The National Biosafety Legislation for Genetically Modified Organisms (GMOs) in South Africa

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September 2010

Published by:

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Introduction

The Genetically Modified Organisms Act 15 of 1997, as amended by Act 23 of 2006, recognises the potential risk associated with releasing genetically modified organisms (GMOs) into the environment, as well as the risks associated with introducing transgenic crops into the human and animal food chain. However, the recognition of biosafety as a holistic approach to the assessment and regulation of genetic modification (GM), based on the Precautionary Principle, is absent in South Africa. GMOs were introduced into the country in a context where no regulatory framework, biosafety policies or laws were in place.

The people whom GMOs stand to affect the most, i.e., the poor, are disarmed by the inadequate public participation processes provided for in our biosafety legislation, which also provides little protection to consumers.

Other legislation such as the Promotion of Access to Justice Act 3 of 2000 and the Promotion of Access to Information Act 2 of 2000 is seriously compromised in our biosafety regime, which is considered unconstitutional by several commentators. The government of South Africa has accepted the industry line that GMO products are substantially equivalent to their natural counterparts, and that no independent safety analysis needs to be done. Consumers are held liable for any accidents regarding GMOs and still have no redress with respect to the developers of the GMOs. The untested claims by industry that GM crops stand to increase yields and reduce reliance on pesticides and fertilizers was bought hook, line and sinker by our government, which aggressively pursues these touted advantages of biotechnology. Attempts by civil society to ensure that a rigorous system of checks and balances is observed, are seen as obstructing the GMO industry’s panacea to the impending climate and food crises.

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1 The significant work of the African Centre for Biosafety (www. biosafetyafrica.org), in the field of South Africa biosafety legislation, is especially acknowledged in the production of this paper.
2 GMO Act 15 of 1997: the opening paragraph and for example Sect 1 (a) definition of accident.
3 The first GMO Act dates to 1997 while the first open field trials were planted as early as 1989. SANBI (South African National Biodiversity Institute) was only tasked with developing a risk analysis and monitoring framework for GMOs in 2008, 11 years after adopting the GMO Act.
Despite the conflict of interest, the biotechnology industry is effectively allowed to regulate itself, and the regulatory bodies are made up of experts in biotechnology as opposed to biosafety. The absence of effective traceability and segregation systems and a labelling regime with respect to GMOs in South Africa, puts us and our neighbours at grave risk. Whether our new Consumer Protection Act\(^5\), which requires that GMOs are labelled in accordance with yet to be drafted regulations, will bring relief to consumers remains to be seen.

Diagram: South Africa’s GMO Timeline


Overview of Biosafety Legislation

The Genetically Modified Organisms Act 15 of 1997 (amended by Act 23 of 2006) - with its accompanying regulations - is the principal instrument for regulating GMOs in South Africa. South Africa also ratified the international Cartagena Protocol on Biosafety which provides a legally binding framework of rules to be applied to the import, export, transit, handling and activities related to the use of GMOs in order to protect the environment, biodiversity and human health. This has now been included as an Annexure to the Act. A draft Biosafety Policy was published post development of the GMO Act in August 2005.

The conceptual framework that informs the GMO Act (15 of 1997) and subsequent draft Biosafety Policy was developed by the South African Committee on Genetic Experimentation (SAGENE). The Apartheid Government established SAGENE in 1979 and tasked it with facilitating the uptake of genetic engineering in food, agriculture and medicines. In 1994 it was given legal power to advise government on any legislation or controls relating to GMOs and it served as the key advisory body to government until 1999, when the GMO Act was adopted. Several industry supported scientists served on the SAGENE committee, which approved the first open field trials in South Africa, and continued to serve on the technical Advisory Committee under the GMO Act when this was constituted.

SAGENE’s point of departure was that GM crops are safe and substantially equivalent to conventional crops, thus not requiring independent safety assessment, yet different enough to patent. In this regard the South African regulatory system has taken its cue from the USA and its multinationals, from where this technology originates.

The imperative to promote genetic engineering and biotechnology overrides holistic biosafety concerns in the GMO Act and draft Biosafety Policy. This is in stark contrast to the objectives of the international Cartagena Protocol on Biosafety which promotes the regulation of GMOs in accordance with the “precautionary principle”. This is contained in Principle 15 of the Rio Declaration on Environment and Development as well as in the African Model Law on Safety in Biotechnology of the African Union. It was hoped that our biosafety regime would provide an overarching framework with common measures, requirements, and criteria to curtail risks and assess environmental and socio-economic impacts, to ensure that society is not exposed to hazardous GMOs.

The GMO Act, however, did not meet these expectations and proved to be a very limited document describing the regulatory authority and outlining the process for case-by-case permitting of GMO events, with little regard for the intricacies of this very risky technology.

The draft Biosafety Policy further detailed what the document described as government’s “coherent” approach – where biotechnology is embraced and biosafety is defined as a risk management measure by means of an implementable regulatory system. The document notes in the problem statement that “it should not be construed that because there is potential risk [with biotechnology] that the risk will materialise”. It also categorically rejects the preventative and

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6 GMO Amendment Act 23 of 2006.
7 Government Gazette No.27913 26 August 2005.
9 To date all of the GMOs approved for release in South Africa were developed in the USA. USDA GAIN Report. 15 July 2010.
10 Draft Biosafety Policy, page 4.
precautionary approaches. This may explain why, to date, not a single environmental impact assessment (EIA) has ever been conducted in South Africa.

Surfacing 13 years after the first field trials were planted, the draft Biosafety Policy did not engage with any of the burning issues for which government should have provided policy guidance. These included the development of pest and weed resistance, cost of patented technologies for small scale farmers, commodity imports where the GMOs had not been approved for growing in South Africa, traceability documentation for bulk shipments, post commercialisation monitoring of GMOs, new scientific information revealing previously unknown risks, food labelling and public participation.11

Several additional pieces of legislation relate to the regulation of GMOs in South Africa. An overview of South Africa's national biosafety and related legislation is presented below and discussed in greater detail in further sections of this paper.

