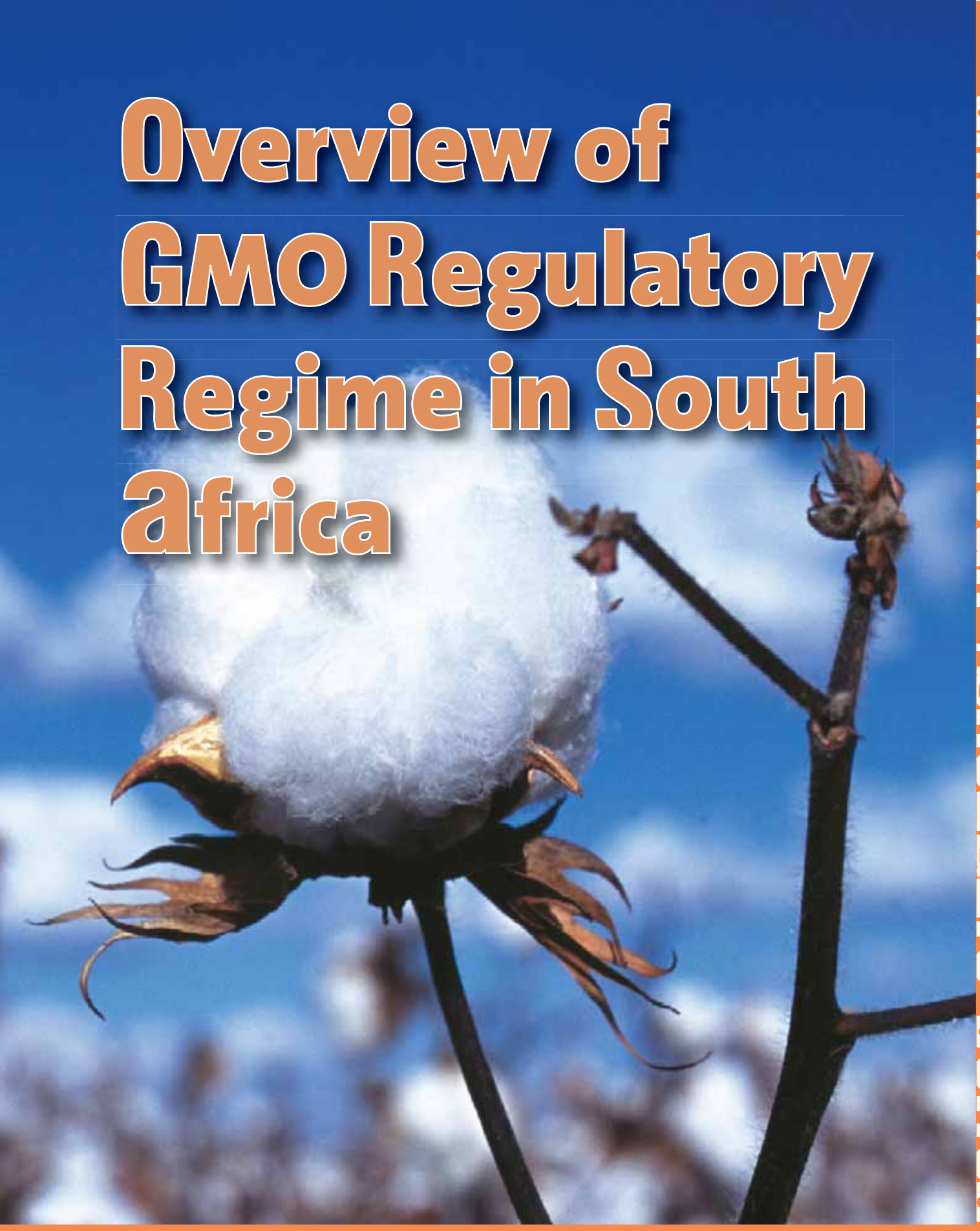
Overview of GMO Regulatory Regime in South Africa



GMOs in African Agriculture series

african centre for biosafety
www.biosafetyafrica.net

The African Centre for Biosafety (ACB) is a non- profit organisation, based in Johannesburg, South Africa. It was established to protect Africa's biodiversity, traditional knowledge, food production systems, culture and diversity, from the threats posed by genetic engineering in food and agriculture. It has in addition to its work in the field of genetic engineering, also opposed biopiracy, agrofuels and the Green Revolution push in Africa, as it strongly supports social justice, equity and ecological sustainability.

