PAJA. It is our view that regulation 6 of the Regulations made under the GMO Act is not in compliance with sections 3 and 4(1) of PAJA. We refer the EC to our numerous objections submitted to the EC over the last few months, to various applications for GM imports and releases, as well as to numerous correspondence wherein we have illustrated amply and clearly to the EC and the Registrar, that regulation 6 of the said GMO Regulations is inherently unfair, prejudicial and obstructs the administration of justice.

It is our contention that regulation 6 of the Regulations made under the GMO Act is inconsistent with the provisions of PAJA. PAJA triumphs the said Regulations made under the GMO Act; whereas the Regulations of the GMO Act came into effect on the 1 December 1999, PAJA came into effect on the 3 February 2000. The Regulations made under the GMO Act are in any event, subordinate legislation and can in no way be said to be equivalent to constitutional legislation such as PAJA.

In any event, we are of the belief that the said regulation 6 which deals with an invitation by an applicant to members of the public in the area where a release is intended to take place, is not within the contemplation of sections 3 and 4(1) of PAJA. Both section 3 and 4(1) of PAJA deal with administrative action. It is clearly the intention of the legislature that PAJA should apply to the duty on the part of the administrator regarding administrative actions vis-à-vis the public, in ensuring fair administrative justice. Since regulation 6 of Regulations of the GMO Act deals with a notice and comment procedure (between an applicant and members of the public where the release is intended to take place).

Recommendation

The current provisions in the GMO Regulations dealing with public input is not consistent with the public participation requirements of Chapter 2 of Regulations promulgated in terms of PAJA (Government Gazette Vol. 446. No 23710, 31 July 2002. These deals with the Notice and Comment Procedure on the part of the administrator, regarding administrative action as is required by section 4(1) of PAJA and not, notices by the applicant, as is required by regulation 6 of the GMO Regulations, for comments by the public. The GMO Act should be amended so as to make specific reference to and incorporate Chapter 2 of the PAJA regulations.

7. ACCESS TO INFORMATION

The proposed amendments to the GMO Act on this issue, will not assist civil society groups in South Africa in gaining access to information concerning permit applications in order to meaningfully participate in the process. This is so, because even summaries of risk assessments will contain sections that have been deleted because the applicants have decided, that it is confidential business information (CBI). Civil society groups have experienced this first hand, and have come to the conclusion that the NDA and the applicants (biotechnology companies) have obstructed us from conducting any meaningful assessment of permit applications. Indeed, it has become self-evident that the NDA gives the applicants *carte blanche* to exercise an arbitrary decision regarding the

information that has been withheld from us, on the grounds that such information is considered by the Applicant to be CBI.

In some instances, we have been furnished with extracts of the results of previous field trials conducted and in other instances, all the results of previous field trials have been withheld, because the applicants have refused to consent to our gaining access to such information.

This biased and grossly inequitable situation has arisen principally, because the NDA has failed to establish a proper formal process for the determination and characterisation of what constitutes CBI.

Recommendation

The NDA must establish a proper formal open, transparent and accountable process for the determination and characterisation of what constitutes CBI.

8. LIABILITY AND REDRESS

The provisions of the GMO Act hold farmers liable for environmental damage caused by GMOs. This situation has not been remedied by the proposed amendments. It is unacceptable for the South African government to excuse the biotechnology industry from liability.

Recommendation

The African Model Law captures extensively, the essential elements for a liability and redress regime, which should be incorporated into the GMO Act.[14] Additionally, the Model Law contains a critically important provision to ensure that those responsible for environmental and other harm, will be required to provide adequate resources for redress. It requires that where approval is granted, the applicant must furnish evidence of insurance cover or some other adequate arrangements to meet its obligations under the law.[15]

9 FAILURE TO ESTABLISH IPS SYSTEM AND COMPLY WITH DOCUMENTATION REQUIREMENTS OF THE BIOSAFETY PROTOCOL

The South African government has failed to establish an identity preservation system, whereby the unique identification of GMOs/GM varieties can be traced throughout the food chain, from farm to plate. Thus, in the event that a variety of GM maize causes adverse affects on animal and/or human health, it will be almost impossible for anyone to trace the offending GM variety, and hence, the offending biotechnology company. **There is no reason why the South African government should shield the biotechnology industry in this way.**

[14] Article 14 of the Model Law.
[15] Article 6(7) of the Model Law.