**Diagram: Overview of key biosafety-related legislation**

<table>
<thead>
<tr>
<th>Department of Agriculture Forestry &amp; Fisheries</th>
<th>Department of Environmental Affairs</th>
<th>Department of Health</th>
<th>Department of Trade &amp; Industry</th>
<th>Department of Science &amp; Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft Biosafety Policy, 2005</td>
<td>National Environmental Biodiversity Act, 2004 (amendments 2009)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12 Full name is ‘Regulations Relating to the Labelling of Foodstuffs Obtained through Certain Techniques of Genetic Modification’, made in terms of Section 15(1) of the Foodstuff, Cosmetic and Disinfectant Act 54 of 1972.
Regulatory Bodies

The GMO Act established a decision-making body on GMOs, the Executive Council (supported by a technical committee), the Advisory Committee, a Registrar, and Inspectors.

The Executive Council

The Executive Council\textsuperscript{13} (EC) is the ultimate decision making body with respect to GMOs in South Africa. The Council includes eight governmental departments: Agriculture; Science and Technology; Environmental Affairs and Tourism; Health; Labour; Trade and Industry; Arts and Culture; and Water Affairs and Forestry. The Department of Agriculture chairs the Council, which works on the basis of consensus.

The Executive Council (EC) tasks include reviewing:

\begin{itemize}
  \item Recommendation reports from the Advisory Committee (see below)
  \item Comments from the public
  \item Responses of the applicant to comments made by the public
  \item Responses from the Advisory Committee to any comment of a scientific nature.
\end{itemize}

In terms of the Amended Act, the EC is also responsible for considering the need for an impact assessment of GMOs on the environment, or whether a report on the socio-economic impact of the GMO should accompany the application.\textsuperscript{14} The EC is also empowered to issue and approve guidelines for activities concerning GMOs. This they can do without consulting civil society, as under the law they are only obliged to make these guidelines available to the public.

The Advisory Committee

Section 10 of the GMO Act allows for the appointment of an Advisory Committee (AC) whose members have tenure for 5 year periods. This is the body of experts that is primarily responsible for interrogating the scientific data contained in applications, but most of these experts are trained in the fields of genetic engineering as opposed to biosafety. The Act requires that two members are from the public sector, and the recent amendments qualified this by requiring that one of these members have knowledge on ecological matters and GMOs and the other on the impact of GMOs on human and animal health.\textsuperscript{15} The AC may have sub-committees, and is able to elicit written opinion from scientific experts on any aspect of their brief relating to genetic modification.\textsuperscript{16}

The Registrar and Inspectors

The office of the Registrar is situated in the Directorate of Genetic Resources in the Department of Agriculture, Forestry and Fisheries (DAFF) and is tasked with the day to day administration of GMOs.\textsuperscript{17} The Registrar is appointed by the Minister of Agriculture, Forestry and Fisheries, and issues permits on instruction of the EC and is responsible for ensuring compliance with permit conditions.

\textsuperscript{13} Section 3 of the GMO Act 15 of 1997 (as amended by Act 23 of 2006).
\textsuperscript{14} Sect 5(1)(a) GMO Amendment Act 2006.
\textsuperscript{15} Section 10 (1) (b) of the GMO Amendment Act 2006.
\textsuperscript{16} Sect 11 (1)(d) of the GMO Amendment Act 2006.
\textsuperscript{17} Several departments have been recently restructured and the DAFF is thus a newly constituted department.
The Registrar is obliged to keep a register of all facilities used for contained use, all trial release sights, and the names and addresses of all people involved in the trials or contained use.

The Registrar can arrange for inspectors to conduct non-routine investigations. Inspectors are empowered to seize any material, documents or GMOs that provide proof that there has been a contravention of the GMO Act, as well as dispose of or repatriate any GMO if it has an adverse impact on the environment. Inspectors must have a warrant to enter premises.

The Registrar is also tasked with posting information on the GMO Act and regulations, summaries of risk assessments and final decisions regarding permit authorisations to the Biosafety Clearing House in terms of the Biosafety Protocol. Procedures for transboundary movements of GMOs and notice of any unintended or illegal transboundary movement must also be posted.

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18 Sec 15 (4)(e) of the GMO Act.
19 Sect 11 (4) of the GMO Act .
The GMO Approval Process

Anyone wishing to import, export, engage in contained use (other than in an academic or research facility)\(^ {21}\) or conduct the trial or general release (and marketing) of GMOs is required to conduct such activity under authority of a permit issued by the registrar. Only three types of permits require public notification\(^ {22}\):

- Commodity release of GMOs (through importation) for food, feed or processing
- General release of GMOs into the environment (e.g. growing of food)
- Trial releases of proposed GMOs

Permit applications must include a scientifically-based risk assessment (for example, a summary of field trials undertaken, pollen spread, seed dispersal, vegetative spread of the LMO (Living Modified Organism), foreign genes and gene products, resistance, human and animal health, pathogenic and ecological impacts), proposed risk management measures and proof of the public notice. The environmental and social impact assessments are included if the Executive Council requires these.\(^ {23}\)

The AC must then interrogate the application and make a recommendation to the EC. The EC then considers the recommendation together with public input and if it is satisfied that a specified activity with a GMO may be conducted, authorizes the Registrar to issue the permit.

\(^{21}\) Such facilities with Containment Level 1 and 2 must be registered in accordance with Regulation 8 under the GMO Act.

\(^{22}\) Regulation 9 (2) as revised, under the GMO Act. Feb 2010.

\(^{23}\) Regulation 3(3) as revised, under the GMO Act. Feb 2010.
Flaws in the Biosafety regime

South Africa has a substantially flawed regulatory system that is skewed in favour of facilitating the issue of permits, without any attendant liability for impacts, or adequate mechanisms to address the human health, environmental protection, food security and socio-economic implications of GMOs.

The public participates from the sidelines

There has never been a full, informed and appropriate public debate or policy process on how to regulate GMOs in South Africa, and indeed the draft Biosafety Policy was only published after the GMO Act had been in force for 6 years.24 As a consequence, the GMO Act was developed and passed without adequate public participation and debate.

The only window of opportunity for the public to be involved in the decision making process regarding GMOs is through the notice and comment procedure in the GMO permitting system outlined in Regulation 6. The regulator has chosen this notice and comment procedure over procedures to hold a public inquiry (contemplated in other legislation for ensuring procedural fairness25).

A cartoon depicting the GMO application process issued by the Department of Science & Technology’s “Public Understanding of Biotechnology” Programme26 starkly illustrates the limited say the public has in decisions relating to fundamental issues such as the introduction of novel organisms and foods.

