COMMENTS ON THE GENETICALLY MODIFIED ORGANSIMS AMENDMENT BILL (revised version), 2005

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TABLE OF CONTENTS

SUMMARY OF FINDINGS

During October 2004, we submitted detailed comments on the Genetically Modified Organisms Amendment Bill published on the 8th October 2005. Now, almost 11 months later, a revised version, Genetically Modified Organisms Amendment Bill has come to our attention. After reviewing these recent proposed amendments, we make the following findings:

Generally speaking, the current amendments have been made within the existing "risk management" approach to the regulation of GMOs as opposed to a precautionary approach. These amendments are also made in a piece-meal fashion rather than a comprehensive overhaul of the GMO Act as a whole, which, despite countless amendments, will always be nothing but a permitting system for GMOs shrouded in secrecy, and based upon self-regulation by industry.

In particular:

1. We are utterly shocked and disturbed to see that no mechanism has been created for public participation and that the dubious terminology of public input continues to haunt us. Our continuous objections to the extremely limited public input/notice and comment procedures laid down in the Regulations are hereby reiterated;

2. The amendments do not fully comply with key provisions of the Biosafety Protocol including its all- important precautionary principle. **Indeed, it is mischievous for primary biosafety legislation to ignore an explicit reference to the precautionary principle in decision-making;**

3. The amendments have utterly ignored the on-going and extremely important and key negotiations under the Biosafety Protocol under Article 18(2)(a). What is at stake is the taking of measures that place legal responsibilities on exporters to:

    (a) test a mixture of GMOs in order to determine the GMO content and the individual variety (genetic transformation event) of GMOs contained in the shipment, to list the GMOs and ascertain that it has been approved by the party of import; and
    (b) ensure that non-GM shipments only contain GMOs that are technically unavoidable and that a threshold is set for such unavoidable quantities (e.g. 0.1%).

    Such measures will go a long way towards protecting the integrity of non-GMO shipments from contamination and ensure that there is zero tolerance for unapproved GMOs.

We cannot understand why the NDA has chosen to ignore this critically important issue when they authorise the import of millions of tons of GM maize from Argentina and the US, taking also into account the recent contamination by Syngenta of exports to Japan and the European Union of unapproved Bt10 GM maize!

4. The amendments introduce WTO language in respect to risk assessment by references to 'science-based assessment" in order to limit the extent to which environmental and socio-economic factors may be taken into account in decision-making and bind the GMO Act to the WTO standards of risk assessment. **We strenuously object to the use of the words "science based assessment."**
5. The amendments ensure that the Registrar is the "kingpin" in respect to compliance with the Act and permit conditions, arranging inspections and monitoring, ordering the cessation of activities, destruction of GMOs and the granting on his or her own accord, extension permits for imports/exports and field trials. The entire co-ordination of biosafety regulatory system thus hinges on the competencies, abilities, capacity, impartiality, integrity and so forth, of one person. This is a worrying turn of events;
6. The provisions dealing with liability for damage have been partially amended, however, the fundamental flaws still remain in that consumers and resource poor farmers can be held liable for damage caused to the environment, human and animal health. Furthermore, no attempt has been made to deal with issues of redress;
7. The previous wholly unsatisfactory and prejudicial provisions dealing with confidential business information and access to information remain unchanged;
8. While socio-economic considerations are to be taken into account in the course of decision-making, these considerations are not mandatory, and are undermined by the terminology 'science based assessment;'
9. Mandatory environmental impact assessments for GMO releases continue to remain outside of the GMO Act; and
10. Operative biosafety provisions such as parameters, principles and methodologies for risk assessment, risk management, extension permits and so forth, continue to remain outside of the GMO Act, even if regulations therefore are contemplated.

DETAILED COMMENTS:

Definitions:

Our comments on the revised amendments are as follows:

1. The preamble has been changed to include a broader reference to compliance with international agreements pertaining to genetically modified organisms (GMOs) as opposed to only referencing the Cartagena Protocol on Biosafety ("Biosafety Protocol"). This is done obviously with the World Trade Organisation ("WTO") agreements in mind.

