
SUBMISSION ON GENETICALLY MODIFIED ORGANISMS AMENDMENT BILL

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EXECUTIVE SUMMARY

This document contains the comments of the Biowatch Trust (“Biowatch”) on the Genetically Modified Organisms Amendment Bill [B34-2005] (“the Bill”) in response to a call for public comment by the National Portfolio Committee on Land and Agriculture.

Essentially, Biowatch is very concerned about the deficiencies in the current regulatory system for genetically modified organisms (“GMOs”) provided for by the Genetically Modified Organisms Act (15 of 1997) (“GMO Act”) and the failure of the Bill to address these deficiencies. In Biowatch’s view, one of the primary causes of this situation is the absence of an underlying policy to direct the drafting of the Act and this Bill. The result is a flawed piece of legislation that is likely to give rise to numerous difficulties with implementation. Due to the material nature of the concerns identified in this document and the significant environmental, economic and other public interests at stake, Biowatch would welcome the opportunity to engage further with the Portfolio Committee and the drafters regarding the content of the Bill.

Biowatch’s key concerns, discussed in the balance of this document, are summarised below.

- 1) The provisions for public participation in decision-making and access to information are defective and do not comply with the constitutional obligation of procedurally fair administrative action. This renders decisions made under the GMO Act susceptible to challenge on substantive and procedural grounds under the Promotion of Administrative Justice Act (3 of 2000) (“PAJA”).

- 2) The Bill emphasises a scientific approach to risk assessment and decision-making, at the expense of an approach that incorporates environmental, social and economic factors. This reduces the likelihood that the interests of the poor and the marginalised will be taken into account when decisions are made about the use of GMOs.
- 3) The Bill provides insufficient guidance for the assessment and regulation of GMO activities. In particular, the circumstances in which a risk assessment, environmental impact assessment or socio-economic assessment would be required are not specified and no criteria are provided against which these assessments may be reviewed.
- 4) The Bill entrenches the self-regulatory approach adopted by the Act in terms of which applicants submit risk assessments without independent review and are given the responsibility for monitoring their own compliance with permit conditions. Given the substantial economic interests at stake in the industry, this self-regulatory approach is highly inappropriate.
- 5) The Bill confers several unfettered powers on the registrar, in contrast to the GMO Act, which requires the registrar to exercise all his or her powers subject to the instructions of the Executive Council. This amendment introduced by the Bill is coupled with a worrying failure to provide for review by or reporting to the Council on the exercise of those powers.
- 6) The liability regime is highly irregular in that it deviates from the conventional producer liability approach, imposing liability on users for activities involving GMOs. This produces unjust results, particularly for consumers and small-scale farmers, in light of the Act's failure to provide protective measures such as mandatory labelling and testing of GMOs.
- 7) The Act and the Bill lack tools for imposing rehabilitation obligations on defaulting permit holders, which is inconsistent with the polluter pays principle in the National Environmental Management Act (107 of 1998) ("NEMA"), and also fail to confer powers on the Council for the suspension or withdrawal of permits.
- 8) The absence of a mandatory labelling regime undermines consumer choice, prevents users from protecting themselves against liability and impedes the monitoring of human health impacts associated with the use of GMOs.
- 9) There are substantial areas in which the Bill fails to provide for the incorporation of the Cartagena Protocol on Biosafety into the domestic regulatory system, despite South Africa's obligations to do so, as a signatory to the Protocol. Examples include the failure to impose the precautionary approach in decision-making and the absence of any provisions incorporating the obligations imposed by the advance informed agreement procedure in the Protocol.
- 10) Similarly, the Bill falls foul of material provisions in domestic legislation that includes the Constitution, NEMA and The Promotion of Administrative Justice Act (3 of 2000) ("PAJA").

- 11) Biowatch has a range of concerns regarding the drafting of the Bill. General and specific concerns in this regard are expanded on below.
- 12) Finally, we urge the honourable members of the Portfolio Committee to instruct the Department of Agriculture to initiate a new consultative process with civil society organisations, with a specific time frame, to revise the GMO Amendment Bill and its regulations. Such a process should ideally include consideration of a National Policy on Biosafety. In the interim we propose that all new applications for GMOs be put on hold.

