Submission to the Department of Environmental Affairs and Tourism on the

'Environmental Risk Assessment Framework for Genetically Modified Organisms'

Draft dated September 2006

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October 17th 2006

SUMMARY OF KEY ISSUES

1. We call for an immediate moratorium to be placed on all environmental releases until such time as an adequate ERA Framework is in place, including the institutional frameworks and resources to assess, identify, monitor and respond to the risks posed by GMOs; taking into account that to date, there have been no independent studies on the impact of GMOs already released into our environment. See our previous submission for a detailed motivation for this.

2. We are of the view that the ERA must be promulgated in terms of Regulations under the Biodiversity Act. We are thus opposed to the drafting of mere "Guidelines" which will have not have the force of law behind it

3. Socio-economic and cultural impacts have been given shoddy treatment in the document. We are of the view that socio-economic impacts must be an inextricable component of the ERA and note the provisions of Article 26 of the Biosafety Protocol and the principles of the National Environmental Management Act (NEMA), in this regard. It is our view that the full implications of the release of GMOs on small and resource poor farmers and women, as well as implications for landrace and heritage crops have been completely ignored to date. The ERA must properly address and describe how socio-economic and cultural impacts will be assessed and monitored with the participation of the public.

4. In general the ERA Framework fails to proceed from a precautionary approach. Although this is mentioned in several places, 'precaution' has not been integrated into the mechanisms and processes described. In particular the 'no-go' option is not part of the ERA steps outlined in the document. Instead the nitty gritty of the document focuses on identifying and 'managing' impacts, and this is not acceptable.

5. The document does not address the issue of meaningful public participation. We note that current regulatory system is not transparent and that the public have not been adequately considered in decision-making. The lack of public participation mechanisms are no longer defensible in terms of the Biosafety Protocol and legislation such as the Promotion to Access to Justice Act (PAJA), particularly, in the face of increasing public pressure. There is urgency for DEAT to resolve this issue and provide mechanisms for effective, fair, transparent, practical and cost-effective (especially for the public) public participation.

6. We call for the use of the CaMV promoter and antibiotic resistance markers to be banned, for a date to be set for when this will come into effect and for plans outlining how GMOs containing these that are currently on the market will be phased out.

7. We support the setting aside of GMO Free Zones to preserve biodiversity hotspots and threatened species and where communities wish to declare areas GMO free, and therefore request that legislation enabling these is expedited.

8. In relation to Environmental Impact Assessments for GMOs we request that:
    i. the regulations requiring a basic EIA assessment (including upfront public participation) are enforced for all GMOs,
    ii. a full EIA is required for all commercial releases of GMOs, and where certain trigger conditions are present.
    iii. In addition to automatic triggers for an EIA, the Minister should also be able to request an EIA for a GMO, which on examination of information supplied as part of an ERA in the normal application process, indicates a high risk even if none of the automatic trigger conditions are present.
    iv. Even though GMO releases are a Schedule 1 activity, EIA applications for GMOs should not be allowed 'blanket' approvals or an EIA exemption.

GENERAL ISSUES

Preamble to this submission

In this submission we are drawn into arguments related to mitigating and managing the risks of GMOs in our environment. Given South Africa's policy to actively pursue the development of biotechnology and having already released numerous GMOs into the environment, we must reluctantly engage on the level of managing the risk, however, we would also like to state that we do not believe that GMOs can co-exist with non-GM organisms without contamination and consequent harmful impacts on our human and ecological ecosystems. We believe that because of the irreversible nature of this technology this issue should be debated in the public arena with fair and balanced information sharing on the problems as well as any benefits.

Overarching purpose of the ERA framework

In the document it is noted that the National Biodiversity Strategy and Action Plan (NBSAP) (DEAT 2005) provides the context for addressing issues around the management of GMOs released into the environment, through outcome 3.5 *"effective management and control measures minimise the potential risk to biodiversity posed by GMOs*". In order for the Minister to implement his powers and functions in terms of section 78, he and his department require the requisite 'tools' to assess the environmental risks in order to avoid their unintended and unwanted consequences. Current Department of Agriculture guidelines are out-dated and incomplete, and neither adequate nor appropriate to fully operationalise Section 78 and enable the Minister to exercise his functions and powers. Thus, while the "Notification" (what is required of the applicant) guidelines under the auspices of the DoA must be updated, this ERA Framework must provide a more holistic toolkit that serves to operationalise section 78. Section 78 is meant to supplement the GMO Act and not duplicate it, so this will then provide a single set of tools that is required for decision-making by the Minister (in terms of the Biodiversity Act), and which can simultaneously be used by the Executive Council (under the GMO Act), in order to inform decision-making.

In general the current draft of the document (issued in September 2006) does not provide clarity on the overall purpose of the environmental risk assessment framework; how the framework relates to other processes mentioned in the document; and how these relate to one other, are operationalised and governed. Furthermore processes and terms are often used interchangeably or defined in ways that overlap

adding to the confusion. The purpose of the ERA Framework needs to be defined and separated from the purpose of the document, which is the means to communicate the framework, and the various risk management tools/processes that fall under the framework.

In this regard we note that South Africa does not have an overarching and comprehensive policy on biosafety that would inform the development of various tools/processes used for ensuring biosafety. This ERA Framework document is then, in a way developing policy as we go along without the benefit of multi-stakeholder input at a more strategic level. Nevertheless, there is an urgent need to properly assess the risks posed by GMOs and the process shouldn't be delayed.

We propose, therefore, that the purpose of this document – that is the ERA Framework for GMOs - should be to provide overall guidance and outline the processes that will ensure that the South African environment and people are protected from the potential harm that GMOs can cause. This must include systems that provide early warnings of potential problems so that GMOs with problematic components are banned and prevented from being developed and entered into the regulatory system, and GMOs which are already developed and released are adequately regulated to prevent harm and where necessary the authorisations for release are withdrawn.

The ERA Framework for GMOs is thus a set of 'guidelines' that will, *inter alia:*

- establish underlying principles for risk avoidance
- provide a scientific summary of the risks and their relevance in a South African context
- outline and inform risk mitigation and management procedures and tools including IEM, ERA, EIA and the DoE permit application process, such that the relationship between each of these and where it fits into the regulatory process is clear
- clearly outline the relationships between relevant legislation, regulations, supporting documents, processes and stakeholders
- inform EIA's for GMOs, and specify the criteria and events that would trigger an EIA
- prioritise issues for research and monitoring
- inform the design of monitoring programmes for GMOs

Furthermore the ERA Framework should be located within the mandate provided through the National Environmental Management Act 107 of 1988 requiring that all organs of State adhere to the principles of environmental management which must, inter alia, be integrated; socially, economically and environmentally sustainable and ensure the participation and inclusion of the interests of interested and affected parties.

We are concerned that the overall theme of this guidance document seems to be to make it easier to identify environmental risks to be 'managed' when the GMO is released, while business continues as usual. While the risk is framed within the context of an ecosystems approach and the precautionary principle, and very serious possible impacts from GMOs are raised in the document, the document does not really outline meaningful strategies to prevent this harm from arising in the first place. This approach is not consistent with the risk averse approach emphasised in the NEMA principles and the NBSAP.

Clarity of document in terms of its purpose

In general the document is very poorly laid out and developed, and fails in its own stated purpose to provide a uniform basis for implementing Section 78 of the NEMBA (2004); provide applicants with assistance in compiling applications and environmental risk assessments and assist authorities in determining their roles and responsibilities as decision-makers. In particular it is still not clear how a duplication of efforts and decision-making processes between DEAT and the DoA will be avoided.

The document does not provide clear guidance on what risk assessment processes are required when, how these interact, and what is required from applicants. For example on page 12 the document states that an ERA will be conducted based on information submitted as part of the application based on testing and analysis and secondly on baseline information (one assumes also submitted by the applicant). There is no clear indication of how this information is different to that currently required by the GMO Council as part of the application notification process. Later on the same page (12) the document states that risk assessments need to move away from desk based assessments and must be independent, but no mechanisms are proposed to move the regulatory system towards this goal. Then in the section on Methodology on page 14 the document reiterates that the application will be considered in terms of the information submitted. Other parts of the document make reference to the ERA as if it is a stand alone document and point 2.6.3 states that the presence of stacked genes will automatically 'trigger' an ERA implying that there should be a list of triggers or circumstances under which an ERA is required or not.