The ACB has a respected record of evidence based work and can play a vital role in the agro-ecological movement by striving towards seed sovereignty, built upon the values of equal access to and use of resources.

www.biosafetyafrica.org.za
PO Box 29170, Melville 2109 South Africa
Tel: +27 (0)11 486 1156

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Contents

1. Introduction

Following the promulgation of the Genetically Modified Organisms Act in 1997, numerous Genetically Modified Organism (GMO) applications have been approved in SA. As of 2007, GMOs commercially available in South Africa included insect resistant maize and cotton, herbicide tolerant cotton, maize and soybean, and herbicide tolerant and insect resistant cotton and maize, making up 62% of the total maize crop, 80% of the total soybean crop and 90% of the total cotton crop in South Africa comprised of GMOs.[1]

The African Centre for Biosafety (ACB) concurs with the emerging groundswell of civil society and scientific opinion that GMOs pose a grave threat to human health, the environment and the establishment of an equitable global food system.

Public interest groups such as the African Centre for Biosafety (ACB) have, over many years, attempted to engage with the government on the regulation of GMOs in South Africa, and to participate in GMO permitting processes. While a valuable contribution to the biosafety debate has been made, these efforts have often been frustrated by a lack of transparency in the decision-making process, and in particular the lack of information made available to the public. The GMO Registrar has consistently insisted on interested and affected parties (I&APs) making formal applications for information under the Promotion of Access to Information Act[2] (PAIA), and even then only a sanitized version is provided that has been expunged by the permit applicant of purportedly confidential business information (CBI) and intellectual property. As a consequence, I&APs are unable to carry out independent evaluation or assessment of the potential risks associated with the transgenic organisms proposed for permitting.

The 1997 GMO Act was amended in 2006,[3] and new GMO Regulations took effect on 26 February 2010. This paper seeks to provide an easy to read critique of the amended GMO regulatory framework, with particular focus given to whether the amended framework provides for a sufficiently robust biosafety framework in terms of decision making. Particular attention is paid to mandatory and discretionary powers and duties, public participation and access to information. Reference is made where appropriate to other developing legislation that has a bearing on these issues, as well as to recent developments relating to the issue of liability within the international legal framework governing GMOs.

2. Regulation of GMOs in South Africa

The permitting of GMOs in South Africa is regulated by the GMO Act (a national statute) and Regulations (subsidiary legislation made under the GMO Act). The GMO Amendment Act[4] came into operation on 26 February 2010.[5] New regulations were promulgated in February 2010.[6]

Amongst other things, the amendments to the GMO Act were intended to give effect to the 2000 Cartagena Biosafety Protocol (Biosafety Protocol), amplify the powers of institutions created under the GMO Act, clarify the procedure regarding permit applications, provide for risk assessment and the determination of liability, amend the information requirements contemplated in the confidentiality clause, and amend the appeal process.

The preamble to the amended GMO Act indicates that its purpose is to provide for the responsible development, production, use and application of GMOs. The Act is intended to provide an 'adequate level of protection' during all activities involving GMOs that may have an adverse impact on the conservation and sustainable use of biological diversity, human and animal health. The Act seeks to prevent accidents, establish common measures to evaluate and

http://www.whybiotech.com/blog/wp-content/uploads/2010/07/16-waxy_maize.jpg

reduce potential risks arising from the use of GMOs, and to lay down requirements and criteria for scientifically based risk assessments, socio-economic considerations and risk management measures. The Act also seeks to ensure, amongst other things, that GMOs are appropriate and do not present a hazard to the environment, and to establish appropriate procedures for the notification of specific activities involving the use of GMOs.