1. INTRODUCTION

Biowatch acts in the interests and on behalf of members of the public concerned about the widespread commercialisation of genetically modified organisms (“GMOs”) in South Africa and the need for wise policy and law regulating their use, control and release.

This memorandum sets out Biowatch’s comments on the Genetically Modified Organisms Amendment Bill [B34-2005] (“the Bill”) tabled in Parliament in October 2005. These comments are submitted in response to a call by the National Portfolio Committee on Land and Agriculture for public comment on the Bill. The Bill must be read with the current Genetically Modified Organisms Act (15 of 1997) (“GMO Act”) as well as the regulations made under the Act¹ (“the Regulations”).

Biowatch previously submitted comments (dated 18 November 2004) on a first draft Genetically Modified Organisms Amendment Bill that was published in Government Notice R2166 of 8 October 2004.² That draft is referred to in this document as “the First Draft Bill”.

References to section numbers in this document are references to the amended sections proposed by the Bill unless otherwise specified.

2. ABSENCE OF GUIDING POLICY AND PRIOR PUBLIC CONSULTATION

The whole issue of genetic modification is a matter of great public concern in South Africa and internationally. It raises issues of serious concern in relation to human health, environmental protection, food security and the socio-economic implications of allowing foreign companies to acquire a high degree of control over essential food production processes through the ownership of seeds. It is also a matter of grave concern to other countries, particularly in Africa, and accordingly affects our relations with the international community. Despite this, there has never been a full, informed and appropriate public debate on how best to regulate GMOs in South Africa nor has an acceptable national policy been formulated and adopted in this regard. As a consequence, the GMO Act was passed without adequate public participation and without an underpinning policy to guide its provisions. The result is a substantially flawed regulatory system that is skewed in favour of facilitating the issue of permits without any attendant liability for impacts associated with permitted activities and an absence of mechanisms to address the human health, environmental protection, food security and socio-economic implications of GMOs.

Although amendments to the GMO Act are welcomed, the amendment process repeated the errors of the adoption of the Act in that there was no public consultation prior to the preparation of the First Draft Bill, in order to identify deficiencies in the Act. As a result, the

¹ Published in GNR 1420 in *Government Gazette No. 20643* of 26 November 1999, as amended.

² In *Government Gazette No. 26848*.

First Draft Bill was wholly inadequate and failed to address the central problems with the GMO Act. Unfortunately, the Bill does not remedy this situation and falls far short of providing the necessary legal framework to address the social, environmental and economic concerns of South Africans. In addition, because of the piecemeal approach to its drafting the Bill lacks coherency in its structure. For example, section 5 of the Bill essentially contains a shopping list of diverse provisions, in no particular order and that lack the detail necessary for effective implementation. The result is a range of ambiguous and incomplete provisions that are likely to give rise to on-going implementation difficulties.

3. **LIMITATION OF PUBLIC PARTICIPATION AND ACCESS TO INFORMATION**

Section 33 of the Constitution entitles all South Africans to procedurally fair administrative action. This is carried through in section 3 and section 4 of the Promotion of Administrative Justice Act (3 of 2000) (“PAJA”), which set out the requirements for procedural fairness. The essence of procedural fairness is that persons affected by administrative decisions must be given prior notice of proposed decisions and the opportunity to make representations to the decision-maker. Notice must include sufficient information to comment meaningfully on the decision. In this regard, PAJA requires that adequate notice of the nature and purpose of a proposed administrative action be given.³

3.1 **Public participation in decision-making**

The GMO Act does not currently meet these requirements and the Bill also fails to do so. There is no requirement in the Bill (or the Act as it currently stands) to notify the public or any sector of the public about applications or provide information on applications for the purposes of representations by the public. In addition, section 5(2) of the Bill gives the Executive Council discretion to consider “public input” when deciding applications made under the Act. In other words, it may choose to disregard that input.

While regulation 6 of the Regulations requires an applicant for a permit to issue a notice inviting comments on the application, this provision does not comply with PAJA for a range of reasons including the following.

- The notification requirement only applies to an application for release and not to any other activities for which permits may be granted in terms of the GMO Act.
- The notification is made by the applicant whereas the obligations in PAJA apply to the decision-maker.