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24 The GMO Act came into effect in December 1999, after regulations to bring the Act into effect were promulgated. The draft Biosafety Policy was published in August 2005.
25 PAJA Section 4.
This notice and comment procedure effectively negates public participation in a number of ways:

- The published notices have limited circulation. Notification requirements are limited to the print media: three national newspapers for general or commodity release and two local newspapers and one national one for a proposed trial release. This effectively eliminates the majority of people directly affected by GMOs, being the poor and illiterate.

- The information provided in the notice is insufficient for the general public to engage with. The notice only provides a description of the LMO concerned, and limited information on the release. No specific information is provided relating to risk assessments or mitigation, or impacts on ecology, people or the economy (this must be specifically applied for using the Public Access to Information Act – see below). Applicants need only to give the name of the town or magisterial district of GMO release, which does not give neighbouring farmers or communities adequate notice of impending GM crops. In the case of **Biowatch Trust v The Registrar, Genetic Resources and Others** 27, the court held that mere reference to a town or magisterial district is inadequate to properly inform the public.

- Once the public have made their submissions, the extent to which these comments are considered and factored into final decisions to permit GMOs are seldom known, as the Executive Council has the discretion to consider or discard public input. The regulator is not obliged to provide any response to the submissions or even notify submitting parties of the outcome of decisions. Permit approvals are typically published on the Department of Agriculture’s website some months after the decision was made.

The licensing of experimental facilities and the use and development of GMOs in contained facilities are not subject to public scrutiny. The GMO Act requires the Registrar to keep registers of contained

27 Trustees of Biowatch v Registrar Genetic Resources and Five others CC.
use as well as trial sites and the people involved therewith, yet no provisions exist for public access to this.

The South African government continues to consider this notification and invitation to comment procedure as different but fair as contemplated by Sec 3(5) of the Promotion of Administrative Justice Act 3 of 2000 (PAJA).

The notice and comment procedure under the Fair Administrative Procedures Regulations\textsuperscript{28} stipulates that:

- Information must be published in gazettes, national newspapers or electronic media and make use of grassroots approaches such as public meetings or loudhailers or flyers to inform people.
- The notice must contain sufficient information so as to facilitate meaningful comment. Where appropriate (as would be the case in GMOs) the notice should specify where further information could be viewed. Notices must take account of the language preferences of the concerned community and must be in at least two official languages.

In the case of GMOs, if members of the public want access to further information they are obliged to make a costly and time consuming application using the cumbersome Promotion of Access to Information Act 2 of 2000. Requests must be phrased very carefully to obtain useful information, and even so a paucity of information is typically received with only summarised versions of risk assessments.\textsuperscript{29}

**Confidential Business Information**

Biotechnology companies are required to submit two copies of their application, one containing confidential business information and the other without it for distribution to the public. Section 18 (2) of the GMO Act 15 of 1997 as amended, limits the type of information to which the public may have access, but states that the following information may not be withheld:

- The description of the GMO and name & address of the applicant
- Purpose of contained use or release and location of use
- Methods and plans for the monitoring of the GMOs and for emergency measures in case of an accident
- The summary of scientifically-based risk assessment of the impact on the environment and human and animal health.

In practice, however, biotechnology companies determine what information is confidential. This is in clear violation of Section 18(2) of the GMO Act which requires the EC to decide whether the information required in terms of Section 18 can be withheld for intellectual property protection and to inform the applicant accordingly.

The risk involved in the use of transgenic crops is acknowledged by the GMO Act, yet the Act affords little protection to consumers and sets low standards for participation, effectively disregarding the national legislative protection provided for in administrative procedures as codified in Section 3(2) of PAJA.

\textsuperscript{28} GN R1022 in Government Gazette of 31 July 2000.

\textsuperscript{29} African Centre for Biosafety, Earthlife Africa and Biowatch submissions to NEAF study.
Civil society has consistently pointed out the inadequacies of the public participation process in matters concerning GMOs.\textsuperscript{30} Biowatch South Africa had to take court action to seek better access to information in order to exercise the right to participate.\textsuperscript{31}

Furthermore the National Environmental Management Act (NEMA) also requires that the participation of all interested and affected parties in environmental governance be promoted and that all people must have the opportunity to develop the understanding, skill and capacity necessary for effective and equitable governance.

Concerns from a wide range of stakeholders prompted the National Environmental Advisory Forum (NEAF), a ministerial body advising on environmental affairs, to commission a legal assessment of “the extent and nature of public engagement” in decision-making concerning GMOs. It is the considered view of several commentators that the procedure provided for in the GMO Act is indeed different to the minimum requirements for fair administrative procedures, but that the procedure is anything but fair, to the extent that the GMO Act is \textit{de facto} unconstitutional.\textsuperscript{32} The NEAF made various recommendations to the then Minister of Environmental Affairs and Tourism for improving on the glaring inadequacies in the public participation process, but the Amendment Act failed to address this lacuna in our GMO law.

\textsuperscript{30} Ibid and numerous letters of complaint by the African Centre for Biosafety (see www.biosafetyafrica.org.za).
\textsuperscript{31} Trustees of Biowatch v Registrar Genetic Resources and Five others CC.
The right of the public to appeal decisions

Parties who feel aggrieved by any decision of the EC, registrar or inspectors have the right to appeal the decision “within 30 days of the appellant being notified in writing of the decision or action”. 33 However, as noted by ACB in a letter of complaint, the Registrar has failed to provide interested and affected public parties with such notifications, even in circumstances where they lodged objections. This situation is compounded by the non-availability of information on the government’s website and the extreme lateness of postings of the minutes of the meetings of the Executive Council. 34 The current provisions in the Genetically Modified Organisms Act also fail to ensure that interested parties are furnished with the reasons for final decisions on permit applications. 35 This makes the review of any decision taken by the EC so much more difficult, especially within the 30-day time frame.

This is in contravention of Promotion of Administrative Justice Act (PAJA), Act 3 of 2000, which requires that an Administrator must give adequate notice of any right of review or internal appeal.