The document states that releases for research purposes will be treated differently to those for commercial release but it is not clear what these differences are and if the ERA steps that are outlined only apply to commercial releases. It is also unclear whether the information supplied by the applicant should include a separate document entitled 'environmental risk assessment' in which the GMO is analysed according to the ERA steps outlined on pages 15- 17, or whether this is the methodology that DEAT will use to assess the information supplied in the normal application process.

A number of different tools / processes are proposed through the document [ERA, EIA, EMF and monitoring] seemingly as part of a broad environmental risk assessment framework. It is not clear what the relationships between these are and how they fit within the broad ERA framework, or what actions need to be taken in terms of legislation and regulations, resourcing and institutional arrangements to ensure that an ERA framework is operationalised and that these tools create a coherent risk management arsenal.

ERA vs. EIA

The document is often not clear about the differences between an Environmental Risk Assessment and an Environmental Impact Assessment. Furthermore it attempts (on page 11) to argue that an EIA and ERA is more or less the same thing. We disagree with this view, and note the following significant differences between EIA and ERA process, as it is outlined in this document currently:

1. In the EIA process the public have an opportunity to input into the decision-making process at several intervals and decision-makers are duty bound to take these inputs into consideration in making decisions. The document makes no provision for public participation in the ERA and the public (according to the table on page 11) are only involved as recipients of communications about the process and potential risks. This is a critical issue, which is further dealt with under a separate point.

2. The issues raised by interested and affected parties, the way these are assimilated into the decision-making process and the decision itself are part of the public record of the process and are required to be available to the public.

3. An EIA asks the questions: is this development necessary and are there alternative, less harmful ways to meet this need? Although practically developers downgrade the requirement to consider alternatives to options for siting for example, there is an opportunity for the public and government to require that alternative development options to the proposed development be investigated including the option of not proceeding with the development. This is very different to the ERA, which simply suggests that different options for managing risk are presented. We propose that the EIA approach to investigating alternatives to the development would ensure a much more rigorous

consideration of the need for a particular GMO, and indeed much more appropriate and safer means would often be available for meeting the need that the GMO is supposedly designed for.

4. An EIA is designed to look at the consequences of a particular action or project, usually where site-specific variables van be analysed. This is challenging in relation to GMOs, which eventually will move freely through the environment and may interact in unpredictable ways within varying ecosystems. An ERA is helpful in this regard, as a broad range of possible impacts can be investigated in both the short and long term.

5. EIAs under NEMA require the independence of the consultants providing and assessing the information, and even make provision for peer review. Although the ERA document states that independence is needed most of the detailed procedures refer to information and monitoring by the applicants themselves.

6. Neither EIAs nor ERAs look at the cumulative and compound impacts of several developments that may be occurring concurrently in a particular environment.

We request that:

- An EIA is required before all commercial releases of GMOs.
- An EIA is required where certain trigger conditions are present (these are listed in the detailed comments). The document must clearly define when an EIA is required over and above an ERA, and how these 2 processes relate to the decision-making process for GMOs under the GMO Act.
- In addition to automatic triggers for an EIA, the Minister should also be able to request an EIA for a GMO, which on examination of information supplied as part of an ERA in the normal application process, indicates a high risk even if none of the automatic trigger conditions are present.
- Even though GMO releases are a Schedule 1 activity, EIA applications for GMOs should not be allowed 'blanket' approvals or an EIA exemption.

Public participation

We highlight the issue of the proper and full participation of the public in decision-making about GMOs as a key issue that has not been given meaningful attention in the document. As noted above, the document has attempted to equate public information sharing in an ERA process with more active public participation in the EIA. This is unacceptable. In order for there to be effective risk prevention and management in relation to GMOS the public have to participate actively in decision-making and monitoring.

We have already noted in many previous submissions that the current involvement of the public in decision-making on GMO applications is grossly inadequate. These issues must be addressed in designing new processes to include public participation with regard to risk prevention and management generally. Problems include:

- the public are only made aware of new applications through a few adverts in local papers. This denies many people the right to be informed about important and long-lasting effects on their environment.

- The information provided by applicants is often either completely insufficient or deliberately overwhelming for an average person to engage with.

- The process of accessing information on applications through the PAI Act is inadequate and ridiculous. As with EIAs all the information needed to enable decision-making should be made available to all those registering as interested and affected parties in an accessible format and this

should be supplemented with the scientific information supplied to the GMO Council where requested. The cost of accessing information through PAIA is prohibitive for all but the most well resourced or committed parties and completely excludes persons on the ground who may be directly affected. The process of using PAIA is complex and confusing even for well-resourced persons, and requires that the public know what questions to ask in order to receive the right information. The use of the PAIA also places an unnecessary burden on the registrar in having to locate and copy the relevant bits, which is a waste of time and money. Thus once again financial and other burdens are shifted from the applicants to the South African government and public. We suggest that some of the secrecy and expense in relation to applicant information can be addressed by placing all the information on a public information website, as described below. This requires that the regulations sunder the GMO Act are amended to require that all information supplied by applicants is provided in electronic format.

- After submission of comments and concerns there is no process whereby an I & AP can find out what the progress of the application is, or how the GMO Council and applicants have responded to the comments that are made. Even after using PAIA to request access to the minutes of GMO Council meetings it is not clear from the minutes why applications have been approved and the basis for decision-making when very serious biosafety concerns have been raised in submissions.

Having noted all the issues above, and that although participation process in EIAs is also not ideal, we request that public participation in the ERA should take a similar form to that used in EIAs and address socio-economic, cultural and scientific issues. This is elaborated further in detail comments below.

We support that mechanisms for ensuring public participation on GMOs are investigated and further developed under the auspices of the National Environmental Advisory Forum, in consultation with public interest stakeholders through submissions and consultative workshops and that once finalised these are translated into legislation.

Analysis of costs vs. benefits of developing a GMO

We propose that applicants must also be required to submit a cost / risk versus benefit motivation as part of their application as to why permitting for particular research or release of GMOs is sought. This document should describe the benefits of the GMO, who will benefit and within what time frame benefits will be felt by each beneficiary.

We furthermore call on government to take a policy decision to only consider applications where a clear benefit to the South African people can be shown, that outweighs the risks posed by the GMO to society and the environment when viewed with a precautionary approach, and the direct costs of processing the application and monitoring the research and release into the future.

We strenuously object to biotech research and environmental releases where the GM is not specifically aimed to benefit South African growers, consumers or the environment or where there is no intention of developing the GMO for commercial release in South Africa. This includes 'research' for purposes of seed bulking (as openly admitted by the representative from Syngenta at the national ERA consultation in Pretoria). The South African people and environment should not carry the burden of risk where corporations or research organisations are the only entities that stand to gain in the process. We call on government to make a policy statement that these types of applications will no longer be authorised.

Environmental vs. Ecological risk

The document often confuses 'environmental risk' and 'ecological risk'. It is our understanding that the purpose of this document is to create a framework for assessing environmental risk, and that this framework falls under the general auspices of the NEMA and the Department of Environment, where environment is defined in its broader sense as "the surroundings within which humans exist, which is made up of (i) the land, water and atmosphere of the earth; (ii) micro-organisms, plant and animal life; (iii) any part or combination of (i) and (ii) and the interrelationships among and between them; and (iv) the physical, chemical, aesthetic and cultural properties and conditions of these that influence human health and well-being." However, despite making reference to this definition in the introduction, the document then goes on to focus on harm caused to ecological systems with negligible attention paid to the socio-economic and cultural environment. For example in Sect 2.1 on page 10 ERA is framed within the context of harm to biological communities and ecosystems only.