³ Section 3(2)(b)(i).

- The content of the notice is left to the discretion of the applicant. In practice, the requirement in regulation 6 that the notice specify the “area of release” has generally been given its narrowest possible interpretation by applicants who refer only to the province in which the release is to take place. This does not facilitate meaningful commentary by the public as, among other things, it prevents farmers on immediately adjacent properties from knowing whether or not they are affected by a release.
- In addition, an adequate notice within the meaning of PAJA should contain the information included in a risk assessment (“RA”) and, if applicable, an environmental impact assessment (“EIA”) submitted by the applicant in order to enable the public to make meaningful comments. However, this is not required by regulation 6. In addition, section 18(2) of the Bill, which deals with confidential information, prevents the public from obtaining anything other than a summary of the RA.
- Regulation 6 only requires notification to be placed in local newspapers. In relation to public interest organisations such as Biowatch that act in the interests of various groups of interested and affected parties, situated in different parts of South Africa, this does not constitute adequate notification. This could be remedied by imposing an obligation for wider notification in national newspapers or other mass media to include groups such as Biowatch that have expressed an interest in particular activities or types of permits.

These defects described above cannot be remedied by requesting the information under the Promotion of Access to Information Act (2 of 2000) (“PAIA”). This is because a request for information under PAIA takes 30 days to process and the period for commenting on an application under the GMO Act is also 30 days, calculated from the date of the published notice. Accordingly, by the time a member of the public obtains a RA or other document under PAIA, the period for commenting has expired.

The Bill must be amended to provide for procedurally fair decision-making. In particular, it must impose obligations on the Council and the registrar to ensure that the public is given prior notification of decisions under the Act in relation to the issue, amendment and withdrawal of all types of permits as well as ongoing monitoring of compliance with permit conditions. Notification must include adequate information and the provision of access to RAs and other assessments undertaken. It must also oblige the Council and the registrar to consider public representations, prior to the taking of decisions.

3.2 Publication of guidelines

Currently, section 5(11) of the Act requires the Council to publish any guidelines that it makes in relation to GMOs. In contrast, section 5(2)(f) of the Bill only requires the Council to “issue” guidelines and make them available to the public. However, without a publication requirement, there is no mechanism for the public to become aware that

guidelines have been issued. It is unclear why this amendment has been introduced but it must be removed, as it is inconsistent with the requirements of openness and transparency to which statutory public bodies such as the Council are bound in terms of the Constitution.⁴

4. **SCIENTIFIC APPROACH**

The Bill has introduced a new emphasis on scientific-based RA and the involvement of scientists, which was not present in the First Draft Bill or the GMO Act. The concern with this is that an emphasis on scientific factors diverts attention away from EIAs, social and economic concerns as well as the involvement of experts in those fields. Examples include the following.

- 1) Section 5(1)(c)(ii) and section 18(2)(c) refer to “scientifically based risk assessments”.
- 2) In terms of section 5(2)(h) and (i), the Council may only co-opt persons knowledgeable in a field of science to serve on or advise the Council or to submit written comment on an aspect of genetic modification. In contrast, section 7(5) and (6) of the GMO Act currently provides for the involvement of generally knowledgeable persons. Given the fact that this involvement is at the discretion of the Council, there is no reason why the involvement of other experts (outside the sciences) should be excluded. The Bill must be expanded to provide for the potential involvement of a range of persons that could include social scientists, economists, biodiversity and other environmental experts and environmental lawyers so as to encourage the widest range of specialist input possible.
- 3) Section 19(4)(d) encourages the appeal board to consider scientific and technical information. This should be expanded to include social and economic information as well as information related to EIAs.

5. **INSUFFICIENT GUIDANCE FOR ASSESSING AND REGULATING GMO ACTIVITIES**

The key means of assessing GMOs and activities involving GMOs are RAs, EIAs and socio-economic assessments. The long title to the Act, provided for in the Bill, specifically states that its objects include: to lay down the necessary requirements and criteria for RAs, EIAs and socio-economic considerations [*sic*]. It is submitted that the latter should be a reference to socio-economic impact assessments.

⁴ See, in particular, sections 1 and 195 of the Constitution.