For information on the labelling of GMOs, please see 'Traceability, Segregation and Labelling of Genetically Modified Products in South Africa: A Position paper on the implementation of the Consumer Protection Act and mandatory labelling of GM food at www.biosafetyafrica.org.za

See also, www.labelgmfoods.org.za

2.1 Institutional arrangements, powers and duties

2.1.1 Executive Council

An Executive Council (EC) was established by the original GMO Act, with its members appointed by the Minister of Agriculture, Forestry and Fisheries (the Minister). The EC consists of not more than 10 members who are required to have knowledge of the implications of GMOs with regard to their sector, and includes officers nominated from various government departments.[7] The Minister is empowered to also include any other person.[8] The objective of the EC is to advise the Minister on all aspects concerning activities relating to GMOs, and to ensure that such activities are performed in accordance with the Act.[9]

The EC exercises a number of important functions in the permitting process, some of which are discussed where relevant under the sub-headings below. Interestingly, the EC makes decisions by consensus of all its members. This means that one dissenting member could potentially prevent the EC from exercising its powers and duties.[10]

2.1.2 GMO Registrar

The office of the GMO Registrar, who is appointed by the Minister in consultation with the EC, continues to play a central role under the amended GMO Act. The GMO Registrar is charged with administering the Act, and exercises powers and duties conferred, assigned or delegated to him or her by the Act or the EC.

The GMO Registrar examines permit applications for conformity with the requirements of the GMO Act,[11] and submits these to the EC.[12] The Registrar also issues permits or extension permits,[13] and has additional duties to satisfy him or herself that all users apply appropriate measures to protect the environment as well as human and animal health during activities involving GMOs.[14]

The Registrar is obliged to arrange for inspections where required by the Act,[15] and to order the cessation of any activities where he or she has ascertained (or on reasonable grounds suspects) that an activity is being conducted contrary to the Act or a condition of a permit or extension permit.[16]

2.1.3 Advisory Committee

The 1997 GMO Act established an Advisory Committee (AC), which is now made up of not more than 10 persons appointed by the Minister (after the recommendation of the EC). This includes eight persons knowledgeable in those fields of science applicable to the development and release of GMOs, and two persons from the public sector (one must have knowledge of ecological matters and GMOs, while the other must have knowledge of the potential impact of GMOs on human and animal health).[17]

The AC functions as the national advisory body on all matters involving GMOs, and is required (either upon request or of its own accord) to advise the Minister, the EC, Registrar and other Ministries or appropriate bodies on matters concerning GMOs, including:

- all aspects relating to the introduction of GMOs into the environment;
- proposals for specific activities or projects concerning GMOs;
- all aspects concerning the contained use of GMOs;
- the importation and exportation of GMOs; and
- proposed regulations and written guidelines.[18]

The AC is required to liaise (through the relevant national departments) with international groups or organisations concerned with biosafety,[19] and to co-opt or invite written comments from knowledgeable persons in specific fields of science on any aspect of the genetic modification of organisms which lies within the Committee's brief.[20] The AC may at its discretion appoint sub-committees to deal with specific matters as required.[21]

2.2 Permitting Procedure

2.2.1 Permit required

The amended GMO Regulations provide that no applicant may conduct any activity (which is defined by the amended GMO Act as meaning any activity with GMOs, and includes the importation, exportation, transit, development, production, release, distribution, use, storage and application of GMOs) without a permit for that activity.[22] However, a permit is not required for organisms that are used under conditions of contained use (containment level 1 or 2) where the facility has been registered.[23]

2.2.2 Permit Application

A permit application has to be submitted to the Registrar on the prescribed form in hard and electronic format. The application is required to include:

- a scientifically-based risk assessment;
- proposed risk management measures;
- a copy of the public notice as required in terms of Regulation 9 (which must be submitted to the Registrar prior to the notice being published[24]); and
- if so determined by the EC, an assessment of the impact of the proposed activity on the environment and an assessment of the socio-economic considerations of the activity.[25]

The application must be accompanied by the prescribed application fee,[26] and the Registrar is required to examine it for conformity with the requirements of the GMO Act. If it conforms, the application is sent to the EC or AC for consideration. If not, it is referred back to the applicant to rectify it.[27]

http://www.uoguelph.ca/research/apps/news/pub/article.cfm?id=134

The EC is empowered to approve or refuse the application, or to request additional information from various parties.[28] Importantly, the EC is required to provide reasons for any decision made.[29]

Interestingly, the EC is also required to determine the terms and conditions under which the Registrar may issue an extension permit for any activity for which a permit has been issued previously.[30]

2.3 Due process, public participation and information

It was mentioned in the introduction that I&APs have struggled to participate effectively in GMO permitting processes in South Africa. These difficulties are documented in various objections submitted by the ACB to the GMO Registrar.[31] The objections relate to applications made in respect of potato, vaccines, grapes, yeast (for use in wine), cotton, cassava, insecticide, sugar cane, wheat, maize, soya, rice, sorghum and canola. Typically, a sanitized version of the GMO permit application is made available to I&APs. Information necessary to conduct a meaningful, independent assessment of the risks associated with the proposed GMO is excluded from this sanitized version of the application. As a consequence, potentially overstated claims made regarding yield performance and safety cannot be independently verified.

This section commences with a brief discussion of the issue of procedural fairness. This is followed by an overview of the public participation process provided for in the amended GMO regulatory regime, including the issues of access to information and confidentiality.

2.3.1. Procedural fairness

Various legal principles and statutes deal with procedural fairness within context of environmental decision-making in South Africa.[32] In essence, these codify and strengthen the common law 'right to be heard'.

It is important to bear in mind that fairness depends on the circumstances of each case. The Promotion of Administrative Justice Act[33] (PAJA), for example, recognises that mandatory requirements can be departed from if it is reasonable and justifiable in the circumstances.[34] The Act also provides that where the administrator is empowered by other legislation to follow a procedure which is fair but different, the administrator may act in accordance with that different procedure.[35] What this means is that an administrator can depart from the requirements of PAJA provided that he or she is empowered to do so, and provided that the alternative procedure is also fair.

In keeping with this paper's objective of providing an easy-to-read critique, the principles and laws relating to fair decision-making procedures are not discussed in detail. However, some of the core requirements of procedural fairness are outlined below:

(a) Notice

I&APs have the legal right to be given adequate notice of the nature and purpose of the proposed administrative action.[36] This includes persons who may be materially and adversely affected by a decision, but also extends to persons who, for example, have an interest in protecting the environment.[37] Notice can be published in the government gazette or in newspapers, depending on the circumstances. The notice should contain sufficient information, and should indicate where further information can be accessed.

(b) Reasonable opportunity to make representations

I&APs have the legal right to make representations[38] to administrative decision-makers in an effort to influence an administrative decision (such as a decision on a GMO permit application). This requires that I&APs be afforded sufficient time within which to analyse any relevant information, seek specialist input where appropriate, and prepare their representations. These are usually made in writing. The right to make representations should not be confused with a right to an oral hearing. An I&AP will only have a statutory right to an oral hearing in circumstances where the empowering legislation makes provision for this right.

(c) Access to information

In order for the right to make representations to be meaningful, I&APs should be provided with sufficient information. Typically, this will comprise of the information upon which the decision will be based. Some information may, however, not be made available for public comment. Such information often includes so-called 'confidential business information' or 'intellectual property'. What information can be legitimately withheld is a contentious issue, especially within the context of GMOs. In some circumstances confidentiality can be overridden in the public interest. This issue is discussed in more detail in paragraph 2.3.3 of this paper below.