Dependence on the applicant for information

Throughout the document the developer of the technology is relied upon to produce information concerning risks and potential problems with the GMOs for which they are applying, to monitor their product in the environment and report on the problems that arise. No salesperson will tell one the faults with their product, and indeed the biotech industry underplay and refute evidence that GMOs cause harm. This situation must be remedied through independent research and monitoring to verify applicants' information and provide government with regulatory oversight.

GM free zones

We especially welcome the introduction of GMO free zones. We support that legislation is drafted to enable GM Free zones under the following conditions:

- in biodiversity hotspots identified by SANBI
- areas where particular species may be threatened through the introduction of GMOs, and these species occur outside of the hotspot areas
- where a majority of landowners or community members in a particular area decide to keep their local environment GMO free.

Legislation relating to GM Free zones will need to address:

- the mechanism by which GM Free Zones will be declared, including the process for landowners and community members wanting to declare their area GM Free (through local referendum, signatures or other)
- given that it is impossible to have coexistence of GMOs and non-GMOs, legislation must also deal with contraventions of GM Free Zones, how contamination will be dealt with and measures to compensate those affected by contamination
- the question of who is liable for contamination – the applicant/permit holder or the farmer. The primary burden of responsibility for contamination must lie with permit holders/applicants to ensure that they take responsibility for the safety and stability of the technology that they develop and sell, and so that they do not sell GMOs within GM Free Zones. The permit holder/applicant can in turn enforce that GMOs are not grown in GM Free Zones through their 'technology use agreements' with individual seed buyers, and have the financial muscle to pay the cost of damages to the state/injured parties and in turn sue seed buyers/ farmers who have contravened stipulations not to grow GMOs in restricted areas.

- a national information system identifying GM Free Zones so that researchers, applicants and farmers do not inadvertently contravene these

Liability and redress for harm

The document does not adequately address how risk mitigation procedures will be enforced, and if something goes wrong for whatever reason, what punitive measures will be taken and how losses to the environment, communities or individuals will be compensated. Given the current weakness of the GMO Act in this regard, the entire ERA Framework becomes meaningless as there is no incentive for biotechnology companies developing and selling GMOs to take cognizance of safety guidelines.

Of further concern is the length of time that it may take to accurately identify GMOs as the cause of biodiversity loss or other impacts, and then where harm is shown it will be even more difficult to identify particular GM events as the cause. As noted by a representative from Monsanto at the consultation workshop, by the time that harm is proven to be associated with a particular GMO the company will have already taken that event off the market and will deflect blame by claiming that the new GMOs on the market have been improved.

There are also a number of other gaps in legislation that make the task of monitoring and identifying harm caused by GMOs that much more difficult. For example, current labelling legislation does not require that any currently commercialised GMOs are identified as ingredients in food. Without mandatory labelling linked to detailed epidemiology studies it is impossible to accurately trace and monitor the impacts of GM foods on the South African population. This is particularly serious given that up to 70% of staple foods have some GM content, known impacts of eating GM foods include allergic and immune responses and that a large proportion of the population suffer from immune related illnesses and already carry a heavy social and economic burden as a consequence. A framework dealing with environmental risk assessment and monitoring cannot shrink from addressing these types of issues and suggesting ways in which blatant gaps in legislation will be remedied.

GMO authorisation permits issued by the Council under the GMO Act

Better use can be made of the authorisation system to set conditions to the authorisation permits to ensure biosafety in South Africa. Conditions could, inter alia, include (many of these suggestions are motivated in other sections, and are only summarised here):

- Areas where the GMO may not be grown because of possible impacts on related and other species, the existence of GM free zones and biodiversity hotspots, and because the behaviour of the GMO has not been tested in these environments.
- The requirements for ongoing monitoring and reporting, based on the monitoring plan, noting that authorisations can be withdrawn or new studies requested that may lead to withdrawal if there is evidence of harm resulting from the GMO.
- The requirement to report annually on the locations and quantity of releases of the GMO into the environment.

The need for a central information database

There is a need for a centralised database of information on GMOs that is open and transparent to the public. Open access to information is a key component of preventing negative impacts. DEAT should investigate the most appropriate vehicle (Plantbio, SANBI etc) for collating and publishing this information, and present these as part of the ERA framework.

Information should be made available on a public website and include the following components:

Maps and GIS overlays

- Maps showing the location of commercialised GMOs. Authorisation of GMOs must be conditional on the applicants supplying this information to government on an annual basis each planting season.
- Biodiversity hotspots and location of threatened species at risk
- GMO free zones

It is important that these maps are at a scale where individual farmers are able to identify their location in relation to GM free zones or GM plantings.

Research

- General local and international research on GMOs and issues relating to risk analysis.
- Results of research and monitoring of GMOs released in South Africa

The regulatory system

- SANBI's reports to the Minister of DEAT
- Summary of GMO applications with an indication of their progress in the regulatory system (e.g. to be discussed at x meeting of Council, EIA underway etc), written reasons for approving or authorising applications and responses to the main points raised in submissions.

Resourcing the regulatory system – the polluter must pay

There are a growing number of applications swamping both the Registrar (who is clearly overworked) and the GMO Council, who will come under increasing pressure in terms of reviewing these. It has been noted that information from applicants is often incomplete or even misleading, and requires independent verification. Unlike approving the design for a car that will typically behave as designed when released into the market, living organisms are dynamic and change and adapt over time and thus require ongoing and careful monitoring. Again, applicants cannot be relied upon to monitor possible adverse environmental effects, not least because they may not have the capacity or oversight required to do so. Given the serious and irreversible consequences of releasing GM Living organisms into the environment these applications and their impacts need to be assessed with great care and diligence. The GMO Council and the DEAT come under increasing pressure, even more resources will be needed for the people-power and equipment to carry out these tasks. It is also noted that SANBI, although mandated to monitor and report on the impacts that GMOs are having on our environment in fact have no capacity or resources to do so.

It is our strong contention that the principle of the 'polluter pays' must also be applied to the regulation of GMOs. Substantial profits are being made in the biotechnology industry, most of which accrue to multinational corporations; and the increasing burden of regulation and monitoring shouldn't fall on the South African tax payer, especially given the other pressing development needs we face. We therefore propose that the 'polluter pays principle' is given effect by:

1. Charging an application fee for all research applications that adequately covers the cost of interrogating the application and monitoring the research sites after approval.
2. writing into law that a percentage of the patent fee paid by farmers to the applicant after authorising the commercial release of a GMO, must be paid by the applicant as a special sales tax. Treasury

must allocate the money generated through this tax to DEAT/SANBI/ a comprehensive monitoring body in proportion to the sale of GMOs to be used for general monitoring of the impacts of GMOs on the broader environment and human health.

DETAILED ANALYSIS OF DOCUMENT

SECTION 1: INTRODUCTION, SCOPE AND AIMS

1.2 Scope of the document

We do not agree with the line "Addressing these questions within any one application is neither a requirement nor a prescription for the successful passage of products through the regulatory system", as this renders this policy document meaningless.

The document notes a focus on GM plants due to the current predominance of plant applications. This is short-sighted and the document must also address upcoming technology applications such as enzymes and in particular micro-organisms, which are even more difficult to control and monitor when released into the environment.

1.3 Aim of document

See the discussion under general issues above.

1.4 Legislative framework

1.4.2 NEMBA 10 of 2004

Role of minister in requesting EIA

Under current legislation "The onus rests on the Minister to communicate his/her belief about the potential threat of the GMO release concerned to the Registrar of GMOs before the application is approved." Given the great number of applications being processed this is too onerous on both the minister and officials investigating applications, and therefore automatic triggers for EIAs need to be put in place, which are supplemented by requests for an EIA at the Minister's discretion where a particular case warrants this.

Role of SANBI

We are seriously concerned that SANBI does not have the capacity or resources to fulfil the mandate: "As one of its functions, the Institute must 'monitor and report regularly to the Minister on the impacts of any genetically modified organism that has been released into the environment, including the impact on non-target organisms and ecological processes, indigenous biological resources and the biological diversity of species used for agriculture'. SANBI are obviously biodiversity focused – will they be able to monitor wider environmental impacts that include social and cultural issues? SANBI has no capacity in-house for working with GMOs, and no prospect of a budget for this work in the next year.

