SUBMISSION TO CHAIRPERSONS OF PORTFOLIO COMMITTEES OF:

AGRICULTURE AND LAND AFFAIRS
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PROPOSED AMENDMENTS GENETICALLY MODIFIED ORGANISMS BILL, 2005 (ACCOMPANIED BY BRIEF EXPLANATORY NOTES)

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Supported by:

- **South African Freeze Alliance on Genetic Engineering**
- **Earthlife Africa**
- **Safe Food Coalition**
- **Ekogaia Foundation**
- **Farmers Legal Action Group-South Africa**
- **Noordhoek Environmental Action Group**
- **Merlin Business Services (Theo Schuurmans)**
- **Earth 52 (Harald Witt)**
- **Permacore, The Permaculture Foundation of the Western Cape (Noel Marten)**
- **Biophile Magazine (Anthea Torr)**

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CLAUSE 1

1. On page 2, in lines 8 and 9, after “unintentional” delete word “environmental”

Explanation: the definition of “accident” must refer to all types of releases, including into the food supply and not only to ‘environmental’ releases, taking into account that the risks are in relation also to human and animal health, as well as socio-economic risks that may arise as a result of inadvertent contamination of organic food by GMOs for instance. Already in the US, Starlink GM maize was accidentally released into the human food supply, resulting in product liability.

2. On page 2, in line 18, after “distribution”, accept the proposed changes in B34-2005) to omit “contained.”

3. On page 2, in line 21, after “the” **do not accept proposed changes in B34-2005)** to omit “avoidance of risk” and to insert “level of safety when risk management measures must be taken to avoid potential risk”.

Explanation: The proposed changes will substantially alter the definition of “biosafety” to refer only to a risk management approach (post approval) regarding the regulation of GMOs as opposed to the scientifically accepted approach also enshrined in the Biosafety Protocol, based on a risk averse approach, which specifically includes **decision-making prior to the approval of an activity. In any case, the current definition of biosafety is flawed and we propose the following amendment:**

3. (a) On page 2, line 22 after “of”, omit in line 23, “exposure to activities with” and insert “ a genetically modified organisms or activity associated with a genetically modified organism”

Explanation: It is extremely important that the risk to be avoided is the result of the GMO and the related activity in question and not only to **exposure** to an activity.

4. Accept proposed amendments on page 3, in line 8 after the second “a” to omit “direct”

5. On page 3, in line 13, after “time”, insert “ in order to determine the risks posed by the genetically modified organism, on the environment, and human and animal health and to avoid adverse socio-economic impacts”

Explanation: A conditional release permit is granted in order to ascertain the risks posed by the GMO, and this should be made clear in the legislation.

6. On page 3, line 18, after “application” omit “storage” and “movement”

Explanation: Storage of GMOs means that storage at grain silos will be covered in a definition of contained use, which is unscientific. The same applies to “movement” which is very broad and includes transport. Contained use is a scientific concept referring to experimentation that takes place in laboratories. Please pay attention to this because activities under contained use do not require permits in terms of the GMO Act.

7. On page 3, in line 21, after “including” omit “including greenhouses”

Explanation: Experiments in greenhouses are no longer under conditions of contained use and are releases. The definition of ‘contained use’ and release must be adhered to in SA legislation.

8. On page 3, in line 24, after “effectively” omit “limit” and insert “avoid”

Explanation: This is a more scientifically accurate definition

7. a. On page 3, in line 33, after “of” omit “an activity” and insert “of a genetically modified organism and activity related to a genetically modified organism”

Explanation: It is important that the environmental impact assessment refers to the impact of a genetically modified organisms and not only a proposed activity, on the environment

9. On page 3, in line 33, after “of” omit “activity” and insert “a genetically modified organism and activity related to such genetically modified organism”

Explanation: Both the impact of the GMO on the environment as well as its related activity needs to be assessed for potential negative impacts.