(d) A clear statement of the administrative action

I&APs should be informed about the administrative decision taken.[39] In other words, the decision must be communicated or made available.

(e) Adequate notice of any right to review or internal appeal

I&APs should be notified of any rights they have to challenge a decision that has been made.[40] Regulations will often provide for administrative appeals, in terms of which I&APs can appeal against the merits of the decision, as well as on procedural grounds (this is known as a wide

http://thegoldenspiral.org/wp-content/uploads/2008/11/corn-ears.jpg

appeal). I&APs can also challenge decisions by applying to the High Court for a judicial review. Judicial reviews are usually limited to procedural aspects or the legality of the decision, and are typically to be resorted to only where other remedies have been exhausted.

(f) Adequate notice of the right to request reasons.
I&APs also have the right to request reasons for a decision.[41] This could be a decision on authorisation (for example granting a GMO permit), or could be a subsequent decision on appeal.

2.3.2 Public Notification of proposed release or commodity clearance of GMOs
The 2010 GMO Regulations follow a similar approach to public notice as that prescribed in the previous regime, although with some noteworthy changes. Public notification is to be given in the form of a notice published in the printed media informing the public of the application.[42] For a proposed general or commodity release of GMOs, the applicant is required to publish the notice in at least three national newspapers. For a proposed trial release, the applicant is required to publish notice in at least two newspapers circulating in the immediate area and one newspaper circulating nationally.[43] Where no newspapers circulate in the immediate area in which the proposed trial release will take place, the applicant is required to inform the public through other means of effective communication (in which case a record of such proceedings must be provided to the Registrar as proof).[44]

It is mandatory that the published notice contains at least the following details:
- the full name and address of the applicant;
- the objective of the application;
- a general description of the GMO, including the name of the donor organism, recipient organism (if different) and inserted genes e.g. novel trait and marker genes (if present);

- where appropriate a description of the place of release, including the name of the town, the size of the release and information pertaining to the surrounding environment;
- information on how to access a copy of the application;
- a request that interested parties submit comments or objections in connection with the application within a period specified in the notice: Provided that such period shall not be less than thirty days after the date on which the last notice appears in the media; and
- the address of the Registrar to which comments or objections may be submitted.[45]

Changes include a requirement that information be published on how to access a copy of the permit application. This provision is discussed further under the heading 'confidentiality and access to information' below. In addition, proposed general and commodity releases must now be published in three national newspapers, rather than the previous requirement of publication in three local newspapers.

The new notice also requires that the objective of the application be published, and is more specific regarding the published general description of the GMO and the area where the release is intended (e.g. the name of the town and the size of the release is to be published).

A study[46] was commissioned by the (now disbanded) National Environmental Advisory Forum (NEAF) regarding public participation in the context of the regulation of GMOs under the 1997 GMO Act and 1999 regulations.[47] A number of concerns relating to public participation process were documented, including concerns relating to the limited opportunity provided for public participation under the public notice requirement.[48] Unfortunately, a number of these concerns have not been addressed under the amended Regulations. For example, the amended Regulations do not incorporate suggestions made by NEAF stakeholders that permit applications be published on an up-to-date website, and that notices be emailed to stakeholders registered on a database. In addition, the 30 day period within which to comment has been retained (resulting in problems where I&APs are required to follow the PAIA procedure for accessing information, or where scientific or specialist input is required to make meaningful representations). It is also not clear how notification will be given to illiterate members of local communities that may be affected by a release of GMOs into their environment (unless this is a proposed trial release in an area with no local newspaper circulation, in which case the applicant is required to inform the public through other, unspecified means of effective communication).