The document makes no attempt to quantify what steps need to be taken to enable SANBI to fulfil this mandate with regard to institutional arrangements, building or bringing in the necessary capacity or accessing the resources that SANBI require. Civil society would like to strenuously express our concern and discomfort in the fact that the only independent monitoring and reporting on the impacts of GMOs in our country is in the hands of an institution that is as yet unable to perform this role and is unlikely to be able to do so in the near future. Furthermore there is no vehicle for seriously assessing the health, cultural, and socio-economic impacts of GMOs and monitoring this in the longer term.

1.5 Importance of biodiversity

The importance of biodiversity in ecosystems as well as in agricultural species cannot be overstated. We object to the subtle introduction of biotechnology as a means to improve diversity while not noting the numerous and proven harmful impacts that biotechnology has on biodiversity. We also object to the assertion that 'traditional breeding' is to blame for the loss of crop diversity when in actual fact it is the green revolutions of international agribusiness (of which biotechnology is the most recent development) that have been largely responsible for the loss of crop diversity and replacement of landrace crops in the last 100 years.

SECTION 2: ENVIRONMENTAL RISK ASSESSMENT OF GMOs

2.1 Objectives of the ERA Framework

We support some of the intentions of the guideline document, in that procedures must be consistent as well as informing all parties of minimum standards. We also support an approach which is rigorous and based on sound and thorough research, rather than conjecture. However, the environment as defined by NEMA includes the social and cultural environment and therefore the emphasis on a 'science-based' approach seemingly without due regard and provision for social, cultural and economic analysis is cause for concern. The document should also aim to provide transparency and participation in decision-making.

Having listed the intentions of the document, the document does not clearly outline what the objectives of ERA should be. These must be clearly stated, as this provides the understanding upon which the rest of the document and framework is built. The objectives of an ERA Framework should include :

1. ensure biosafety to protect the South African environment and people from harm
2. prevent the loss of natural resources which are the heritage of the people of South Africa
3. good governance in regulating GMOs so that the public are confident that they are protected

See the detailed discussion on the purpose of the ERA Framework in the 'general issues' section above.

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We very much support the provision that risk assessment is not finite and that as new information on risks to human and ecosystem health comes to light, that the risk assessment will be amended. We would furthermore support wording to the effect that decisions made based on prior risk assessments are also therefore open to change including the reversal of a decision to trial or release GMOs and recall released GMOs.

Of course, given the difficulty with recalling GMOs that have been released into the environment, and the uncertainty of genetic engineering we believe that the document does not adequately incorporate the 'precautionary principle' in terms of emphasis or inclusion in the decision-making process.

p 10 ERA phases

The document is fundamentally flawed in not providing for a 'no-go' option in decision-making and the emphasis on managing risks rather than taking a precautionary approach where certain risks are not tolerated. In the ERA phases that have been outlined on page 10, Phase 5 should read thus:

"Phase 5: Based on assessment of the risks in previous phases a decision is made to either not proceed or to proceed with management strategies in place to limit the risks resulting from the release".

p 11 Similarities between EIAs and the ERA framework

This box is misleading in equating the EIA process with the ERA framework. Please see detailed discussion on this issue above.

2.2 Approach to ERA of GMOs

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We are really concerned that this section dealing with the approach to risk assessment does not clearly frame ERA within a precautionary approach. The need for a precautionary approach, which may result in non-authorisation and banning of certain GMOs must be stated upfront.

The approach that is currently described in the document is one that accepts that there are risks and that these will simply be managed as best we can. Although various ways in which risk assessment can be handled are described on page 13, the document makes no clear commitment to any approach. We support a precautionary approach to handling risk – that is assuming a worst case scenario given that once a GMO is released this is irreversible. Furthermore where there is concern about the safety of a GMO to human health or ecology, government must require further information from independent sources in addition to that supplied by the applicant. The independence of consultants conducting the risk assessment, an EIA and carrying out additional research is key, given that it is paid for by the applicant. To remedy bias we propose that applicants submit a list of potential consultants to DEAT, which must exclude those who have received funding from the applicant, and I & APs must be given the opportunity to object to specialists with obvious bias. Resources must also be found to enable to conduct it's own independent research, and to conduct general monitoring and spot checks on the implementation of permit conditions – see our suggestions for resourcing this described in the general section above.

We support testing and analysis under SA conditions. It is not acceptable to extrapolate potential impacts based on data from other countries. However, permits for field trials must only be given for one growing season at a time, and test sites must be restricted to one site per ecological biome. We reiterate that field trials should only be allowed for GMOs that are intended for commercialisation and based on a benefit analysis that shows direct benefit to South Africans. Furthermore the use of experimental sites for seed bulking must be banned.

2.3 Ecosystems approach

p 13

We support an integrated approach to risk assessment, but this must be analysed in the broadest sense to include socio-economic and cultural influences on ecosystems.

Also while we are pleased to see that a participatory approach is emphasised in the ecosystems approach, the document makes little meaningful contribution to improving participation of potentially affected communities and the public.

p14

The second paragraph makes a good start in recognising the uncertainties involved in GE in relation to the location of spliced genes and the functions and inter-relationship of genes in the organism. However, the extent to which a genetically engineered organism is unpredictable (with genes from other species, aggressive promoter genes and techniques for forcing incompatible genes into an organism and the instability these may cause for example) is under emphasised, and cannot be compared with conventional hybridisation. The document must place stronger emphasis on the uncertainties in the technology and our rudimentary understanding of genetics, and consequently greater emphasis on a precautionary approach and independent analysis of risks.

2.3 Methodology

The methodology described doesn't take sufficient cognisance of the 'ecosystem approach' that is apparently being proposed. The document continues to refer to laboratory tests and field trials, which are currently required in the regulatory process and that clearly are inadequate to assess impacts within the context of an ecosystems approach. Information from releases of similar organisms and their interactions in similar ecosystems must be considered during the application stage, and a precautionary approach taken where there is indication of possible harm. Where no comparable information exists more stringent field trials and post release monitoring must be conducted. Furthermore more innovative approaches could be considered, linked to research and monitoring, to screen out organisms upfront that would carry a high risk before resources are wasted on developing these and making applications. In this regard SANBI's mandate to conduct research and monitoring should be linked to such an 'early warning' system with a protocol for informing the GMO Council convened under the GMO Act of the latest developments. Research should include active monitoring of field trails and commercial releases in the South African environment as well as desktop monitoring of international research highlighting risks, as more of these come to light daily.

Research areas that could input into an early warning system resulting in requirements for more stringent risk assessments or an upfront refusal of applications could include:

- organisms that will impact on endangered ecosystems
- organisms that have the potential to impact red data / threatened species either through crossbreeding, impacts to the organisms habitat or related species that are required in the organisms lifecycle.
- where the organism will impact on soil micro-organisms in sensitive environments
- organisms that are similar or can crossbreed with organisms that are indigenous to South Africa or have been developed over time to have significance in indigenous cultural, agricultural and economic systems.

It is not clear from the document whether an ERA procedure will be applied to both commercial as well as research releases. An ERA procedure should be applied as early as possible in the development of a GMO to avoid both wasting resources and harm to human and ecosystem health.

Main steps in environmental risk assessment

p 15

Step 1

Although the scope of this guideline is to look at the impacts of GMOs (which implies only considering how the organism has changed post modification) and the document specifies comparisons of the modified organism and parent we believe that the scope of this should be broadened:

1. The following must be added: "Any characteristics ~~**of the GMOs**~~ linked to the genetic modification, **the GMO, gene constructs and by-products** that may result in adverse effects on human health or the environment should be identified
2. The potential impacts of the parent material must also be assessed when identifying adverse characteristics (step 1) where that parent material wouldn't ordinarily be grown were it not for the introduction of the GMO. For example introducing new crops or new hybrids into areas where these are not usually grown, such as GM hybrid crops in an area where crops using saved seed have been grown.