2. The definition of "accident" has been revised and is more comprehensive than the previous version.

3. A new definition of "biosafety" has been created, which is on the face of it, appears to be quite good, however, the risk to be avoided is to result from the **activities** with GMOs and not also, the GMO itself, which is a major shortcoming because harm will not only result from the actual activity e.g. planting in open field trials but from the GMO itself and the interaction between the GMO and the external environment or in the context of human health, allergic reactions resulting from the GMO itself. It is also interesting to note that the Draft Biosafety Policy (GN 1576 of 2005) published for comment on the 26 August 2005, adopts a distinctly different "risk management" approach to "biosafety" which it defines as follows "the management of risks to human and animal health and safety, and to the conservation of the environment, as a result of activities with genetically modified organisms."

4. Similarly, the definition of "environmental impact assessment" refers to the impact of a proposed activity on the environment and not also, the GMO itself. It is generally accepted that GM crops for instance, are not the same as conventional crops. Moreover, there are different events or varieties of GMOs, which require case-by- case evaluation. Hence, both the proposed activity as well as the specific GMO has to be assessed for potential impacts on the environment. It is also worthwhile to note that it is not known **in respect to what exactly**, the potential impacts of the proposed activity are to be assessed.

5. The definition of "contained use" has been substantially redrafted but still is deficient in that "movement" and "storage" are included in the definition. This renders what should be a scientific definition, unscientific. The word 'movement" is not defined yet, it also appears in the definition of "transboundary movement", see discussion below. It is commonly accepted that "contained use" refers to different levels of containment within laboratory conditions to avoid releases of GMOs into the environment. Furthermore, attention should be given to the regulation for instance of the disposal of naked DNA, i.e. genetic material because the definition only applies to GMO and not to parts of the genetic construct. Having said this, we welcome the inclusion of greenhouses in the definition of contained use.

6. We welcome the deletion of the previous proposed amendments, which opened the door to human gene therapy.

7. The definition of transboundary movement is generally speaking consistent with that of the Biosafety Protocol. However, we are concerned that the word 'movement" which clearly denotes the transportation either by road, water or air of GMOs be included in the definition of contained use. Separate regulations should be drafted for the transportation of GMOs within the jurisdiction of SA and for transboundary movement, as is contemplated by Article 18 of the Biosafety Protocol.

8. We deeply regret that the definition of "user" has not been amended, in the light of the provisions of section 17 dealing with liability.

Unacceptable WTO Language Used For Risk Assessment

The proposed amendment of section 5 introduces WTO (World Trade Organisation) language in respect to risk assessment by the reference to 'science-based assessment" which has been introduced for several reasons, not the least of which is to limit the extent to which environmental and socio-economic factors may be taken into account in decision-making. Indeed, reference to "science-based assessment" or "science based risk assessment" is littered throughout the proposed amendments.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), in particular, Articles 5.1 and 2.2 establishes the obligation to base measures on risk assessment on scientific principles. The specific reference to "science based risk assessment" means that South Africa will have to comply with the risk assessment standards set under the SPS agreement. Currently the parameters of Articles 5.1 and 2.2 dealing with risk assessment, are being tested before the WTO by its Dispute Settle Panel (and perhaps later by its appeal apparatus), in the *EC Biotech* dispute. South African legislation should not anticipate the outcome of the dispute but should be guided by the principles of the South African constitution concerning matters of public health and public goods, and its obligations of the Biosafety Protocol, which is the only international agreement that deals directly with GMOs. Indeed, South Africa must take decisions based on the balance of all its obligations under international law and not only those that are trade related.

It is worthwhile to note that throughout the Biosafety Protocol negotiations, the biotechnology industry, supported by the Miami Group of countries lobbied heavily for 'science based risk assessment" terminology to be inserted in the Protocol. This did not happen because the WTO agreements are concerned with trade liberalisation whereas the Biosafety Protocol and indeed, biosafety legislation, is concerned with the need to protect the environment and human health.