The Department of Agriculture has been drafting revised guidelines for lodging appeals and these have been approved in principle by the Executive Committee. 36 However, these revised guidelines have not been made available to the public for comment, nor has this issue been addressed in the provisions with regard to appeals in the amendments to the Regulations published in February 2010. 37

33 Regulation 11 (1) (a) amended on 26 Feb 2010 under Sect 19 of the GMO Act.
34 African Centre for Biosafety Letter to Compliance Committee August 2009.
36 Department of Agriculture, Fisheries and Forestry. 3 March 2009. Minutes of the meeting of the Executive Council under the GMO Act, 1997.
37 Regulation 11.
Conflict of Interest

The Public Service Act (103 of 1994) and the Code of Conduct contained in Chapter Two of its Regulations (of 2001, as amended) elaborate on the requirements of section 195 of the Constitution (1996) that public administration must be characterized by a high standard of public ethics. Public servants are required to avoid a conflict between their public duties and their private interests. The Code sets a high standard in this regard, stating in clear and obligatory terms that employees must recuse themselves “from any official action or decision-making process which may result in improper personal gain”, and this should be properly declared by the employee. These standards are reinforced by the provisions of the Public Finance Management Act (1 of 1999, PFMA) and the Prevention and Combating of Corrupt Activities Act (2004).

The GMO Act stipulates in Section 13 that any member who faces a potential conflict of interest should recuse him or herself. However, several former SAGENE members whose research is substantially connected to industry, continued to advise government after the adoption of the GMO Act, and this was not frowned upon, even though big business have a vested interest in having permits approved.

Following pressure from civil society, the EC had to replace a certain member of the AC who was exposed as having interests in private companies. The member concerned stated that there was no conflict of interest and due to scarcity of experts in the GMO field, it may happen that an AC member may consult for industry as well as government. This revolving door strategy is very reminiscent of the American policy that allows industry players to occupy high office in the public regulator.

Inadequate assessment of impacts and risks

A key concern of GMO critics is the general lack of independent safety and risk assessments of GMOs that are being introduced into our foods and environment. Approvals for GMOs have been based on dossiers submitted by the biotechnology industry. These rely heavily on the approvals granted by the Environment Protection Agency (EPA) in the US, using protocols that fail to meet international standards as expressed by the UN Food and Agriculture Organisation (FAO) and World Health Organisation (WHO). Furthermore environmental assessments have been cursory and often relate to studies in other countries or data produced by the applicant under conditions of contained use or in field trials where agronomic performance and not environmental safety are the key considerations.

Civil society has lobbied continuously on this issue, calling for independent risk analysis and monitoring of impacts. Finally, the GMO Amendment Act requires that the EC consider scientifically based risk assessments and Regulation 4 of the amended Regulations published in February 2010 describes what such scientifically-based risk assessment shall entail. This includes risks to the environment and human and animal health and makes reference to risk assessment methods applied at an international level. However, given the paucity of funding for independent research and the persecution of scientists who publicise negative impacts, it remains to be seen whether these new provisions result in better risk assessment in decision-making.

The GMO Amendment Act also for the first time enables the EC to request an assessment of the socio-economic impact in addition to an environmental impact assessment. The amended Regulations describe the socio-economic impacts that may be considered. In addition to economic

issues these can include impacts on biological, genetic and natural resources; cultural knowledge and practice; and food security.\(^\text{40}\)

The GMO Amendment Act aligns the requests for an EIA with the requirements of the National Environmental Management Act of 1998. Neither of these additional provisions nor the amended regulations address the issue of what circumstances should trigger an EIA or social impact assessment and the requirement for these remains at the discretion of the EC or Minister of Environmental Affairs.

**Environmental Impact Assessments**

The fact that no Environmental Impact Assessment has ever been conducted prior to the environmental release of a GMO in South Africa has been a major bone of contention for many. The African Centre for Biosafety has been particularly diligent in engaging with the Department of Environment Affairs and Tourism and subsequently the Department of Water and Environmental Affairs on environmental risk assessment procedures and requests for EIAs to be conducted prior to the commercial release of GMOs. To date these requests have been stone-walled.\(^\text{41}\)

Three separate Acts make allowance for an EIA to be conducted prior to the introduction of GMOs. These can be summarised as follows:

*National Environmental Management Act 107 of 1998 (as amended)*

Revised EIA Regulations published in accordance with Chapter 5 of NEMA, classify the release of a GMO as a Schedule 1 activity where only a basic assessment is required (this is elaborated below).\(^\text{42}\)

*The GMO Amendment Act 2006*

Makes provision for the EC to request that the applicant submit an EIA in accordance with the provisions of NEMA,\(^\text{43}\) but offers no guidance as to what would trigger an EIA, or how it should be conducted.

The amended Regulations to the GMO Act note that an EIA may be required in accordance with Sect 78 of NEMBA (National Environmental Management Biodiversity Act), and that the EC may on a case-by-case basis recommend to the Minister of Environmental Affairs that an EIA is required.\(^\text{44}\)

*National Environmental Management Biodiversity Act 10 of 2004 (NEMBA), (amended in 2009)*

NEMBA suffers from similar flaws as the GMO Act as it does not compel risk or environmental impact assessments but leaves EIAs to the discretion of the Minister of Environmental Affairs and

\(^{40}\) 5(1) of the Regulations under the GMO Act (No 15 of 1997) published by GN No. R 120 of 26 February 2010.

\(^{41}\) See numerous briefings on Environmental Risk Assessment and EIAs as well as letters to the Ministers at www.biosafetyafrica.org.za

\(^{42}\) GN No R386 Listed Activities of NEMA Table 1. Listed activity No 25.

\(^{43}\) Sec 5(a) of Act 23 of 2006.

\(^{44}\) 6 (1) and 6 (2) of the Regulations under the GMO Act (No 15 of 1997) published by GN No. R 120 of 26 February 2010.
Tourism. There are no clear criteria that would prompt the Minister to make this request and no procedures outlined for the Minister to interact with either the EC or the public in this regard. 45

Nevertheless NEMBA provides two opportunities for the Minister to require an EIA:

1. Section 78 of NEMBA, as amended in 2009, provides for the Minister to call for an EIA “if the Minister has reason to believe that the release of a genetically modified organism into the environment under a permit applied for in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), may pose a threat to any indigenous species or the environment, no permit for such release may be issued in terms of that Act unless an environmental impact assessment has been conducted in accordance with Chapter 5 of the National Environment Management Act [NEMA; Act no. 107 of 1998] as if such release were a listed activity contemplated in that Chapter”. In other words, a basic environmental assessment would be required.