9a. On page 3, in line 33, after “such” delete “activity” insert “genetically modified organism or related activity, in terms of the National Environmental Management Act 1998, (Act. No 107 of 1998), and the National Environmental Management Biodiversity Act 2005 (Act. No of 2005)”

10. On page 3, in line 43, after “longer” omit “contained by any system of barriers” and insert “under contained use”

11. Accept new definition of transboundary movement [number 14 B34-2005]

12. “Movement” needs to be defined to specifically to include ‘transit’ and all modes of transportation of GMOs into and out of South Africa. Separate provisions in the Regulations should be drafted for the transport of GMOs, within South African borders.

13. We accept the new definition of user but not in the context of the liability and redress provisions, see below dealing with Clause 11 and the proposed new Clause on redress on pages 5-6.

CLAUSE 2

1. Accept proposed changes in number 2, in document B34-2005, and numbered (1A) subject to the following changes:

In line 2 of proposed 1A, after "alternate" insert "provided that such alternate shall have knowledge of the implications of genetically modified organisms with regard to the sector represented by his or her department, <u>including any existing policies and legislation applicable within that sector</u>

CLAUSE 3

1. On page 4, in lines 28 and 29, after "concerning" insert "biosafety measures to be taken concerning genetically modified organisms and"

2. On page 4, in line 29, after "that" insert "adequate biosafety measures are taken to ensure that risks posed by genetically modified organisms to the environment, human and animal health are avoided and if they cannot be altogether avoided, minimised and that"

3. On page 4, in line 31, omit "such activities" insert "activities related to genetically modified organisms"

Explanation on 1, 2 and 3 above. It is imperative that the Executive Council have wider powers than just advising the Minister on all aspects concerning activities related to GMOs, but that these powers be specifically widened to include the GMO itself as well as the biosafety measures that must be taken to avoid or minimise risks to the environment, human and animal health.

CLAUSE 4

1. On page 4, in line 37, after "manner" insert "as set out in Annex I"

Explanation: The legislation must make specific reference to the information that the applicant will have to comply with, in the interests of transparency and legal certainty

2. On page 4, in line 39, after "determine" insert "having due regard to the provisions of section 78 of the National Environmental Management Biodiversity Act, and where relevant, the provisions of section 11(1)(b) of the Biodiversity Act"

Explanation: It is imperative, that the GMO Act brings about the much needed co-ordination between the decision-making on the part of the Executive

Council in terms of the GMO Act, and the Minister of Environment, in terms of section 78 of the Biodiversity Act and the provisions of NEMA dealing with environmental assessments of GMOs and the mandatory monitoring functions that the South African National Biodiversity Institute (SANBI) is required to perform in terms of section 11(1)(b) of the Biodiversity Act.

NOTE: Current legislation does not address the process and mechanisms required, for the assessment of socio-economic impacts. The Portfolio Committee on Science and Technology must be aware that this is an issue that should be provided for, in relevant legislation dealing with socio-economic impacts relating to the rights of indigenous and local communities vis-à-vis biodiversity conservation and sustainable use issues.

3. On page 4, in line 42, after the word “approve” insert the words “or refuse”

5. On page 4, on line 49, after “assessments” insert “concerning the risks to the environment, human and animal health”

6. On page 4, amend section 5(1)(c)(ii) by inserting a new (iii) and a new (iv), as follows:

(iii) the environmental assessment referred to in section 78 of the National Environmental Management Biodiversity Act;
(iv) an assessment of the socio-economic impacts;

7. On page 4, after the amendments proposed above, insert a new paragraph 5(1)(c) bis as follows using the terminology of Articles 10(6) and 11(8) of the Biosafety Protocol:

“ 5(1)(c) *bis* Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a genetically modified organism on the environment, human and animal health, shall not prevent the Executive Council from taking a decision, as appropriate, with regard to refusing to grant an application, in order to avoid or minimise such potential adverse effects.