In any event, we expressly point out that the relationship between the Biosafety Protocol and the WTO agreements is not addressed by the substantive provisions of the Protocol. The Preamble of the Biosafety Protocol emphasises on the one hand that the Protocol shall not be interpreted as implying a change in the rights and obligations of a Party existing under existing international agreements, and on the other, it states that this is not intended to subordinate the Protocol to other international agreements. The Preamble

also states that trade and multilateral environmental agreements should be mutually supportive. Thus, how the implementation of the provisions of the Biosafety Protocol relates to the WTO agreements is an open question. If a conflict were to arise between the WTO agreements and the Biosafety Protocol, there would be ambiguity about which agreement would prevail. It is noted therefore, that the current WTO challenge discussed immediately below, is not a challenge of EU measures taken under the Biosafety Protocol.

It is not appropriate for South Africa to incorporate into our legislation, loaded terminology from WTO agreements. **We strenuously object to the use of the words "science based assessment."**

Self Regulation/Risk Management Approach Unchanged for GMO Releases

Section 5(d) has been amended to make it mandatory as opposed to discretionary as was the previous situation, that the Registrar require the applicant to notify it of any intended change in the type of activities or release involving GMOs. This provision does not really change anything because the status quo will remain unchanged: no direct legal obligation has been created on the applicant to comply with permitting requirements; and self-regulation of GMO activities in facilities and releases will continue with no mandatory and on-going independent biosafety oversight taking place.

Decision-Making Still Problematic, Exclusion Of Protocol's Precautionary Principle

The previous paragraph 5(g) has been amended to take into account our objections that decision-making takes place within the context of **approvals**. However, the terminology of 'science based risk assessment" is again repeated and we once again reiterate our strenuous objection to this terminology being used. We are also not comfortable with the introduction of the words 'potential benefits' because it now makes it a legal requirement for industry to use the regulatory system as part of its public relations work. It is much more important to require applicants to engage with biosafety requirements such as the need to provide evidence of **safety** as opposed to requiring that they set out the benefits arising from the use of their patented GM seeds.

The dubious terminology of "public input" has also been repeated here, making it clear that no mechanism for public consultation is contemplated within the framework of the legislation. Most importantly, however, is the failure to incorporate the precautionary principle as set out in Articles 10(6) and 11(8) of the Biosafety Protocol. What this means is that we are left with the formulation of the precautionary principle as set out in the Regulations to the GMO Act, which contains the deficient wording of the **precautionary approach** from Annex III of the Protocol, which in any event, deals with **risk assessments AND NOT DECISION-MAKING**. We strongly recommend that the formulation of the precautionary principle of the Biosafety Protocol be inserted into these amendments. There is no good reason why a deficient and inappropriate formulation of a principle central to biosafety regulation should be used and then to, only in secondary legislation. **Taking into account the objective and structure of the Biosafety Protocol to which South Africa is a Party, as well as its precautionary principle, we strongly recommend the explicit recognition of the fundamental role**

of precaution in the context of genetic engineering and GMOs! Indeed, it is mischievous for the primary piece of biosafety legislation to ignore an explicit reference to the precautionary principle. Finally, we welcome explicit reference to the requirement of risk assessments in respect also of activities for which extension permits are sought.

Information Sharing & BCH

It remains to be seen to what extent South Africa will comply with her obligations under the Biosafety Protocol dealing with information sharing as contemplated by Article 20 of the Biosafety Protocol, since the regulations (still to be drafted?) will deal with this. The same applies to the information that the applicant must supply the registrar in the event of an accident, which includes an unintentional transboundary movement.

We welcome the provisions of the proposed 5(i), (iA), and (iB) which is are improved versions of previous provisions and are more consistent with Article 17 of the Biosafety Protocol dealing with notifications and actions to be taken in the event of an accident/transboundary movement occurring.