2. Section 53 of NEMBA provides that the Minister may by notice in the Gazette identify any process or activity in a listed ecosystem as a threatening process. 46 GN No. R387 (Government Notice of Regulation 387) of the EIA Regulations lists as an activity requiring a full environmental impact assessment “any activity or process identified in terms of Section 53 of NEMBA”. 47 The Minister has, however, to date not published any list of activities considered threatening to listed ecosystems.

To further support the provisions of Section 78 of NEMBA an Environmental Risk Assessment Framework was developed by the Department of Environmental Affairs and published after public consultation in September 2008. Unfortunately this is not a legally binding framework and only serves to provide guidance to the EC on how to assess the environmental impact of a GMO and a suggested list of criteria that could be used to trigger an EIA. This guideline makes specific reference to the effects of stacked GMOs and antibiotic resistance markers. The criteria for EIAs are concerned with microbes, GMOs for bio-terrorism, impacts on threatened or protected organisms, impacts on indigenous plants and cultural practice, significant negative socio-economic impacts and substantial changes to conventional use or agricultural practices. 48

**The imperative for Environmental Impact Assessments**

Conducting an Environmental Impact Assessment for the release of a GMO would introduce a considerably new dynamic into the both the public participation and risk assessment aspects of GMO decision-making. Notwithstanding the flaws in EIA processes, even a Basic Environmental Assessment as described in Part 2 of NEMA (as amended) would be a significant improvement on the current provisions of the GMO Act and Regulations. These requirements of a basic assessment include the following:

- The process is managed by relatively independent consultants, not the applicant.
- Owners and occupiers of land adjacent to a proposed activity must be notified.
- The Ward Councillor in the area of the proposed activity must be notified.

46 Part 3 of Chapter 5 of NEMBA.
• A map of the location of the activity must be included in the report.
• The impact of the activity on all receiving environments including the socio-economic and cultural environments must be described for the public to comment on.
• The consultants must compile a register and correspond with all interested and affected parties that register interest in the process.
• The consultants/applicants are obliged to consider and respond to all comments received by the public and summarise and submit these to provincial or national Departments of Environmental Affairs for decision-making.
• The report must describe the need for the activity and outline possible alternatives for consideration.
• The environmental impact and its significance must be assessed, possible mitigation measures described and planned, and motivation included as to whether, based on this, the activity should go ahead or not.
Socio-economic Considerations

Until recently socio-economic factors have not formed part of the biosafety enquiry in South Africa. Only with the GMO Amendment Act was provision made for the EC to request that applicants submit a socio-economic assessment, but this is not mandatory.\footnote{Sect 5 (1) (a) of the GMO Amendment Act, 2006.} The regulatory system and biosafety policy provide little guidance as to how government should approach the numerous socio-economic impacts that have arisen from the use of GMOs in South African agricultural systems. These include, for example, the impact of the import of subsidised and cheap GM maize from Argentina and the US on food security strategies in South Africa, and the impact of the use of herbicide-tolerant crops and the concomitant reduction in agricultural labour and job losses.

Since modern biotechnology is mostly developed by multinational companies, and the products are aimed at maximizing corporate profits, the socio-economic implications for the public, particularly in developing countries, may not always be beneficial. Introduction of new technologies without solving the underlying structural problems will only exacerbate the problems of hunger and food insecurity.

GMOs pose a number of ethical challenges to the public, and can cause social disruption. The insertion of human genes into genetically modified crops, livestock or food may be unacceptable to many people. The insertion of the genes of certain animals may also be unacceptable to certain religions. Finally, there is the matter of consumers’ and farmers’ rights to choice. With GMOs being produced in secrecy and the dearth of labelling, the public’s right to reject GMOs on whatever grounds is not being adequately respected.
The Labelling Regime

South Africa follows the US model where due to the ‘substantial equivalence’ argument the use of GM techniques per se does not currently trigger labelling. Thus foods containing GMOs as well as GM animal feeds and foodstuffs derived from animals fed on GM feeds, have all escaped the need for labelling under current South African law.

Only in 2004, seven years into commercially GM crop production, did the Department of Health issue “Regulations Relating to the Labelling of Foodstuffs Obtained through Certain Techniques of Genetic Modification”, made in terms of Section 15(1) of the Foodstuff, Cosmetic and Disinfectant Act 54 of 1972. These regulations only require labelling if there is a significant difference in the final product. None of the currently commercialised GMOs fall within the scope of the “significant” differences defined in these regulations: the transferred genes in GM foods are from microbes rather than from animals or humans, do not require different cooking, are arguably not known allergens, and do not have a different nutritional value or characteristic composition.

Some South African companies have through their own initiative labelled products as “GM Free”, but since this is not regulated, food producers are left to interpret for themselves what this entails. One of the few studies done in South Africa, revealed that approximately 71% of a random sampling of products labelled “non-GM”, “GMO-free” or “organic” were found to contain GM ingredients.50

The consumer is at risk in the absence of a mandatory labelling, traceability and segregation system. Labelling does not ensure the safety of GMOs, but enables consumers to avoid them on health, religious or other grounds. Continued demands from civil society for GMOs be labelled to enable the consumer to make an informed decision on whether to consume these or not, has eventually resulted in the inclusion of GMO labelling in Section 24(6) in the Consumer Protection Act which was signed into law in April 2009.

This section now makes it compulsory that “Any person who produces, supplies, imports or packages any prescribed goods must display on, or in association with the packaging of those goods, a notice in the prescribed manner and form that discloses the presence of any genetically modified ingredients or components of those in accordance with applicable regulations.”

The regulations to the Act are in the process of being drafted, so no clarity exists as to how and what products will be labelled. Concerned parties fear that the GMO section of the Consumer Protection Act will just be glossed over, as DAFF do not have the capacity or the willpower to effectively administer a strict labelling regime.51

Initially, the clause was dropped when DAFF as well as the Department of Health resisted the inclusion of labelling for GMOs citing cost implications and concern about the technical expertise required to implement and enforce it. After public debate,52 sparked by civil society and NGOs, the Department of Trade and Industry finally decided to re-insert the clause.