Explanation: It is extremely important that the decision-making on the part of the Executive Council be based on as is the case here, a scientifically sound risk assessment, but also, an environmental assessment and an assessment of the potential negative socio-economic impact.

Furthermore, the time is long overdue, for South Africa, to operationalise the **precautionary principle**, as is set out clearly in the decision-making Articles of the Biosafety Protocol, which these amendments are ostensibly implementing. **Failure to do so, will indicate bad faith on the part of the South African government**.

8. On page 5, in line 56, and “Council” omit “may” and insert “shall”

9. On page 5, in line 59, after “public” delete “input” and insert “consultation.

10. On page 5, in line 60, after “assessment” omit “or” and insert “and”

11. On page 6, lines 1-4 omit the entire paragraph (b) in its entirely and insert the following:

(b) After consideration of-

(i) the risk assessment;
(ii) the environmental impact assessment;
(ii) the assessment of the potential socio-economic impacts; and
(iii) public input pursuant to public consultation

The Council, may authorise an application in circumstances where it is of the opinion, based on the precautionary principle, and acting on the advice of the Advisory Committee, that the genetically modified organism and the related activity in question, does not pose unacceptable risks to the environment, human and animal health.

Explanation: It is extremely important that the decision-making on the part of the Executive Council be fully stipulated. The current provisions are wholly unsatisfactory as they require only that the Council take into account the risk assessment and risk management measures OR paragraph (a)?? No mention is made of public consultation.

14. On page 6, after the amendment above, create a new chapeau, before (c) as follows:

“(3) The Council may”

Thereafter, renumber (c), (d), (e), (f), (h), and (i) to read “(3) (a), (b), (c), d), (e) and (f) accordingly.”

15. On page 6, lines 16-19 delete (g) in its entirely and insert a new paragraph as follow:

“(4) The Executive Council may, at any time, *mero moto* or when new scientific information on potential adverse effects on the environment, human and animal health comes to its attention, review and change a decision regarding any approval granted in terms of this Act. In such case, the Council shall, within thirty days, inform the applicant, as well as the Biosafety Clearing House, and shall set out the reasons for its decision.

Explanation: This has been taken virtually verbatim from Article 12(1) of the Biosafety Protocol dealing with Review of Decisions. This is a much clearer and better formulation as it represents the global consensus dealing with review of decision. This new formulation also makes it clear that the scientific information triggers a decision to change or review of decision and that what

is at stake is adverse effects on the environment, human and animal health and also provides an opportunity for anyone, to bring new information to the Council's attention.

NEW CLAUSE 5 *TER*

"EXTENSION PERMITS"

" 5 ter Extension permits may only be granted in the following circumstances

(i) in respect of commodity imports, where subsequent imports are not likely to have adverse impacts socio-economic impacts;
(ii) in respect of field trials, where the applicant has complied fully with all permit requirements in respect of previous trials and an extension permit is sought mainly for biosafety purposes, subject to the condition that no extension permits will be granted for commercial seed multiplication purposes.

Explanation: It is extremely important that the GMO Act fully sets out the circumstances when extension permits may be granted since, in terms of section 5(1)(a)(ii) see, page 4, lines 46-47, such permits may be granted by the Registrar without recourse to the Executive Council. It is important that this provision is not used, as is currently the case with some field trials by Syngenta, to BULK seeds for commercial sale. This is not only dishonest but is an abuse of the regulatory system.

NEW CLAUSE

"5 (A1) PUBLIC PARTICIPATION"

(1) The Executive Council shall consult the public in regard to the decision-making process regarding an application for approval, in respect of a genetically modified organism, and associated activity in terms of this Act, and the Council shall make the results of such decisions available to the public
(2) The Minister may make regulations with regard to the form and manner of the consultation referred to in paragraph (1).