We welcome the provisions of the new section 5(j) dealing with co-operation agreements, which is now consistent with Article 14 of the Biosafety Protocol.

Review of Decision Not Consistent with Biosafety Protocol

A new provision 5(k) is provided for the review of by the Executive Council of any decision it makes. It is important to note that the Biosafety Protocol deals with review of decisions in Article 12. Article 12 addresses the changing state of knowledge about GMOs and their potential impacts on biodiversity and human health and provides for review of decisions in the light of new information or circumstances. Additionally it allows a review of decision to come about at the instance of:

- The party of import;
- The party of export; and
- The notifier.

It is important that Article 12 be given effect to and in addition, that some mechanism be created for the public to initiate a process to review approvals in the light of new scientific information on potential adverse effects. Review of decision by the EC is an essential component of biosafety regulation, and not only in a more formal manner by the appeal board for instance. We strongly recommend that a mechanism be created which the public can trigger, in order to bring new scientific information to the attention of the EC. We believe this to be a fundamental right to administrative justice, taking into account the evolving nature of the scientific information regarding GMOs.

Functions Of Registrar: Too Much Power?

Entirely new provisions have been drafted for the functions of the registrar, which repeat some of the previous powers exercised by the Registrar but which also give the Registrar additional powers. Whilst it is acknowledged that the Registrar can only act on the instructions and conductions of the Executive Council (except with regard to the issue of

extension permits,) the new powers given to the Registrar are worrying. Taking into account that the Council meets only 4 times a year, the role of the registrar is not only pivotal to the functioning of the legislation, but in terms of the new powers, the Registrar is the kingpin in respect to compliance with the Act and permit conditions, arranging inspections and monitoring, ordering the cessation of activities, destruction of GMOs and the granting on his or her own accord, fast track permits for imports/exports and field trials. The entire co-ordination of biosafety regulatory system thus hinges on the competencies, abilities, capacity, impartiality, integrity and so forth, of one person. The Council members are not engaged in biosafety issues on an on-going basis, and will thus rely on the work, recommendations, inputs, suggestions and so forth of the Registrar.

These provisions need to be more carefully thought through, as good governance favours checks and balances. How will the Council check whether the Registrar has acted in accordance with its instructions? Or indeed, whether the Registrar has exceeded or abused his/her powers? These are key questions concerning good and transparent governance.

In regard to extension permits, the Registrar is given powers to issue on his/her own accord and without any oversight or instruction by the Council, additional permits for the import and export of GMOs for contained use purposes and for food, feed and processing. The Registrar is also allowed to issue extension permits, which extend the period of time for field trials especially. We would be more comfortable, if the Registrar at least post information on its website, advising of its intention of grant a further period of time and allow the public to make inputs to the Registrar and the Council.

Better Resourcing of Advisory Committee, but Greater Transparency Needed

Several amendments are proposed with regard to ensuring that the Advisory Committee is comprised of people having appropriate expertise and is able to access experts from discreet scientific disciplines concerning GMOs and financial remuneration therefore. Does this imply that to date, the Advisory Committee has been unable to properly advise the Council because of lack of expertise and financial resources?

In the interests of transparency, we would like to request the Department of Agriculture to put in the public domain, the names of the scientists that have served on the Advisory Committee and who have reviewed GM applications. We make this request because we believe that section 13 of the GMO Act dealing with conflict of interest has been contravened in the past because industry linked scientists have served on the Advisory Committee. This form of disclosure will augur well for fostering public confidence in the regulatory system as well as contributing to an analysis of the effectiveness of the GMO Act in general, in enforcing compliance with provisions.

Seizure

We welcome the amendments made to section 15 dealing with powers of inspectors to seize GMOs.

Small Changes to Liability Provisions, but Fundamental Flaws Remain

We welcome the proposed amendments to section 17 of the Act which will now place the onus on the **user** to take appropriate measures to avoid an adverse impact non only on the environment but also, on **human and animal health** which may arise from the use of GMOs.