The South African Government rationale for resisting mandatory labelling was explained as follows:53

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51 Charmaine Treherne, South African Freeze Alliance on Genetic Engineering (SAFeAGE).
52 SAFeAGE Press Release. NGOs slams sham GM labeling Regulations.
• Compulsory labelling would result in the increase of food prices and negatively affect street vendors and those with limited purchasing power. Systems to detect and identify GM genetic material/protein by way of diagnostics are subject to error, abuse and are expensive.
• Compulsory labelling of GM foods is not practical since GMOs may increasingly appear in more than 30 000 products that contain maize and soya ingredients.
• Segregation of GM foods from non GM foods is expensive.

The biosafety function of mandatory labelling is to enable the traceability of GMOs from “farm-to-plate”, thus facilitating risk management and monitoring, product recall in the event of an accident as well as issues of liability and redress. National legislation has also yet to be brought on par with Article 18(2) of the Biosafety Protocol, regarding the identification and labelling of GM content in bulk shipments of grain.

It is hoped that the new labelling regulations will remedy this lacuna in our law, and will go a long way in minimizing GM contamination of foods as well as honouring our right to know that we are consuming safe and nutritious foods.
Traceability Systems

There can be no effective and pragmatic labelling regime if proper traceability systems from “farm-to-plate” are not in place.

The global food system is becoming increasingly contaminated with GMOs because GM producing/exporting countries such as the US, Argentina and Canada, have refused to introduce appropriate systems to segregate GMOs from non-GMOs. South Africa has imported hundreds of thousands of metric tonnes of GM maize from Argentina and the US, which although primarily used for animal feed also enters the human food chain directly. All of this happened in the absence of a traceability and segregation system or functional labelling regimes in place. In addition, we are the only country that has allowed the genetic modification of our staple food, maize; yet we have not yet developed adequate systems of checks and balances to protect the poor and vulnerable.54

South Africa does not have a mandatory traceability and identity preservation system. Whether the yet to be released regulations to the Consumer Protection Act will address this in support of a labelling regime is an open question. Issues the regulations would have to deal with include:

- testing of a mixture of GMOs to determine not only the GMO content, but also the individual varieties of GMOs contained in the shipment, to list the GMOs and to ascertain whether these have been approved for import
- ensuring that non-GM shipments only contain GMOs that are technically unavoidable and that a threshold is set for unavoidable quantities (e.g. 1%)
- protecting the integrity of non-GM shipments from contamination
- ensuring a zero tolerance for unapproved GMOs
- developing modalities for sampling and detection techniques

Certain measures have been adopted to segregate non-GM foods from their GM counterparts as well as preserving the identity of the GM varieties from other GM varieties, but these have been done voluntarily in order to secure overseas markets. 55

A de facto regime exists under Article 18 of the Cartagena Protocol, which requires that exports from and imports to South Africa from other parties of the protocol, including our African trade partners, of “living modified organisms” (LMOs) intended for use as food, feed or processing must be clearly identified as “containing GMOs”. In addition, information such as whether the GMO is intended for general release in to the environment; the common, scientific, and (where available) commercial names of the GMO; its unique identifiers/event code, etc. should also be provided.

Liability and Redress

GMOs may cause irreversible ecological and social changes. While this may be the case for most technological innovations introduced in any society, GMOs have unique characteristics that make their impact far-reaching. Even when the technology is withdrawn or people totally discontinue using the technology, its socio-economic impacts may persist and leave a permanent imprint in society, its history and its people. This is even more serious in GMOs which may introgress with wild populations or contaminate conventional crops long after farmers decide to stop planting these GM crops. This stark reality underlines the critical importance of assessing the potential socio-economic impacts of GMOs before and during their introduction in any society.

The GMO Act holds a “user” responsible and liable for damages arising from the use of a GMO. The new amendments did not change this despite civil society protests, and in fact extended responsibility from environmental impacts to those on human and animal health.56

The new Amendment Act defines the user loosely as “a person who conducts an activity with a GMO”.57 This definition would include farmers and the end consumer (buying, eating or cooking GMOs would qualify as conducting an activity with a GMO.)

The Act is ambivalent as to whether the person to whom the permit is granted will also be the person “who is conducting the activity with a GMO”. This is especially relevant in situations where small scale farmers are recruited to plant GMO crops as part of field trial experiments.

Section 17 of the new Amendment Act 23 of 2006 places a strong duty of care on the user to ensure that appropriate measures are taken to avoid an adverse impact on the environment and human and animal health arising from the use of GMOs. These provisions seem to have been drafted in the context of GMOs used in the agricultural industry, where farmer-users are meant to take certain preventative measures (e.g. to plant refugia, adopt pest management strategies to prevent the outbreak of secondary pests, and avoid negative impacts on human health and the environment).

Section 17 does not, however, address situations where something goes wrong as a result of the GMO itself because of its intrinsic properties and where there is no culpability on the part of the person using the GMO. The new provisions do not place an unequivocal duty on GMO developers to ensure the safety of products they introduce into the environment. Instead it effectively absolves the developers of GMOs from liability once the product is commercially grown, as the farmer will be the one conducting the activity. Whether the new regulations to the Consumer Protection Act will extend product liability to the developer of the GMO remains to be seen. Commercial farmers in South Africa asked parliament to hold the GMO license holder/owner responsible for damages that may arise.58 This was not incorporated into the amendments. Farmers could insist that developers absolve them from liability when they purchase GMOs, but this would require a powerful farmer lobby to effectively bargain with developers. This is unlikely in the context of small scale farmers who are given GM seed packages as part of free incentive packages.

Strict liability for damages

An obligation is placed on the user to notify the Registrar of any accidents and then, in consultation with the Registrar, the user is expected to take certain actions. These include investigating, assessing

56 Sect 17(1) of the GMO Amendment Act of 2006.
57 Sect 1 (m) of the GMO Amendment Act 2006.
58 GRAIN SA submission to Parliament on GMO Amendment Bill Nov. 2006.
and evaluating the damages caused to the environment or human health. This is to be followed by measures to “minimise, contain or prevent the movement of the GMO causing the damage in the event that an activity cannot be reasonably avoided or stopped; to eliminate the source of damage; and remedy the effects of the damage.” Damages are not defined in the Act. If the user fails to, or inadequately implements, these measures the Executive Council may take reasonable measures to remedy the situation and in this event the EC may recover a proportion of the cost of this operation from anyone who benefited there from.