Despite this, the Bill does not require the submission of an RA by an applicant for a permit. Section 5(1)(c) does refer to scientifically based RAs but does not indicate when an RA must be submitted or provide any guidance on the criteria against which it should be assessed.

Further, section 5(1)(a) of the Bill gives the Council the discretion to decide whether an applicant should submit an EIA or an assessment of socio-economic considerations without providing any guidance as to the circumstances in which these would be required or the criteria against which they should be assessed. Even where such assessments are requested by the Council, it still has discretion as to whether it will consider them, in terms of section 5(2)(a) of the Bill.

Section 20 of the Bill empowers the Minister to make regulations prescribing the procedures to be followed by an applicant in drawing up RAs, EIAs and socio-economic considerations [*sic*]. Again, the latter should be a reference to socio-economic impact assessments. It is not appropriate for these matters to be left entirely in the discretion of the Minister. Parliament must provide guidance on the circumstances in which RAs, EIAs and socio-economic assessments are required and the criteria against which they should be assessed. In this regard, the Constitutional Court has ruled recently that it is the duty of the legislature to ensure that, when legislation is drafted, the risk of an unconstitutional exercise of the discretionary powers conferred by that legislation is limited.⁵

6. **SELF REGULATORY APPROACH OF CONCERN**

The GMO Act adopts an approach that relies predominantly on self-regulation by applicants and permit holders. The substantial economic benefits associated with biotechnology and GMOs mean that this approach is highly inappropriate as applicants and permit holders have a huge vested interest in securing authorisations under the Act.

The Bill compounds this self-regulatory approach, in various ways. Firstly, the defects in the public participation process, described above, remove the opportunity for public scrutiny of documents submitted by applicants for permits. Secondly, there is no provision for independent review of assessments and other supporting documentation to applications submitted under the Act. Further, there is no provision for monitoring of compliance with permit conditions by officials from the Department of Agriculture or public interest organisations, such as Biowatch. The current practice is for permit conditions to require the permit holder to monitor its own compliance. For the reasons described above, this approach is highly inappropriate.

Although section 15 of the Act provides for the appointment of inspectors, they require warrants (issued by magistrates) in order to inspect any place or facility and may only undertake such inspection if they have reason to believe that a contravention of the Act is taking place. It is unlikely that a potential contravention of the Act would come to the knowledge of an inspector, in the absence of an inspection, given the secrecy that often

⁵ *Dawood and Another v Minister of Home Affairs* 2000 (3) 936 (CC) at 967B/C - D, F - F/G and 969D - F/G

characterises the activities of the biotechnology industry. Accordingly, this provision is of little practical use.

In order to remedy these defects, the Bill must empower the Council to commission an independent review of assessments submitted by an applicant and for the costs to be borne by the applicant. Provision for external monitoring of compliance with permit conditions must be introduced and the powers of inspectors must be expanded considerably.

7. UNFETTERED POWERS OF REGISTRAR

In section 9 of the GMO Act, as it currently stands, all the powers conferred on the registrar must be exercised subject to the instructions of and in accordance with the conditions laid down by the Council. In contrast, section 9(2) of the Bill confers a range of powers on the registrar, including facilitating an inspection by an inspector and directing the cessation of an activity related to a GMO, that may be exercised unsupervised. There is no provision in the Bill for the registrar to report to the Council on the exercise of these powers. In addition, given that the Council meets infrequently, it is unlikely to conduct any review of the registrar's activities.

Provision must be made for the registrar to report to the Council on the unsupervised exercise of powers and for public scrutiny of the exercise of such powers.

8. UNJUST DEVIATION FROM PRODUCER LIABILITY

The inclusion in section 17(1) of the Bill of reference to liability for impacts on humans and animal health is welcomed. However, one of the most egregious and unfair aspects of the GMO Act is the imposition of liability on users imposed in section 17(2). This is a reversal of the conventional rules of liability (e.g rules in relation to product liability) in terms of which the producer bears primary liability. In addition, it is inconsistent with the polluter pays principle that is entrenched in section 2 of the National Environmental Management Act (107 of 1998) ("NEMA").