The South African government grants approval to importers in a single application for the import of several GM varieties for use in South Africa as food, feed and/or processing. Additionally, the South African government has made no attempt to safeguard non-GM food from contamination through co-mingling on farms, silos and along the food chain. Neither the Department of Agriculture nor any other government agency has conducted any reliable or proper post commercialisation testing and monitoring to determine the extent of the contamination of non-GM crops in the fields.[16]

Such single approvals have three adverse consequences:

(1) It reduces the liability by those responsible, in the event of a mix-up occurring as it did in the Starlink case.

(2) It does not allow food producers to indicate on their labels, that foodstuff of feed is derived from a particular GM event, that contains antibiotic resistance marker genes for example, Bt 176 maize which has recently been banned in Spain because it contains the contains the *bla* marker gene that confers resistance to ampicillin.[17]

(3) It makes it extremely difficult for South Africa to fully comply with the outcome of negotiations under Article 18 of the Cartagena Protocol on Biosafety. The First Meeting of the Parties (MOP), Kuala Lumpur, Malaysia 23-27 February 2004, adopted an important decision on the documentation that accompanies bulk shipments of GMOs imported for food, feed and processing. In this regard, the MOP decided that in regard to GMOs imported for direct use as food, feed and processing, the documents should clearly identify that the shipment **may contain LMOs for direct use as food, feed or for processing and not intended for direct introduction into the environment.** The documents should include the **common, scientific and commercial names of the LMOs, the transformation event code or its unique identifier code to establish clearly the identify of the LMO and any unique identification.**

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[16] It must be noted that according to Cotton South Africa, and contrary claims by Monsanto, Syngenta and indeed the South African government, cotton does have a wild relative, *Gossypium herbaceum* subsp. *Africanum*, found in South Africa. The possibility for gene transfer in locations within the United States where wild or feral cotton relatives exist (Hawaii and Florida) has led the Biopesticides & Pollution Prevention Division (BPPD) proposing containment provisions for these states. EPA Pesticide fact sheet for Bollgard Cotton. Monsanto Biotech Basics.
http://www.biotechknowledge.com/biotech/bbasics.nsf/product_information_bollgard_cotton_pest.html?OpenPage
The USEPA has reviewed the potential for gene capture and expression Cry endotoxins in cotton by wild or weedy relatives of cotton in the United States, its possessions or territories. The possibility for gene transfer in locations in Hawaii and Florida, where wild or feral cotton relatives exist has led to the EPA imposing stringent sales and distribution restrictions on Bt crops within these states. These containment measures are intended to prevent the movement of Cry1Ac from Bt cotton to wild or feral cotton relatives that exist in Hawaii and Florida. Cotton Relatives.
http://www2b.abc.net.au/rural/grow/newposts/0/post38.htm

[17] 29th April 2004, Spain banned Syngenta's genetically modified (GM) Bt176 maize for commercial cultivation on the grounds that it may confer resistance to ampicillin. (*EIEstado espanol retirara un OGM a instancias de la UE. El maize Bt 176 Podrian provoca resistencisas a los antibioticals, GARA*). According to Richard Lopez de Haro, Spain's Office of Crop Varieties, Spain's food safety authority banned Bt 176 after the European Food Safety Authority (EFSA) published its report on the utilisation of antibiotic resistance market genes in GM plants.
http://www.efsa.eu/int/press_room/press_release/386_en.html

Recommendation

It is incumbent upon the South African government to urgently establish a sound unique identification system in order to come in line with the Biosafety Protocol, particularly the provisions of Article 18 of the Protocol dealing identification and traceability of GMOs. As a Party to the Biosafety Protocol, South Africa is expected to fully comply with the provisions of the Protocol including the outcome of on-going negotiations, including the decisions of MOP 1. It should start doing this sooner, rather than later, before especially its neighbours from the Southern African Development Community (SADC) take it to the Protocol's Compliance Committee.