When assessing potential adverse effects of GMOs these must be analysed over time, and predictions made on how the risk may change over time. For example economic impacts must be assessed in the long term.

The list of potential adverse effects of GMOs should make reference to the comprehensive table on page 17.

p 17 Steps 5 and 6

As with the ERA phases outlined in the box on page 10, the steps outlined must include the option of turning down the application and halting further development of the GMO as part of both Steps 5 and 6 where the risks are assessed to be too great. This should NOT simply be a process for devising risk management strategies.

2.4 Environmental safety assessment criteria

Likewise in the first paragraph under 2.4 the last sentence should read: "These activities need to be managed and the risks assessed, and measures put in place to AVOID, PREVENT, AND minimise the known and unknown impacts."

p 18 Table on Major environmental concerns regarding transgenic organisms

The table of major environmental concerns provides a useful summary checklist of potential impacts to be assessed in the risk assessment process, and as such should be as comprehensive a checklist as possible using the broadest definition of environment under the NEMA. Section 2.5 in the document can then be used to expand on the issues summarised in the table. The additional table that follows summarising potential hazards doesn't add much value and the issues listed here should rather be incorporated into the table of major environmental concerns. All of the issues listed under major environmental concerns have the potential to be serious depending on the circumstances under which they occur, and therefore the document should not single out any as more important than another.

The following concerns should be added to the table of major environmental concerns to create a more comprehensive summary (and new issues added as these are discovered over time):

1. Under the heading of horizontal gene flow the range of serious possible impacts must be noted (based on research results). For example this includes transferral of antibiotic resistance, transferral of genes within the body of animals and from food to digestive microbes, and the potentially disastrous consequence of insecticidal gene transfer to soil organisms which form the basis for soil fertility and ecosystem health.
2. Under the heading 'gene flow to wild relatives or non-transgenic varieties' the potential harmful impacts of this must be noted including pollution of the gene pool of indigenous, heritage and organic varieties; social and cultural costs of contamination of species used in cultural practices and indigenous farming; economic costs of contamination of organic farms; conferring selective advantages to wild species; secondary impacts on other species in the ecosystem resulting in a loss of biodiversity.
3. Instability of transgenes with expression of unpredicted or previously repressed traits. Under this heading problems with stacked genes and pararetroviruses should be mentioned.
4. Changes in agricultural practice: Changes in agricultural practice, especially the transformation of sustainable, traditional multi-crop farming practices through the introduction and aggressive marketing of GM crops linked to free inputs must be noted. We strongly object to rural marketing techniques which offer the non-choice of no assistance whatsoever vs. assistance in the form of free hybrid and GM seeds coupled to inputs and agricultural advice services as communities are not informed of the long term implications of this 'choice'. This has the potential to seriously impact on the food security of rural communities and biodiversity in terms of food crops as well as sensitive eco-systems where current traditional farming practice is integrated within the natural eco-system.
5. Increased reliance on chemical pesticides and herbicides must be noted as a separate and serious issue, in addition to the development of chemical resistance. Research in counties like the USA and China indicate that chemical use typically remains the same or increases over time with the use of GM crops, contrary to claims made by the industry. There are serious consequences for human and ecosystem health related to the use of Roundup and other stronger chemicals, which are an integral part of the GM crop package.
6. Impacts on workers and communities working with and adjacent to GM crops must be noted, for example allergic responses to GM pollen and when handling GM crop residues and toxic effects to animals eating crop residues.
7. Potential unknown impacts must be noted as a result of the instability of GM organisms and the possibility of gene movement and expression of currently suppressed traits as the organisms reproduce and respond to environmental stimuli over time.
8. Unplanned releases from inappropriate management of LMOs, plant residues, waste products, soil, water and other effluents during and post research. This is a serious issue considering the recent contamination of US rice supplies by unapproved GMOs.
9. Climate change response. Changes to ecosystems that affect the cycling of carbon must be considered. Another important issue is the ability of GM crops to withstand climate instability and the implications this has for all farmers, but particularly subsistence agriculture, when hardy traditional crop varieties are lost through contamination or aggressive marketing of GM varieties.
10. Transgenic organisms that reproduce easily. This issue may overlap with the first issue listed 'transgenic organisms persist without cultivation' and perhaps should be incorporated here. However, under this heading crops must be included that may not easily self propagate without being cultivated, but due to their ease of cultivation could easily be spread through the environment by people without control. E.g. potatoes.

p 20 Potential environmental benefits

We strongly object to highly speculative benefits of GMOs that are interspersed throughout the text of this document, and which are unsupported by credible research or even are being proved untrue by recent

peer-reviewed research conducted in countries that have been growing GM crops for longer than we have. Specifically we object to the inclusion of the following in the table of benefits:

▪ Adds Environmental value due to the reduced release of pesticides into the Environment
▪ Decrease the pressure on the land use
▪ Reduce environmental burden
▪ Due to the decrease use of chemical insecticides on GMO crops fields, the resulting renewed ecology observed around the GM plantings
▪ Promote conservation tillage which: Prevents soil erosion Conserves top soil Preserves soil moisture and reduces run off
▪ Allow the use of less environmentally damaging pesticides and herbicides
▪ Safer farm environment to live in and work in.
▪ Reduce air pollution (which can be caused by the spraying of pesticides on non-transgenic crops using aircrafts)
▪ Less energy is used in processing (less wastage)

p 21

2.5 Baselines on Environmental harm

We support that risk assessment identifies GM crops whose use leads to more intensive agricultural practice as a potential problem area. Furthermore, while it may be argued that hybrid monoculture should be the base line in assessing GM crops, we believe that this is not correct and we strenuously object to this as the base line. The role of GM technology in furthering and promoting multinational agribusiness with its concomitant impacts cannot be de-linked. GM crops are driving the conversion of sustainable and diverse agriculture to monocrop agribusiness models because the agribiotech companies can extract patent fees through GM technology. This profit motive is the cause of aggressive marketing and introduction of new hybrids into areas where these would not normally be used. This must be carefully managed and curtailed to protect ecosystems, crop diversity and rural livelihoods from a range of negative impacts. [For example in the Eastern Cape unethical marketing of GM crops through traditional leaders has resulted in intercropping of GM maize and contamination of traditional varieties. As a result a maize crop has been created that rots in the conditions of the Eastern Cape, where previously the traditional varieties could keep for long periods.]

We therefore propose that in all research and risk assessments that 3 types of baseline are established:

a) natural environment
b) traditional multi-crop agriculture
c) monoculture agriculture

Furthermore in considering GM technology as an appropriate course of action to further sustainable development (as should be done in an EIA), that organic farming is also considered as a base line.

Proof that GM crops pave the way for increasing control by multinational agribusiness at the expense of small-scale farmers and local food security is shown by Argentina. Argentina is now the second biggest producer of Roundup Ready (RR) Soya in the world, and is often lauded as a GM crop success story. However, statistics show that GM crops serve to widen the gap between wealthy large-scale farmers and the poor. Soya is Argentina's biggest agricultural export, but only 11th out of 14 food sectors in terms of generating employment. In addition 30 % of small and medium sized farms disappeared between 1992 and 2000, driving scores of people into city slums. The average farm size is now 40% larger, and just five

companies control an increasing proportion of Soya exports. We do not support this development model, which is against stated pro-poor and job creation policies of government.

p 22

2.5.2 Potential of the GMO to become a weed

Although current commercialised crops tend to have few weedy characteristics, the potential of new crops that may be introduced to be weedy cannot be overlooked. Research into this potential based on experiences in other countries is of importance as an early warning mechanism to forestall development and potential applications of plants which are likely to be problematic e.g. GM Canola and alien tree species. Coupled to this is independent research into pollen and seed dispersal mechanisms and distances, as distances on this issue relating to containment of experimental crops often appear to be underestimated in applications.
There also needs to be careful monitoring of currently released GMOs to ensure that they do not express new traits that contribute to weediness over time.

p 23 and 26

2.5.3 Herbicide Tolerance Management and 2.5.5 Insect resistance management

We support the requirement for HTM and IRM plans as part of the ERA submission but fail to see how this plan will be adhered to over time. Problems with the efficacy of this system that need to be addressed in the ERA framework and related legislation:

- The document makes HTM and IRM the applicant's responsibility, but there are no measures to enforce the provisions of the HTM / IRM thus making this a voluntary agreement.
- As we have repeatedly noted in prior submissions, current legislation protects the applicant/developer from liability. The GMO Act places responsibility for problems with the user not the developer/applicant and does not provide for an adequate liability and redress regime. Therefore, what onus and incentive does the applicant have for ensuring that the measures outlined in the HTM / IRM are adhered to post approval?
- Currently farmers are legally obliged to plant refuges to prevent insect tolerance from Bt crops, but it is not clear how many farmers apply these conditions, understand the need for refuges or have understood their responsibility when signing the technology use agreements. The bigger question then is who is monitoring and enforcing these conditions (and conditions that may be stipulated to prevent herbicide tolerance), how will increasing insect and herbicide tolerance be identified and who and how will damages be claimed once tolerance develops.
- There is critical need for a mechanism that obliges applicants and retailers who may be selling GMOs under license from applicants to provide government with the details of where crops are grown and to report on any problems that develop.
- Furthermore, it is our contention that due to the nature of living organisms tolerance will develop over time, GM crops are speeding up the rate at which tolerance develops and the South African environment and people will suffer as a result in the long term. We therefore support the paragraph that stipulates that herbicide resistant GMOs that could introgress to related species will NOT be authorised. The document must also outline a mechanism for independently assessing this potential.

p 24

2.5.4 Impact on non-target organisms

The document describes some of the impacts that may occur on non-target organisms. The issue of herbicide and insecticide tolerance in non-target organisms should be added. The impact on vectors may create a vector that is as dangerous as the GMO in terms of the impact on the ecosystem, and cumulative and downstream impacts must also be analysed.

The impact on micro-organisms (where horizontal gene transfer is more likely to happen) must also be added to this section as a very important area for concern.

Again the document does not clearly lay out any strategy for ensuring accurate research in the lab and field trials, or how research will be independently verified. It is known that applicants have conducted experiments which monitor non-target and target organisms at the wrong time in their breeding cycles, to conclude that there are no impacts. How will this be prevented? Given that South Africa has many diverse biomes with complex relationships between fauna and flora, how will research be conducted to prevent impacts when plants are commercialised across the country? For example the impact on insect vectors in one area may be completely different when the GMO is grown in another area – localised impact must be verified, and one cannot necessarily rely on data from other biomes or worse, other countries.

It seems that this section has come from American policy, which needs adaptation to the SA context. What are the key indicator species in different biomes in South Africa, which must be researched as part of an application, and what information do we have on their lifecycles to determine standard predictive tests that should be carried out? If this information is not currently available how will this be developed?

Impacts on non-target organisms are often only discovered over time – what ongoing research and monitoring will be done on this issue? SANBI is mandated to carry out this monitoring but they do not have financial or human resource capacity to do this. How will this be addressed?

p 25
We object to speculative paragraphs that falsely promote GM such as the one that says that GM has the potential to protect endangered species or bring back species. The latter premise is based on technology that doesn't really fit within the ambit of this document and conservation of species through GM is not backed up by research. The opposite seems to be true.

p 26-28

2.5.6 and 2.5.7 Gene flow between species and in the soil

The section on plant reproduction does not adequately address the unpredictability of human and animal behaviour in moving seeds and plant material in ways that create opportunity for gene flow. Documented cases of contamination of non-GM crops with GM material have predominantly been as a result of the movement of grains within transport systems or through trade. As was the case in Mexico, even borders are not impermeable to the movement of plants and seeds. South Africa must recognise its role and responsibility as a major food distributor in the region and take cognisance of the fact that the majority of people in the region rightly view food, feed and seed as the same commodity. In assessing the risks of gene flow we must also take into account impacts on endemic plant species in the wider continent.

Because we have no control over the use of GM plants once these have been commercialised or the way in which genes will move in nature, it is also foolhardy to assume that risky plants such as transgenic trees are ok provided the are not grown in conservation areas. All plants that are likely to pose a risk to indigenous and culturally significant species (including indigenous and landrace crops) in the region should not be authorised.

We request that an analysis of currently available research is carried out to identify species that have a high likelihood of gene flow from GM to non-GM varieties, and that these are listed on a national information database as species for which there is a high risk and therefore little likelihood of approvals for GM research and release. This list should be updated as more information is generated through ongoing monitoring and research into this issue.

We support research that creates greater understanding on the extent of pollen movement, as it seems that there are very divergent opinions for example on the ability of maize pollen to spread. We do not believe it is possible for co-existence of GM and non-GM crops, but agree that the issue of effective buffer zones is a critical issue in terms of protecting conservation areas and the organic farming industry. Again recommendations on minimum distances for buffer zones are meaningless without mechanisms to enforce these and have redress to damage payments where these are not followed.

Two critical issues are ignored in the discussion on gene flows and must be included:

The section on gene flow between microorganisms in the soil has completely ignored the possibly critical impacts of transferring insecticidal traits to soil organisms. This could have catastrophic impacts on soil ecology with ripple effects to earthworms, fungi and various other organisms, which are the foundation of soil fertility and ecosystem health. There have been reports in the media of farmers struggling to grow other crops in soil planted with GM crops in the previous season. These need to be taken seriously and investigated.

Section 2.6.4 notes the concern that antibiotic resistance genes could be transferred to bacteria. No mention is made of the transfer of other gene constructs, particularly to stomach bacteria in animals and from here into the circulatory system. Transfer of insecticidal traits and aggressive promoter genes is of concern as this could have serious impacts on digestion and unintended effects on organs and the immune.

p 28

We object to the paragraph that compares standard breeding to genetic modification – it should be removed. Even in circumstances where genes cross the species barrier these tend to be through natural reproductive processes between similar species. This does not compare with aggressive gene insertions through virulent carriers or gene guns to force genes from unrelated and organisms into the host. Also genetic engineering results in far more unpredictable behaviour as a result of the instability and random replication of inserted gene fragments than occur through a natural process.

2.6 Additional issues of concern

In general this section of the document is badly organised. In particular item 2.6.9 on EIAs and 2.6.10 on an environmental management framework for GMOs are a different sort of issue relating to the way in which the risks posed by GMOs will be treated in the regulatory system, rather than a description of the risks themselves. These points should be included with items 2.7 Quality of data/ submissions and 2.8 Administrative issues in a separate section on the various components/tools for assessing and managing the broad environmental risks associated with GMOs. This separate section must unpack these issues in much greater depth in the document and should outline inter alia:

1. the purpose of each component / tool with in the broader ERA framework
2. what conditions will trigger the use of each of these e.g. criteria for triggering an EIA or which require the development of an environmental management framework
3. the institutional relationships that have bearing on these processes with respect to the lead department, responsibilities for administration and other issues and final decision-making authority and structure
4. the quality and minimum requirements for information to be supplied in each of these processes
5. requirements for changes in legislation, regulations or institutional relationships to enable these processes and an action plan for achieving these

p 29

2.6.1 Changes in agricultural management practices

We object to speculation that GM is resulting in higher productivity and thereby releasing land for conservation, or that GMOs can ameliorate the impact of 'traditional' (i.e. high input monocrop) agriculture. Trends worldwide show that GM crops are part of an industrial agriculture model increasingly used in monocropping, plantation timber and biofuel production. This agricultural model is replacing natural vegetation, small-scale farms and multicrop systems. As noted elsewhere research in countries where GM crops have been used for some time shows a greater use of chemical inputs over time with consequent negative impacts on the environment and financial independence of farmers. The document notes increased use of herbicides, for example in the USA, in the next section in seeming contradiction to the claim that negative impacts of conventional agriculture are lowered.

p 29 - 33

2.6.3 Intentional stacking of GM traits

We support the ring fencing of stacked genes and the provisions requiring additional assessment no matter if the individual constructs have received previous approval. However, we require not only that stacked genes always require a full ERA but also that this should be an automatic trigger for a full EIA. Plans should also be included in the ERA for longer term monitoring and reporting to government of the GMO after release to ensure that the GMO remains stable, and does not express unexpected traits over time that may be dangerous to health and the environment.