The Registrar is required to refer any comments received from interested parties to the EC within the prescribed time period.[49] The Registrar is also empowered to take any other measure to notify interested parties of applications made, and to invite written comments from such parties.[50]

The new GMO regulatory regime does not make provision for further comment within the GMO permit process, for example in circumstances where the GMO applicant responds to any comments made and furnishes additional information to the GMO Register. Notwithstanding this, it is submitted that in accordance with the principles of fairness, the GMO Registrar should in such circumstances afford I&APs a further opportunity to make representations.[51]

It is relevant to note that the Biosafety Protocol provides that the Parties (which include the South African State) shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms (LMOs), and shall make the results of such decisions available to the public.[52]

http://www.robertscottbell.com/wp-content/uploads/2010/10/soybean_1_608.jpg

2.3.3 Confidentiality & Access to Information

One of the problems consistently experienced by parties seeking to participate in the GMO permitting process is an insistence by government officials that a formal application under PAIA must be made in order to access information relating to the application. And even where PAIA applications are submitted, the result is often a refusal by the government officials to provide access to some of the information submitted during the course of the application. The usual reason given for such refusal is that the permit applicant claims that the information is commercially confidentially or contains intellectual property. In practice this has led to the permit applicant putting up a version of the application that excludes information claimed as commercially confidential. This problem is discussed in more detail below.

Another problem that arises is that I&APs are given 30 days to submit their comments, while the information officer considering the PAIA application has 30 days within which to decide the request (which period can be extended by a further 30 days). This means that the time available for commenting will have expired by the time the PAIA application is decided. While late filing of comments can be condoned, the PAIA process is clearly not aligned with the time periods in the GMO regulatory framework.

Access to information relating to GMO permitting applications is governed in part by the GMO Act and Regulations, while PAIA also applies. This hotly contested issue has also come under the judicial scrutiny of both the High Court and Constitutional Court in the Biowatch case. This paper turns to discuss these issues in more detail.

(a) GMO Act

The amended GMO Act prohibits any officials from disclosing information acquired during the permitting process,[53] but stipulates that the following information shall not be kept confidential:

- the general description of the genetically modified organisms, the name and address of the applicant, and the purpose of the contained use or release and the location of use;
- the methods and plans for the monitoring of the genetically modified organisms and for emergency measures in the case of an accident; and
- the summary of the scientifically based risk assessment of the impact on the environment and human and animal health.[54]

The EC must decide – after consulting with the permit applicant – which information will be kept confidential.[55] The EC may decide to withhold such information if it is satisfied that the information should be withheld in order to protect the intellectual property of the applicant.[56] This is an important provision, as in practice the Registrar and/or the EC allows the permit applicant to make this decision, resulting in the applicant making a version of the application available to I&APs that has much of the relevant information removed (this is referred to as a 'non-CBI' version of the application). Such an approach is irregular, as the amended GMO Act obliges the EC to make this decision. The permit applicant should be consulted only (i.e. invited to comment or express its views on what should be regarded as confidential). Importantly, this decision is an administrative action, and the EC must also comply with the requirements of the common law and PAJA before making a decision. In particular, I&APs should also be afforded an opportunity to make representations on the issue of confidentiality before the EC makes a decision on what information should be kept confidential. Abrogation of its statutory obligation to make the decision, as well as a failure to provide I&APs with an opportunity to make representations before making the decision, renders the decision administratively unfair and liable to be set aside on appeal or review.

(b) The Biowatch case

The issue of the state's obligations to provide certain information regarding GMOs to the public was the subject of litigation instituted by the NGO Biowatch. In the cased of the Trustees, Biowatch Trust v Registrar, Genetic Resources, and Others[57], Dunn AJ addressed the issue of how commercial confidentiality should be approached. The permit applicants (which included Monsanto, Stoneville and D&PL SA) had argued that the issue of the protection of confidential, technological and private information would justify a refusal to grant access to information sought by Biowatch. While it was noted in the judgment that the right of access to information is not an absolute right, and has to be balanced with justifiable governmental and private concerns for maintaining confidentiality of certain information,[58] it was also noted in the judgment regarding any refusal to grant access based on PAIA or the limitations clause contained in the SA Constitution that:

> Obviously the *onus* of justifying such a limitation would be on the person who seeks to limit the right... The same applies to PAIA, because the burden of establishing that the refusal of a request for access is justified rests on the party claiming the refusal.