However, we continue to object to the definition of "user" in this context as it includes consumers, small-holder/resource poor farmers, the general public etc.

While we welcome the proposed amendment that liability will arise not only from the **release of a GMO into the environment but from activities relating to GMOs**, we strenuously object to the exclusion of liability also arising from the GMO itself, as has already been discussed earlier.

Reference is made to the multilateral process underway in terms of Article 27 of the Biosafety Protocol, which may be concluded only in a few years time. In any event, such a process is unlikely to result in a liability and redress regime that does not give Parties enough leeway to craft their own systems. We believe that whilst South Africa should participate actively in the multilateral process, the national process should continue to evolve and in this regard, much more thought should go into the development of a sound liability and redress regime. We note that the GMO Act does not deal with issues of redress.

Major Problems With Confidential Information & Access to Information Remain Unchanged

We note the changes proposed to section 18 of the GMO Act and find these to be unacceptable.

The proposed changes appear at first glance, to repeat the minimum provisions as set out in Article 21(6) of the Biosafety Protocol with one important exception: whereas Article 21(6)(c) only refers to a summary of a risk assessment, the proposed amendments refer to " a science based risk assessment," terminology we reject. We also note that the description of the GMO is now to be limited to the "general" description.

We remind South Africa, as a Party to the Biosafety Protocol that the information contained in Article 21(6) represents only the minimum amount of information that the public is entitled to. We find that this information is inadequate for us to properly exercise our rights to access to information, as has recently been supported in the court case brought by Biowatch South Africa against the Minister of Agriculture and Land Affairs *et al.* Article 2(4) of the Biosafety Protocol specifically mandates Parties to the Biosafety Protocol to take more stringent measures than that established by the Protocol.

More worrying, however, is that the provisions dealing with the determination of information that the public is not entitled to, have not been changed notwithstanding our consistent objections. Our experience with the current provisions in sections 18(1), (2) and (3) prior to the successful outcome of the Biowatch court case, was the following;

1. We would submit an application in terms of the Promotion of Access to Information Act;
2. The Registrar would call the applicant into her office (applicant here refers to the multinational agrochemical companies such as Monsanto, Dow Agrosciences and Syngenta) to indicate to her, what information we are entitled to;
3. We would receive 18 pages of a 2000 page docket, excluding even such basic information as the molecular characterisation of the GMO in question. In other words, these companies are given *carte blanche* over the information we are entitled to.

We have recommended to the Executive Council that it establishes a proper panel and scientific criteria, for the determination of **confidential business information**. Until this happens, we will continue to be severely prejudiced and unable to fully exercise our rights as contemplated by several pieces of post-apartheid legislation dealing with access to administrative justice.

Criterion for Setting Aside Appeals Not In Favour of Biosafety

We are extremely concerned about the proposed amendment of the new section 19(4)(c) which will read as follows " after due consideration of the potential risks and potential benefits related to the matter of appeal, make such order as it may deem fit in order to minimise a significant negative impact on the environment or human and animal health."

We are utterly confused as to why the following new elements have been introduced;

- Cost benefit analysis
- Minimising a significant negative impact

Surely, similar standards that underpin or guide decision-making must also guide the decision-making on the part of the Appeal board? Here, we are thinking immediately of the precautionary principle and repeat here, what we have already discussed above, with respect to decision-making.

Regulations

We welcome the proposed amendments for regulations to be made on key biosafety issues after almost six years of the GMO Act being in force, namely, risk management measures, socio-economic considerations, extension permits etc. However, while we believe that regulations on risk assessment are well overdue by six years, we continue to reject the reference to science based risk assessments.