2.6.4 Antibiotic resistance markers

We request that antibiotic resistance markers are banned for use in any new applications for field trial or release in South Africa and that the document stipulate time frames for the withdrawal of commercialised GMOs containing these from the market.

Furthermore we request that the introduction of new technologies to replace these receive special attention over and above scrutiny by the Advisory Committee to the GMO Council. Possibly the ecology group that DEAT proposes to coordinate to develop research priorities and conduct research should also provide advice on new technology.

2.6.5 Impact on soil organisms

We support the serious attention given to this issue in the document, but would like that the following be added:

The scope of GMOs of concern in this section must not only focus on plants that will be grown in soil but also other GMOs such as enzymes and microbes which would not normally contact the soil but may find their way into ecosystems over time through waste disposal and other means.

Analysis of soil organisms must be a part of all field trials. We cannot rely on information from previous relevant studies as an indicator of potential problems as these may be lacking and organisms may behave differently in our unique environment.

2.6.6 Research and development with indigenous organisms

The scope of this section should be broadened to include those species that have through religious, medicinal and crop use become endemic in South Africa and / or through cultivation over time developed properties uniquely suited to our local climate and culture. This would include, for example, varieties of specially adapted crops that have been handed down through families over several generations and which are now threatened through the introduction of GMOs.

We request a ban on the development of any GMOs from plants where the Southern African region is the centre of origin of that plant, as the gene pool of indigenous species must be protected and international experience has shown that co-existence of GMO and non-GMOs is not possible.

We are concerned that in exercising an additional level of scrutiny with respect to indigenous organisms, that the decision about the risk to, and value of those organisms is left to a very small group of people on the GMO Council. While we respect their commitment we also note the increasing number of applications that must be considered and respectfully submit that decisions of this nature must be made more democratically. Mechanisms must be introduced to ensure public awareness and involvement in these decisions.

We reserve the right to make further substantive submissions on this issue.

2.6.7 Inclusion of GMO activities in National Spatial Biodiversity assessment

We especially welcome the introduction of GMO free zones in biodiversity hotspots and adjacent areas and the commencement of mapping that will help to identify these. However, GM Free zones shouldn't be confined to hotspot areas, but should be extended to include:

- areas where particular species may be threatened through the introduction of GMOs, and these species occur outside of the hotspot areas
- where a majority of landowners or community members decide to keep their local environment GMO free.

It is important that when GM free zones are demarcated, analysis must also be done on the spatial needs of those species that are part of the lifecycle of the species at risk. For example a tree species may need a further 200m of undisturbed land around it to provide habitat for pollinators.

Information on GM free zones should be made available to all authorities and members of the public through a national GIS system linked to a publicly accessible and readable website. This could fall under SANBI's mandate and be linked to a national logging system for GMO plantings.

We again note that is nearly impossible to have coexistence of GMOs and non-GMOs, and therefore the issues relating to contamination in GM Free zones and how these will be dealt with, including compensation for loss and decontamination, must be addressed in the document.

2.6.8 Socio-economic and cultural considerations

This section is completely inadequate, and must be reworked. The response that the inclusion of a representative from the Departments of Arts and Culture and Trade and Industry on the Council will take care of concerns about the socio-economic and cultural impacts does not do justice to the issues. Although SANBI may not have a mandate to address broader socio-economic issues it is our contention that DEAT does have a mandate as per the NEMA definition of the environment to coordinate input concerning the wider environment beyond ecology. This contention is supported by the fact that EIAs under the auspices of the DEAT consider socio-economic issues.

The document needs to outline processes to engage with the public on issues of socio-economic and cultural concern and to lend these due weight in the decision-making process, even where these may not be scientifically valid.

Cultural impacts include, but are not limited to:

- Loss of cultural heritage where wild species and heritage crops of cultural value are contaminated by modified genes or hybrid traits that are able to transfer due to advantages conferred to the GMO. The intrinsic value of landrace / heritage crops to traditional communities must be recognised without the community having to justify economic harm.
- Loss of culture where the organisation, values and rituals of societies are linked to a traditional farming model.
- Ethical questions inherent in transferring genes from one species to another, from the perspective of South Africa's major faith groupings.

Socio-economic impacts include, but are not limited to:

- Direct economic and opportunity losses resulting from contamination of organic varieties leading to a loss of organic seed stock which may have been developed over time
- Contamination of organic varieties leading to a loss of export markets
- Loss of the use of Bt as an organic pest control remedy when insects develop a resistance to GM Bt crops
- Contamination by unapproved GMOs requiring recall
- the implications of the release of GMOs on small and resource poor farmers and women

2.6.9 Criteria for Environmental Impact Assessments

GMOs are included as Schedule 1 activities, under the new EIA regulations. We support that an EIA process should be mandatory for all applications where the GMOs will not be contained in laboratory conditions. All general releases and releases to hothouses /greenhouses, open ponds and so forth, should require a basic assessment under the EIA regulations, which includes upfront public participation. No release of GMOs should be eligible for exemption from at least the basic assessment procedure.

Table 2.3

This table is not satisfactory as a stand alone means for deciding whether and EIA should be required or not In principle we support the approach that the potential for some or definite negative impacts on biodiversity,

the broader environment, culture and socio-economics should elicit a cautious response or non-approval of the application. This table could therefore form the basis of a tool for assessing the nature of the risk posed by a GMO for the purpose of authorising or refusing an application. The purpose of an EIA would be to uncover information related to the issues outlined in the table, on the basis of which decisions can be made to proceed with the release or not give the application approval. It is precisely because applicants are likely to downplay impacts or may not have investigated the full range of potential impacts that an EIA is required as part of the decision-making process.

Instead we suggest that:

An EIA is required before all commercial releases of GMOs, but that where the following conditions arise an EIA must automatically be conducted (i.e. this is known to applicants upfront) before release as part of field trials:

- A GMO is being introduced into an area where there has been no history of monocropping of either the same crop type, or another type of monocrop.
- A GMO is being introduced into any 'natural' or as yet undeveloped area
- A GMO will be introduced into an area where there are land claims. The future community must be given the opportunity to decide whether it wants to take on the risk of contamination by GMOs. [Given that it is becoming evident that certain GM crops affect the soil and decomposition processes, and that contamination can potentially result in patent claims, rightful owners of land must be given the opportunity to decide if this is the development path they choose for their community]
- The GMO is engineered from a species that has not previously been grown commercially in South Africa, or in the particular region of South Africa where it will be introduced as a GMO. [In many ways GMOs should be considered as potentially invasive and often alien species because they are engineered with traits that provide them with an advantage. We suggest, therefore, that we take guidance for the requirement for an EIA from the protocol prepared by DWAF for invasive alien species.]
- The GMO is similar to or can impact on a related indigenous species or a naturalised or landrace species of cultural, food or economic significance to local/indigenous farmers and communities.
- The GMO is similar to or can impact on a red data species or related species that are critical to the habitat or reproduction of the red data species.
- Where the introduction of a GMO could have a negative economic impact on a particular farming sector. For example, where a majority of farmers rely on an export market that is negatively disposed to GMOs.
- Where a GMO is for a crop that is a staple food for any community in Southern Africa.
- Where the introduction of a GMO could compromise food security or the livelihoods of people in a particular area [E.g. introducing Roundup ready crops in an area with delicate soils where soil conservation is dependent on intercrop farming with constant groundcovers]
- The GMO is a pharmacrop
- Where the GMO contains new technologies, such as to replace CaMV promoters

In addition to automatic triggers for an EIA, the Minister should also be able to request an EIA for a GMO, which on examination of information supplied as part of an ERA in the normal application process, indicates a high risk even if none of the automatic trigger conditions are present.

The purpose of conducting an EIA at the field trial stage is to prevent the release of high risk GMOs where these will be detrimental, as well as acting on early warnings of high risk so that there is an opportunity to cut short the development process and associated costs of GMOs that are likely to be refused authorisation. This is prudent in view of administrative justice legislation.