Explanation:

This provision is based almost verbatim on Article 23(2) of the Biosafety Protocol, which creates a binding obligation on South Africa to consult with the public. To date, the notice and comment procedure in the Regulations to the GMO Act have proved to be hopelessly inadequate and in non-compliance with South Africa's obligations under the Biosafety Protocol, quite

apart from the administrative justice provisions that the GMO Act must comply with, in terms of South Africa's Constitution and Promotion of Administrative Justice Act.

It is not defensible that the GMO Act continues to exclude the public from the process on important issues such as food safety, environmental health, agricultural biodiversity, socio-economic impacts on local communities and so forth.

CLAUSE 11

LIABILITY

1. Document [B34-2005] has introduced new provisions on pages 5 and 6, dealing with liability.

Explanation of proposed provisions

1. Damage is not defined.
2. The user has to inform the Registrar when damage arises;
3. The user and the Registrar assesses the damage **caused by the activity not a GMO;**
4. The user is then required to implement measures made by whom? It is not clear.
5. The user (farmers, researchers) continue to be held liable
6. The provisions imply that damage will not arise to human and animal health as a result of consumption of GMOs.

Whilst we are pleased to see a more open approach to the issue of liability, we do not believe that the proposed amendments are adequate for a number of reasons not the least of which, is that damage to the environment, human and animal health must be defined. Furthermore, issues concerning socio-economic damage are also extremely important. The scope of damage is important and this can easily be left to the courts but at the very least, the damage that may arise must clearly be in reference to a GMO and its related activity with reference to the biodiversity, environment, human health, animal health and socio-economic harm. Furthermore, the notion that the user namely the farmer or the research institution to advise the Registrar when harm occurs is to absolve the state of the responsibility of monitoring risks and harm to the environment, human and animal health etc. Furthermore, to continue to hold the user even as newly defined, liable and completely absolve the applicant –gene giants and patent holders from all liability is unacceptable and inequitable.

There must be no misunderstandings on this important issue: All the GMOs being grown commercially in South Africa, and around the world, as well as those being imported for commercial use in SA, "belong" to Monsanto and to a lesser extent, Syngenta, both agrochemical companies and Gene Giants. These companies own the patent on the genes, do the risk assessment, apply

for permits and then, either the seed companies Monsanto already owns, or other multinational seed companies such as Delta and Pinelands, sell the GM seeds on their behalf.

Finally, the manner in which the clause has been drafted assumes that harm will only arise whilst a GMO is being 'used' and not as a result of consumption.

Why does the Department of Agriculture continue to shield multinational biotechnology corporations from damage from their GMOs and hold our farmers and researchers liable?

In any event, these new provisions do not alter the provisions in the GMO Act dealing with fault- based liability, which we disagree vehemently with.

It is our respectful submission that strict or absolute liability is appropriate for ultrahazardous activities such as the use of GMOs. An activity is regarded as ultrahazardous even if the probability of occurrence is low (quantitative) but the magnitude of the resultant harm is huge (qualitative).

We therefore propose that the following be taken into account:

Liability in Austria

The Austrian Gene Technology Act[1] imposes strict liability and holds the party releasing GMOs liable for harm to health, property or the environment and requires companies to carry liability insurance.[2] The operator must repair damage caused as a consequence of the genetic modification including for an impaired environment.[3] There is a presumption that the damage is caused by characteristics resulting from the genetic modification, or in combination with other hazardous characteristics of the GMO.[4] There are exemptions for war, civil hostilities, third party intervention (with conditions) and observance of legislation or administrative measures.[5]

Liability in Germany

Similarly to the Austrian legislation, under the German Genetic Engineering Act (GenTG)[6] there is a presumption that where damage was caused by living modified organisms (LMOs), it is presumed to have been caused by the

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[1] Austrian Gene Technology Act (Gentechnikgesetz), Nr. 510/1994), in force 1 January 1995, amended in 1998 and 2002 at http://www.gentechnik.gv.at/gentechnik/gesetz/gesetz_bund.html,.