These new amendments seem to have created strict or non-fault based liability. Only activities relating to the use of the GMO are considered whilst damages arising from the GMO are not covered. This in effect means that the user would not be able to defend himself/herself by arguing that they are not at fault. If damages arise the user will be responsible, which is why strong provisions with respect to the duty of care have been created.

If damages occurred whilst the GMO was in the possession of an inspector pursuant to a transgression having occurred, then the user will only be liable if he or she foresaw the damage and could have prevented it but failed to do so. The liability is thus fault based and the user can only escape liability if he/she can prove that they could not reasonably foresee damages occurring. This exception is of little practical use to users in that it only operates where: non compliance with the Act occurred, non compliance came to the attention of the state, the GMO was confiscated and damages occurred whilst the GMO was under the protection of the state. One is hard pressed to envisage situations where damages occur after the fact since the very reason for confiscation would be a transgression of the Act or permit conditions.

In the context of GMOs where the science surrounding these organisms keeps on re-inventing itself, it is futile to have a fault based liability regime as many hazards cannot reasonably be foreseen.

In the event that the state is saddled with cleaning up the environment and has to take remedial action, the new amendments make provision for those costs to be recovered from third parties. The new provisions require that damages are minimized and contained, the source is eliminated and finally that the effects of the damages are remedied with an overarching mandate to protect the environment. These provisions only make sense in a situation where remedial action can actually be taken, where the damage is reversible and a monetary value can be placed on remedial action.

A mandatory duty is placed on the EC to apportion damages where more than one person is liable. The EC must convene a fair hearing in this regard. Such apportionment of damages does not absolve persons from their joint and several responsibilities for the full amount of the costs. The EC’s apportionment has the same legal effect as a civil judgment of the Magistrate Court and a right of appeal is created for those who are affected by the cost order.
**Cartagena Biosafety Protocol**

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Biosafety Protocol) is an international, legally binding framework of rules that apply to the transboundary movement, transit and handling of “living modified organisms” (LMOs)\(^{59}\) that may impact negatively on the conservation and use of biological diversity and human health.\(^{60}\) The precautionary principle, coupled with the Advanced Informed Agreement procedure, are central features of the regulatory approach of the Biosafety Protocol.\(^{61}\) This procedure seeks to ensure that importing countries have the opportunity to assess the environmental and human health risks associated with GMOs and take a decision based on the precautionary principle, before agreeing to their import.

Although South Africa has been a party to the Biosafety Protocol since 2003, the Precautionary Principle has not been included in our biosafety legislation. The entire Biosafety Protocol was recently included as an Annexure to the GMO Amendment Act, but without clear guidance as to how this Annex should be interpreted in terms of our own law.

South Africa’s GMO Amendment Act seized the opportunity provided by the Biosafety Protocol to deal with its trading partners and neighbours in the event of a contamination occurring. In this regard, at least 8 new provisions dealing with accidents and/or unintentional transboundary movement have been created.\(^{62}\) This brings our GMO Act in line with Article 17 of the Biosafety Protocol with respect to unintentional transboundary movements and the emergency measures that must be undertaken. It however creates the distinct possibility that contamination of South African neighbours by GMOs grown here will be deemed an unintentional transboundary movement and thus an accident. The recent amendments ignore the obligations created under Article 18(2) (a) which deals with the identification and labelling of GM content in bulk shipments of grain.

Another important provision of the Protocol is the transparent and open sharing of information, primarily through the “Biosafety Clearing House” (BCH). This requires that parties to the Protocol publicly share information through the BCH.\(^{63}\) At a minimum this encompasses laws and regulations including those on the transit of GMOs,\(^{64}\) final decisions to release\(^ {65}\) and import\(^ {66}\) GMOs; decisions on GMOs that may become subject to transboundary movement;\(^ {67}\) risk assessments; agreements with other countries; and reports on the implementation of the Protocol including the advanced informed agreement procedure.

South Africa’s ongoing lack of compliance with the Biosafety Protocol has been severely criticized. As recently as August 2009 the GMO watchdog, The African Centre for Biosafety (ACB), lodged a complaint with the Compliance Committee of the Cartagena Protocol on Biosafety\(^ {68}\) about the refusal of the South African government to respect its responsibilities under the Protocol. They argue that to date, the South African government has failed to comply with any of their obligations and have not even supplied the barest minimum of the information required to be posted to the Biosafety Clearing House.

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\(^{59}\) LMOs thus exclude processed products derived from GMOs that are unable to reproduce.

\(^{60}\) Article 4 of the Biosafety Protocol.

\(^{61}\) Article 7-10 of the Protocol.

\(^{62}\) Sec 4(1) (f)-(l) and Sec 4(2) of the GMO Amendment Act 2006.

\(^{63}\) Article 20 of the Protocol.

\(^{64}\) Dealt with in Article 6.1 of the Protocol.

\(^{65}\) Dealt with in Article 10.3 and 20.3(d) of the Protocol.

\(^{66}\) Dealt with in Article 11.4, 11.6 and 20.3(d) of the Protocol.

\(^{67}\) Article 11.1

\(^{68}\) http://www.biosafetyafrica.org.za Media releases.
For example, the ACB notes in its complaint that by August 2009:

- South Africa had approved 1521 permits since the Cartagena Protocol came into force but only posted 13 decisions on the BCH website.
- Not a single risk assessment has been posted.
- Maize seed exported to Kenya from South Africa in early 2008 was found to be contaminated with MON810, a variety not approved in Kenya. This was not posted as an illegal transboundary movement to the BCH.

The ACB points out that “in the circumstances, the South African government has fallen short of complying with its obligations under the Biosafety Protocol to ‘promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health’.\(^{69}\)

\(^{69}\) Article 23.1(a) of the Protocol.
African Model Law

The Organisation of African Unity (OAU)\(^70\) finalised the African Model Law on Safety in Biotechnology (Model Law) in May 2001 in anticipation of the coming into force of the Cartagena Protocol on Biosafety. The OAU recognised that Member States would face capacity and other challenges in implementing the Protocol, but also that Africa had unique biodiversity to safeguard. The OAU’s intention was to create a model biosafety law that Member States could adopt to ensure a consistent and precautionary approach that would adequately protect this heritage, and was thus drafted through a process of consultation by Africans from many countries and diverse sectors. According to Mariam Mayet, the Model Law “provides a carefully crafted and comprehensive framework of biosafety regulations that have been specifically designed to protect Africa’s biodiversity, environment and the health of its people, from the risks posed by GMOs”.\(^71\)

The Model Law uses the Biosafety Protocol as a starting point and minimum standard on which to build more stringent and wide-ranging biosafety measures, and thus includes a number of additional issues of concern in Africa that are not addressed in the Biosafety Protocol. These include provisions to strictly regulate GMOs imported for food, feed and processing with food aid being a major concern; guidance on how socio-economic concerns should be approached; labelling and identification; a liability and redress regime, etc. The Model Law includes products of GMOs and pharmaceutical GMOs in its purview which are not addressed in the Biosafety Protocol.\(^72\)

In July 2003, the African Union’s (AU) Executive Council urged Member States to use the African Model Law on Biotechnology to guide the development of their domestic biosafety legislation,\(^73\) advice which South Africa has ignored.