It is unacceptable for the producers, distributors and suppliers of GMOs to escape liability. Substantial injustice results from holding users such as small-scale farmers and consumers liable for damage caused by activities relating to GMOs. In the absence of appropriate labelling laws (discussed below), consumers do not have the ability to protect themselves against liability arising from use of GMOs. In addition, farmers may unintentionally utilise GMOs due to contamination, the likelihood of which increases in the absence of mandatory testing of seed under the Act.

The absence of a binding liability regime under the Protocol is no justification for delaying much needed revision of our domestic liability regime. South Africans are entitled to appropriate protection to end-users and consumers while ensuring that those responsible for developing and distributing GMOs are held accountable for any adverse consequences associated with their products.

Liability must be imposed primarily on the applicants for permits in relation to the impacts of GMOs to which their permits relate. Further, once the liability regime has been brought in line with the conventional approach of producer responsibility, it is recommended that the imposition of liability be extended to include any impact caused by a GMO. Currently, section 17(2) of the Bill limits liability to the impact of any activity relating to a GMO.

9. **INADEQUATE PROVISIONS TO ADDRESS NON-COMPLIANCE**

The polluter pays principle in section 2 of NEMA is applicable to the application of all legislation that concerns environmental management and protection. Despite this, the GMO Act fails to give effect to this principle and the Bill does not remedy this position. By way of example, where an activity is performed contrary to the Act, section 5(1)(m) of the Bill empowers the Council to take steps for the removal, disposal or repatriation of a GMO; however, it does not empower the Council to impose any necessary rehabilitation obligations on the offender. The same defect exists in relation to the registrar's powers in terms of section 9(2)(c) of the Bill.

In addition, although section 5(2)(g) of the Bill empowers the Council to reconsider a decision taken by it, presumably including a decision to issue a permit, on new information, it does not empower the Council to amend, suspend or withdraw a permit. Section 9(1)(c) of the Bill empowers the registrar to amend or withdraw a permit, subject to the instructions of and conditions laid down by the Council. However, without the Council being empowered to issue these instructions, section 9(1)(c) is meaningless.

10. **MANDATORY LABELLING REQUIRED**

Article 18 of the Protocol contains a number of labelling requirements in respect of GMOs (or, more specifically, living modified organisms). For example, article 18.2(a) requires each party to provide for documentation accompanying GMOs for direct use as food, feed or processing to be clearly identified as "may contain" GMOs.

The GMO Act and the Bill are silent on labelling requirements. Without mandatory labelling requirements, freedom of choice for users, such as farmers and consumers, is compromised and the monitoring of health and environmental impacts of GMOs is severely restricted.

Currently, the only legal requirements regulating the labelling of food or food ingredients containing GMOs are provided by regulations made under the South African Foodstuffs, Cosmetics and Disinfectants Act.⁶ Labelling is only required where the composition or nutritional value of the foodstuff differs significantly from the characteristic composition of foodstuff in its non-modified form.⁷ A "significant difference" is defined in the regulations to

⁶ Act 54 of 1972 and published in GN R25 in *Government Gazette* 25908 of 16 January 2004.

⁷ In terms of regulation 2 of the regulations made under the Act.

exist only where characteristics are different in terms of a scientific assessment of an appropriate analysis of data.⁸ In other words, these regulations do impose a mandatory labelling regime for GMOs. The Bill must address this issue.

11. RELATIONSHIP BETWEEN THE GMO ACT AND THE PROTOCOL

South Africa is a party to the Cartagena Protocol. The Protocol requires South Africa to align its domestic regulatory framework with the Protocol. In particular, article 9.3 states that the domestic regulatory framework of parties importing GMOs must be consistent with the Protocol and article 33 requires parties to monitor the implementation of their obligations under the Protocol and report to the Conference of the Parties on implementation steps.

In order to give effect to the Protocol, it is necessary for South Africa to incorporate its provisions into domestic laws such as the GMO Act. The preamble to the First Draft Bill stated that it was intended to amend the GMO Act so as to, among other things, incorporate provisions of the Protocol. However, the preamble to the Bill no longer refers to the Protocol. Instead, it refers in general to international agreements pertaining to GMOs. This must be amended so as to refer specifically to the Protocol. In addition, the Bill fails to incorporate a number of fundamental provisions of the Protocol. Specific examples are highlighted below.