2.6.10 Environmental Management Framework for GMOs

This section is not dealt with adequately. It is not clear what the document is trying to say on this issue, or how the Management framework relates to the ERA framework. We reserve our right to submit further comments on this, once there is more clarity.

2.6.11 Pararetroviruses

We note and concur with the very serious risks associated with pararetroviruses. While the document describes these risks it does not outline a response to this risk. We request that pararetroviruses represent an unacceptable risk and that these are banned for use in any new applications for field trail or release in South Africa and that the document stipulate time frames for the withdrawal of commercialised GMOs containing these from the market.

Furthermore we request that the introduction of new technologies to replace these receive special attention over and above scrutiny by the Advisory Committee to the GMO Council. Possibly the ecology group that DEAT proposes to coordinate to develop research priorities and conduct research should also provide advice on new technology.

2.7 Quality of data / submissions

This section is inadequately dealt with, and would be better placed in a comprehensive and separate section of the document dealing with the environmental risk assessment process. (See comments at the beginning of this section) The type and quality of information needed would depend on what particular process and stage in the assessment process is being considered and should be outlined in detail. The paragraph on quality of data to be submitted on page 13 of the document is more comprehensive than the stipulations in this section.

In general we support that applicants provide references for all information provided, indicating clearly which supporting information comes from peer reviewed sources and which is generated by the applicants, as well as details of all methods used.

Point (c) referring to antibiotic resistant markers should be broadened so that the particular risks to the environment (defined in NEMA's broad sense) are examined for any medium or high risk component of a GMO such as weediness potential, contains a pararetrovirus, potential for gene transfer etc.

2.8 Administrative arrangements

Detailed comment cannot be made on this section as it is blank

SECTION 3: MONITORING GMOs RELEASED INTO THE ENVIRONMENT

3.1 Monitoring

The first point under 'objectives' is not clear – perhaps rephrase as " to confirm that assumptions made in the environmental risk assessment about the behaviour of the GMO in the environment and the impact of potential adverse effects were correct."

A third objective should be added: 'to provide ongoing data to enable the fine-tuning of risk management strategies, as outlined in permit conditions and including the withdrawal of the authorisation where necessary.

3.2 Case specific monitoring

We support case specific monitoring that leads to further risk assessment studies when problems are detected. Case specific monitoring should not be confined to hypotheses in the ERA, as monitoring may also detect impacts related to a particular GMO that were not foreseen in the ERA process.

3.3 General surveillance

Similarly the focus of general surveillance should not be confined to impacts that weren't foreseen prior to releasing particular GMOs, but should rather be concerned with monitoring general changes in the environment that could be linked with several or one particular GMO. General surveillance should serve as an early warning system to pick up trends and cumulative impacts that may be overlooked in case specific risk assessments. It is very important that the definition of environment under NEMA is used, and that this monitoring includes trends in health such as increases in allergies and immune response and socio-economic and cultural impacts.

We recognise that SANBI is legally mandated to perform this monitoring and reporting. However, we question SANBI's ability to perform this mandate given a shortage of staff and resources. The document must suggest a plausible action plan for resourcing SANBI and establishing the monitoring system.

3.5 Examples of parameters for monitoring

The parameters described are very focused on particular crops. The parameters need to be more encompassing of the variety of applications that may be submitted. For example:

- all forms of 'resistance' should be monitored including resistance to herbicides, insecticides, antibiotics and any other resistance traits that may be included in a GMO.
- Gene transfer in general should be monitored including between similar species, to wild or organic populations, transfer of traits to unrelated species such as from crop to soil bacteria or stomach bacteria etc
- Changes to populations of target and non-target organisms and dependent organisms in general should be monitored – not only insects.
- etc

Table 3.1 Structure of a monitoring plan

The steps and headings in the monitoring plan are not defined so it is difficult to comment on whether this monitoring plan contains all the aspects that it should. Rather than simply reporting impacts against a

baseline (especially where this will be an agribusiness / monocrop baseline, the monitoring plan must rather include thresholds for tolerable ecological and health effects, against which performance is reported. These thresholds will need to be developed and included in the monitoring plan by DEAT when applications are approved. In this way management of harm will be focused on achieving the environmental standards we want rather than simply comparing which system is worse.

Section 3 notes the need to communicate and publish the results of monitoring. We support that this is done in an accessible and transparent manner via a national reporting system linked to publication on a public website.

p 46 Resistance evolution and management

This section must also address all forms of possible resistance such as herbicide resistance, rather than only focusing on insect resistance. Language and descriptions must be amended accordingly, for example in Step 3 factors influencing risk should include reproductive behaviour and not just mating behaviour etc

An important step has been missed out in the 'Resistance evolution and management' steps. Step 6 has been omitted from the process, namely the 'review and amendment of risk management strategies in response to the results of monitoring'.

General omissions and concerns relating to the section on monitoring

This section is silent on who will undertake monitoring and how this relates to the other processes that are a part of the overall risk management framework. The implication, we assume, is that applicants will undertake case specific monitoring according to a monitoring plan submitted with their application and SANBI will undertake general surveillance and reporting to the minister. There are 2 problems with this:

1. in monitoring their own developments, applicants will be both player and referee. Independent monitoring and spot checks by authorities must be a part of monitoring, and provisions for this must be included in the document.
2. SANBI is biodiversity focused, and the resource constraints that we have already noted aside, are not well equipped to monitor the other aspects of environmental harm, including socio-economic, cultural and health impacts. Whatever, the mandate of SANBI in terms of monitoring and reporting on GMOs, DEAT cannot shrink from its responsibility for integrated environmental management, which includes the general well being of people under NEMA. The document must therefore make proposals to ensure that this broad monitoring takes place, whether it is by extending SANBI's mandate or creating a new cross-sectoral team that can draw on expertise from different backgrounds that reports directly to the Minister.

In general monitoring must investigate possible foreseen and unforeseen impacts, as well as checking that applicants are adhering to risk management plans and any conditions contained in the approval permits, so that infringements are picked up early and can be remedied.

This section on monitoring only refers to post commercialisation releases into the environment, but there is also a need for monitoring of research activities. As we have seen from the USA rice debacle contamination can arise from carelessness in the research phase. Random inspections and reporting on both laboratory research and field trials is needed to ensure that permit conditions for containment, waste management etc are met to ensure maximum biosafety.

Government must be able to act on information and feedback generated through the monitoring process. The document does not outline any procedures for dealing with and acting on evidence that harm has been

caused or for ensuring that parties that have been harmed (whether individuals or South Africa in general) are compensated for losses.

We propose that as a minimum, all authorisations include clauses which state that:

- as a condition of the release the monitoring plan must be implemented and reported on
- the authorisation can be withdrawn or have conditions imposed at any time following evidence of harm based on monitoring or new research (whether local or international),
- where a GMO is authorised for commercial release that the GMO Council or Minister of Environment can at their discretion, depending on the perceived severity of the harm, institute an immediate moratorium on further releases and/or call for an EIA to investigate new risks.

SECTION 4: RESEARCH PRIORITIES FOR GMOs

We support the proposal by DEAT to convene a group of independent ecologists (study group) who will further identify and develop parameters for a set of research priorities to drive the monitoring mandate of SANBI, and form the basis of reporting to Parliament about in terms of section 11(1)(b). In this regard we request that DEAT provides civil society with a formal undertaking that:

- we are involved in developing the terms of reference for this group
- we can put forward nominations for experts that will be appointed, and comment on the balance and impartiality of the experts appointed to the group
- Civil society will have the opportunity to engage with and comment on the work of this study group and any other processes that develop from this

The need for many different types of research and monitoring has already been noted throughout the comments above. In relation to the research priorities listed in the document:

- Study on gene flow: which maize, soya and cotton events will be studied?
- Research into soil organisms should also investigate impacts related to the interaction between GM crops, the soil and related processes that may result from non-target impacts on soil organisms. E.g. the study should follow up on reports by farmers that GM crops do not decompose in the same way as other crops.