MAJOR OMISSIONS

Documentation-Article 18(2)(A) of Biosafety Protocol

One of the most controversial issues that could not be agreed upon during the Protocol was the rules for the identification of GM content in bulk agricultural trade. Article 18(2)(a) of the Biosafety Protocol, which embodies only interim arrangements, allows

bulk shipments of GMOs traded directly as FFP, be identified ambiguously as "may contain" GMOs.

Article 18(2)(a) makes it incumbent/obligatory on the Conference of the Parties serving as the Meeting of the Parties (COP MOP1) to take a decision on the detailed requirements for this purpose, including specification of their identify and any unique identification, no later than 2 years after the date of the entry into force of the Protocol.

However, at COP MOP1 in Kuala Lumpur, Malaysia in 2004, Brazil and Mexico, both Parties to the Biosafety Protocol, emerged as opponents of more stringent requirements relating to agricultural commodities, with the result that no final decision could be taken by the Parties and a further set of interim solutions were devised.[i] At COP MOP2 in Montreal, Canada, and after five days of intense and controversial negotiation, Brazil again, this time led by New Zealand repeatedly blocked possibilities for consensus building, with the results that the negotiations on the issue of documentation for bulk GM shipments collapsed completely.[ii]

What is at stake is the negotiation of a mechanism that places legal responsibilities on exporters to:

(a) test a mixture of GMOs in order to determine not only the GMO content but also the individual variety (genetic transformation event) of GMOs contained in the shipment, to list the GMOs and ascertain that it has been approved by the party of import; and
(b) ensure that non-GM shipments only contain GMOs that are technically unavoidable (mostly, where non-GM crops/food have become contaminated by GMOs) and that a threshold is set for such unavoidable quantities (e.g. 1%). This may also mean that shipments of grain and other agricultural exports from GM producing countries may be affected and will have to be tested, and where GMOs are found and these constitute more than the permissible threshold level, then (a) will apply.

Implicit in the devise of this mechanism, is the need to:

(i) protect the integrity of non-GMO shipments from contamination;
(ii) ensure that there is zero tolerance for unapproved GMOs; and
(iii) keep the door open for the development of modalities for sampling and detection techniques.

In regard to thresholds for adventitious GM content in non-GM shipments, industry groups have been pushing for a 5% threshold. Since the Biosafety Protocol does not foresee nor provide a mechanism for the setting of thresholds, a few countries have established their own thresholds for adventitious GMOs, including the EU, Australia, New Zealand, Japan, South Korea, Thailand and China. Controversially, a trilateral agreement between the North American Free Trade Agreement (NAFTA) countries of Mexico, the US and Canada has been concluded which includes the 5% threshold for adventitious GMOs. The trilateral agreement provoked widespread condemnation especially by environmental organisations. According to Greenpeace, there is general agreement within the scientific and technical community that reliable detection is practically feasible at a level of 0.1 %.[iii]

Public Participation

We are deeply disturbed that no attempt has been made to create a mechanism in the legislation for public participation. We repeat hereunder, our fundamental problems with the notice and comment procedure set out in the Regulations:

It is our view that regulation 6 of the Regulations made under the GMO Act is not in compliance with sections 3 and 4(1) of PAJA. We refer the EC to our numerous objections submitted to the EC over the last few months, to various applications for GM imports and releases, as well as to numerous correspondence wherein we have illustrated amply and clearly to the EC and the Registrar, that regulation 6 of the said GMO Regulations is inherently unfair, prejudicial and obstructs the administration of justice.

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

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

Since regulation 6 of Regulations of the GMO Act deals with a notice and comment procedure (between an applicant and members of the public where the release is intended to take place).

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

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[i] See further, Implementing the Biosafety Protocol: Key Challenges Robert Falkner and Aarti Gupta, Sustainable Development Programme, November 2004

[ii] See further, Brazil, New Zealand Block Decision on Documentation on GMOs, Lim Li Ching and Lim Li Lin, Third World Network, June 2005.

[iii] How to implement Article18 of the Cartagena Protocol on Biosafety on handling, transport, packaging, and identification of living modified organisms, Greenpeace (undated).