- 1) Most importantly, the Protocol affirms the application of the precautionary principle to decision-making involving GMOs in a number of provisions that include the preamble, article 1 and article 10.6. Despite this, the Bill fails to incorporate the precautionary principle as the decision-making approach. Regulation 3(2) of the GMO regulations contains a wholly unsatisfactory formulation of the precautionary principle that is materially different from the precautionary approach contained in the Protocol.
- 2) Article 8 deals with advance informed agreement. Article 8.1 of the Protocol requires an exporter to notify the party of import regarding an intended export and article 8.2 requires the party of export to ensure that legal requirements are imposed on the exporter regarding accuracy of information contained in the notification. The Bill does not meet any of the requirements imposed by the Protocol in this regard.
- 3) Article 10.4 of the Protocol requires the party of import to provide reasons to the importer for its decision to allow or refuse the import. This requirement is not addressed by the Bill.
- 4) Article 16.4 of the Protocol requires each party to endeavour to ensure that any living modified organism (whether imported or locally developed) undergoes an appropriate observation period commensurate with its life-cycle before it is put to its intended use. As noted above, the Bill fails to provide guidance on environmental and risk assessment of GMOs and also fails to provide for monitoring aside from self-

⁸ In terms of regulation 1 of the regulations.

regulatory monitoring by the permit holder, which does not meet the requirements of article 16.4.

- 5) Article 23.2 requires parties to consult the public in the decision-making process regarding living modified organisms and make the results of such decisions publicly available. As noted above, the public participation provided for in terms of the Bill is completely inadequate and fails to meet the requirements of domestic legislation, including PAJA and the Constitution. It also falls foul of article 23.2.

12. **RELATIONSHIP BETWEEN THE BILL AND DOMESTIC LAW**

While the Protocol provides a minimum standard that the Bill must meet, the Bill must also be consistent with domestic laws, including the Constitution, NEMA and PAJA. In other words, it is not enough for the Bill to meet a standard set in the Protocol if it falls short of the standard set in the legislation referred to above. As noted above, there are a number of areas where the Bill falls short of domestic legislation.

13. **GENERAL DRAFTING CONCERNS**

There are numerous grammatical errors and inconsistencies in the Bill that create ambiguity and uncertainty in its interpretation. Overall, the Bill creates an impression of a piecemeal approach to drafting that possibly results from the absence of a coherent policy guiding its content. Section 5, in particular, reads like a shopping list with items appearing in no logical order and a lack of attention to detail that will undermine effective implementation.

Biowatch has concerns about a number of the definitions provided for in the Bill.

- 1) The definition of “activity” is very awkwardly worded and excludes reference to “use” (as opposed to “contained use”). This is inconsistent with Article 2.2 of the Protocol which specifically refers to “use” as one of the activities that must be regulated.
- 2) The definition of “biosafety” should encompass measures to avoid the exposure of sensitive environments and biological resources to GMOs in accordance with the precautionary approach, as opposed to focusing only on the avoidance of risks once exposure has already occurred.
- 3) The definition of “commodity clearance” refers to “direct release into the environment”. This phrase is undefined and creates confusion as it is unclear how it relates to the definition of “release” in the Bill.
- 4) The definition of “contained use” refers to physical barriers that limit the impact of GMOs on the external environment. The current definition in the GMO Act and the definition in Article 3(b) of the Protocol both refer to the limitation of contact in addition to impacts. The definition in the Bill should be expanded to encompass

this. In addition, the Bill should clarify the meaning of “external environment” as opposed to “environment” which is already defined.

- 5) The definition of “environmental impact assessment” should include the assessment of the potential impact of a GMO itself on the environment, rather than being limited to assessing the impact of activities involving GMOs. The definition should also clarify that, in the case of an activity, the assessment must be undertaken prior to the activity taking place.
- 6) The definitions of “general release” should refer to the release of a single GMO. If this not done, it will be inconsistent with the definition of “trial release”, which refers to a single GMO. This will create uncertainties in interpretation.
- 7) The definition of “release” should specify that it relates to release of a GMO as it is currently silent in this regard. This is inconsistent with the definitions of trial and general release, creating uncertainties for interpretation.