While Biowatch was largely successful in obtaining a High Court judgment in its favour relating to information requested, it was burdened with an adverse costs order in favour of Monsanto. On appeal against this costs order, the Constitutional Court commented that the state had a duty to:

> ... grasp the nettle and draw an appropriate line between information to be disclosed and information to be withheld.[59]

The judgment noted further that Monsanto was joined in the matter:

> ...because the governmental authorities had failed to exercise their constitutional and statutory obligations to separate the confidential wheat from the non-confidential chaff.[60]

In the circumstances the appeal succeeded, with the Constitutional Court concluding that where the state is shown to have failed to fulfill its constitutional and statutory obligations, and where different parties are affected, the state should bear the costs of litigants who have

http://www.cosmosmagazine.com/files/imagecache/news/files/20061121_cotton.jpg

been successful against it, and ordinarily there should be no costs orders against any private litigants who become involved.[61]

The reasoning of the High Court and the Constitutional Court therefore supports the ACB's contention that the permit applicant has the onus of establishing that any refusal is justified on the basis of commercial confidentiality, and that the EC has a statutory obligation to decide what information can justifiably be withheld on the basis that it is bona fide commercially confidential information. Any abrogation of this duty would taint the permitting decision as unfair and legally flawed.

(c) GMO Regulations

As mentioned earlier in this paper, the amended GMO Regulations include a requirement that the public notice includes information on how to access a copy of the permit application.[62] The permit application is made up of a scientifically based risk assessment, proposed risk management measures, and (where the EC required it) any assessment conducted in accordance with NEMA of the impact of the proposed activity on the environment and an assessment of the socio-economic considerations of the activity.

If the permit application as submitted to the GMO Registrar is made available to I&APs, this will go a long way towards ensuring that I&APs can make informed, meaningful representations. If, on the other hand, only a sanitized version of the risk assessment (and any other documents forming part of the application) is made available, the acid test will be whether or not the EC discharged its statutory and constitutional obligations to sort the confidential chaff from the non-constitutional wheat. If the permit applicant is given carte blanche to make this determination, the EC/Registrar will be in breach of these statutory and constitutional obligations.

What will also be important in assessing whether or not a fair procedure has been followed is the issue of how the requester will be granted access to the permit application referred to in the notice. Unfortunately, the Regulations do not provide any guidance on the manner in which access to the application is to be afforded. This results in uncertainty. Conceivably, the GMO permit applicant might simply state that the permit application can be accessed on request from the Registrar. However, it is just as conceivable that the GMO Applicant might state that the application can be accessed by way of a formal request for information under PAIA (an onerous process discussed in more detail below). Regardless of the means of access indicated by the permit applicant, it is undesirable that the GMO regulatory regime should not provide guidance on the manner in which an I&AP is to be afforded access to a copy of the application. This means of access should then be reflected in the public notice. In the circumstances, it is suggested that the amended GMO Act and Regulations need to be further amended to include clear provisions on how access to a copy of the permit application is to be obtained.

In contrast, Environmental Impact Assessments (EIA) Regulations made under the National Environmental Management Act[63] (NEMA) provide that the notice given to IA&Ps must state where further information on the application or activity can be obtained. The person conducting the public participation process is obliged to ensure that information containing all relevant facts is made available to potential I&APs,[64] and this person must also be independent.[65] This stands in stark contrast to the anemic public participation provided for in the GMO regulatory framework, where participation is limited to making representations on an abridged version of the permit application made available by the permit applicant him or herself.