[2] Austrian Gene Technology Act §79j. Ins0075rance required ranges from €712,200 per occasion for limited release to €4,609,700 per occasion for large scale releases.

[3] Austrian Gene Technology Act §79a.

[4] Austrian Gene Technology Act §79d.

[5] Austrian Gene Technology Act §79c.

[6] German Genetic Engineering Law (Gentechnikgesetz), ("GenTG"), came into force 1 July 1990, amended 16 December 1993 at http://www.bba.de/gentech/gentg.pdf. See paragraphs 32 ff.

properties caused by genetic engineering.[7] Germany is drafting laws on coexistence and liability, which are expected in March 2004.[8]

Liability in Norway

The Norwegian Gene Act of 1993[9] provides for strict liability.[10]

Environmental remediation can be ordered even when GMOs are legally released into the environment if the risk to human health or the environment is greater than foreseen when the use of GMOs was approved.[11]

NEW CLAUSE ON REDRESS

Document [B34-2005] on page 6 sets out a new clause dealing with redress. This clause is linked to the new clause on liability. We are taken aback by these provisions because they make several erroneous assumptions:

(a) that the damage that may arise is capable of redress;
(b) that the damage is something that the user can remedy;
(c) that the NDA will be responsible for taking the redress measures if the user refuses etc;
(d) that the NDA is the responsible person to claim back the costs for the redress measures.

These provisions do not address the following situations:

(a) Damage suffered by organic farmers for loss of markets as a result of contamination;
(b) Damage suffered to human and animal health;
(c) Damage suffered to biodiversity (loss or impairment of species);
(d) Damage suffered by local communities as a result of contamination of traditional varieties.

RECOMMENDATION: POLICY DECISIONS ARE REQUIRED TO BE TAKEN ON THE ISSUE OF **WHO SHOULD BE LIABLE FOR WHAT DAMAGE** ARISING FROM GMOS. WITHOUT CLEAR POLITICAL DIRECTION ON THIS IMPORTANT AND CRITICAL ISSUE, WE WILL ALL GO AROUND IN CIRCLES. GOVERNMENT CAN NO LONGER AVOID THIS ISSUE.

CLAUSE 12

ACCESS TO INFORMATION/CONFIDENTIAL BUSINESS INFORMATION

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[7] GenTG, §34.

[8] See Bloomberg, January 12 2004, at http://www.gene.ch/genet/2004/Jan/msg00047.html.

[9] Act relating to the Production and Use of Genetically Modified Organisms ("Norwegian Gene Act"), Act No. 38 of 2 April. 1993. Translation at http://www.bion.no/lov/lov-19930402-038-eng.pdf.

[10] Norwegian Gene Act, section 23.

[11] Norwegian Gene Act, section 22.

1. On page 8, in line 35, create new subsection (d) as follows:

(d) Notwithstanding the provisions of this section, the Council shall establish an *ad hoc* panel of independent experts, consisting of no more than 3 persons, to determine appropriate criteria for the determination of confidential business information, in respect to claims made by the public for access to information.

Explanation: The government must take responsibility for setting our clear criteria for the limits of the public's right to access to information, and the genuine **confidential business information** of the application. At the moment, the applicant has the sole discretion to allow or disallow the public, access to information. A summary of the risk assessment still has large sections blank. There is also a great deal of discrepancy between what for instance, Monsanto allows us access to and what Dow Agrosciences has given us.

CLAUSE 13

Appeals

1. On page 8, in line 55, after "and" omit "potential benefits".
2. On page 9, in lines 1 and 2, after "to" omit " minimise a significant negative impact on the environment, or human and animal health" and insert "ensure that the risks to the environment, human and animal health, and potential negative socio-economic impacts are avoided, and if these cannot be completely avoided, minimised."

Explanation:

The grounds for setting aside a decision on appeal must match the standards that under-pin or guide decision-making in the first place when an application is granted. Both sets of decision-making i.e. on the part of the Council and on the part of the Appeal board must resonate with each other.