To further assist Member States a Biosafety Unit was established to provide technical assistance and capacity building. By 2006 an African Strategy on Biosafety was developed and adopted.\(^74\) The Strategy aims at guiding biotechnology development at national, regional and sub-regional levels; guiding African positions in relevant international forums; and creating and strengthening regional centres of excellence in five sub-regions. A major concern about the strategy and recent developments is that the drive to harmonise regulatory frameworks may be hijacked by the biotechnology industry through locating the biosafety discourse within the realm of the Regional Economic Communities (RECs) which have a pro-trade agenda. As the ACB points out “placing biosafety in the domain of the RECs affords the pro-GM lobby yet another opportunity to position GMOs as agents of development rather than serious threats to biosafety, cultural and socio-economic wellbeing.”\(^75\)

\(^70\) predecessor to the current African Union (AU).
\(^72\) Ibid.
\(^74\) Ibid.
Conclusion

Scientists have for a long time been warning that GMO technology is unstable and likely to behave in unexpected ways. Recent crop failures suggest these warnings are accurate, but South Africa’s lax and corporate friendly legislation is allowing this alarming episode to be swept under the carpet.

South Africa is set for a new onslaught of GMO releases as new stacked-gene events are brought to the South African market, new crops are trialled, and commodity import permits are processed (these have been stalled since 2005 while the DTI investigated economic impacts\textsuperscript{76}). Whereas our government desperately wants to keep abreast of the economic opportunities in new technologies as well embrace GMO technology as the panacea to climate and food crises, it is not proving to be a responsible steward of the South African and African food crop heritage as well as the continued safety of our citizens and environment.

\textsuperscript{76} A \textit{de facto} moratorium was put in place during September/October 2005 by the GMO decision-making body, the Executive Council, at the request of the Department of Trade and Industry (DTI). The DTI was of the opinion that GMOs are not freely traded on the international market and negatively affect the price levels at which these products are traded.
ADDENDUM:

Recommendations for strengthening public participation in GMO decision-making in South Africa

The following is an abridged version of the recommendations made in the 2008 study “Public Participation in the Context of the Regulation of Genetically Modified Organism in South Africa”. The recommendations arose from a 2007 National Stakeholder Workshop. The study was commissioned by The National Environmental Advisory Forum (NEAF), prepared by Adrian Pole Environmental Law and published by the national Department of Environmental Affairs and Tourism (now Department of Water and Environmental Affairs). Unfortunately, NEAF was disbanded in 2008.

1. GMO Act and Regulations

Notice of permit applications

The practice of giving notice of a permit application (in respect of proposed trial and general releases) in three local newspapers was considered inadequate. Various practical methodologies for improving notice were suggested, including:

- publishing notices of permit applications on an up-to-date, dedicated website;
- e-mailing notices to stakeholders registered on the database; and
- publishing notices in national and local newspapers.

It was also recommended that the notice should indicate where further information concerning that permit application can be accessed by Interested and Affected Parties (I&APs).

Particular consideration needs to be given to methods for notifying illiterate members of local communities that may be affected by a release (for example, community meetings in the area in which a release is to take place).

It is also recommended that the notice requirements should be extended to include applications for GMO import and export permits.

Access to information

Copies of the full non-CBI (Confidential Business Information) version of the permit application and supporting documentation should be made available to stakeholders at the inception of the permitting process. It was suggested that the information should be posted on the dedicated website to facilitate access.

Criteria for deciding what is CBI

Clear criteria should be established for deciding what information is is bona fide confidential business information and what information is not. The decision should be taken by the Executive Council in consultation with applicants and not by individual applicants.

New information

Any new, material information supplied by the applicant in response to comments or representations received from I&AP should be made available to the I&AP. The I&AP should in turn be afforded a reasonable opportunity to submit further representations in response to this new information.

Advisory Committee recommendation report

A general view was expressed that the recommendation report of the Advisory Committee should be published on the dedicated website. There was a difference of opinion as to when the report should be published, but it was the author’s view that principles of fairness would require that the report be made available to stakeholders prior to the decision being made in circumstances where it contains new material information.
Notice of permitting decision

Stakeholders agreed that all participants in the decision-making process should be notified of any permitting approval or refusal. It is recommended that the Executive Council’s decision should also be posted on the dedicated website, together with reasons for the decision. Stakeholders also indicated that the reports of the different departments that make up the Executive Council should also be published.

Notice of appeal

Stakeholders agreed that all participants should be notified of their right to appeal a permitting decision. In addition to the above, it was emphasized that resources need to be made available to promote public participation, and to provide opportunities for I&APs to develop the understanding, skills and capacity necessary to achieve effective participation.

Participation should not only be limited to case-by-case applications, but should be promoted on a broader level to inform government policy relating to GMOs.

2. Environmental Impact Assessment

a) Basic assessment

There is contestation as to whether the public participation process between NEMA and the GMO Act is consistent. It is recommended that DEAT (now DWEA) meets with NDA (now DAFF) with a view to coordinating the assessment requirements of GN R386 (NEMA) and the GMO Act and regulations.

b) Full EIA

It is recommended that consideration be given to identifying GMOs that could be considered threatening processes in listed ecosystems. This would have the effect of triggering full EIAs in respect of GMOs, which could have a significant impact on indigenous land races or staple food sources.

3. National Environmental Management: Biodiversity Act

It is recommended that criteria be established to facilitate this decision by the Minister. Criteria could, for example, include the potential for the GMO to outbreed with local land races or with staple food crops.