(d) Promotion of Access to Information Act

In terms of PAIA, a requester must be given access to the record of a public body if that requester has complied with all of the procedural requirements for making a request, and if access is not refused in terms of any of the mandatory grounds for refusal envisaged by the Act.[66] As mentioned in the introduction to this section above, the information officer is obliged to decide within 30 days to grant or refuse the request.[67] This period can be extended for a further period of 30 days under certain circumstances.[68]

In the ACB's experience, the Department of Agriculture has relied on the mandatory grounds of refusal contained in PAIA.[69]

Section 36 provides for the mandatory protection of commercial information of a third party held by a public body, and obliges the public body to refuse a request for access if the record contains:

- trade secrets of a third party;
- financial, commercial, scientific or technical information, other than trade secrets, of a third party, the disclosure of which would be likely to cause harm to the commercial or financial interests of that third party; or
- information supplied in confidence by a third party the disclosure of which could reasonably be expected:
  (i) to put that third party at a disadvantage in contractual or other negotiations; or
  (ii) to prejudice that third party in commercial competition.

PAIA provides further that a record may not be refused on the above grounds insofar as it consists of information:

- already publicly available;
- about a third party who has consented in writing to its disclosure; or
- about the results of any product or environmental testing or other investigation which would reveal a serious public safety or environmental risk.[70]

Section 37 provides for mandatory protection of certain categories of confidential information of a third party if the disclosure would constitute an action for breach of confidence owed to a third party in terms of an agreement. The public body also has the discretion to refuse access if the record consists of information supplied in confidence by the third party if the disclosure could reasonably be expected to prejudice the supply of similar information or information from the same source, and if it is in the public interest that such information should continue to be supplied.[71] Again this information may not be refused if it is already publicly available, or if the third party has consented to its disclosure.[72]

Section 43 deals with mandatory protection of research information of a third party. It provides that a public body must refuse access if the record contains information about research being

http://horticultureintheord.files.wordpress.com/2008/04/cotton.jpg

or to be carried out by or on behalf of a third party, if the disclosure would be likely to expose the third party, the person carrying out the research, or the subject matter of the research to serious disadvantage.

Importantly, section 46 provides for mandatory disclosure in the public interest in certain situations, including if the public interest in the disclosure clearly outweighs the harm contemplated in the provision in question.

It is relevant to note that PAIA operates to the exclusion of any provision of other legislation that prohibits or restricts the disclosure of a record of a public or private body, and if it is materially inconsistent with an object or specific provision of PAIA.[73]

(e) Promotion of Access to Information Bill

PAIA currently provides that nothing contained in its provisions prevents the giving of access to records of public or private bodies in terms of legislation referred to in Part 1 or Part 2 respectively of the Schedule to PAIA.[74] This Schedule currently refers to section 31(1) of NEMA and s36 of the Financial Intelligence Act.[75] Confusingly, section 31(1) of NEMA was deleted in September 2009.[76]

Shortcomings with this provision have been recognized by the Department of Justice and Constitutional Development, which recently published an amendment Bill for comment.[77] The background note to this Bill states that its aim is to provide a requester who wishes to request access to records held by public or private bodies, and who is faced with a choice between using PAIA or another piece of legislation (which is regarded as covering subordinate legislation such as rules and regulations),[78] with an efficient point of reference to help him or her make a choice.

The proposed amendment to PAIA removes reference to legislation listed in the Schedule, and simply provides that nothing in PAIA will prevent the giving of access to a record of a public or private body in terms of legislation which provides for access in a manner that is not materially more onerous than PAIA.[79]

To the extent that the GMO Act or regulations provide for access to records, an I&AP would be entitled to choose to access the applicable records through these provisions. As it has been mentioned above, it is not entirely clear whether the GMO regulatory regime provides a mechanism for accessing information, save for the regulation 9 requirement that a permit applicant shall provide information on how to access a copy of the application.

In the circumstances, the GMO regulatory framework needs to be amended to include clear provisions on the manner in which information relating to GMOs can be accessed.

2.3.4 Appeals

Where a permit has been refused or granted, the applicant or any objector aggrieved by the decision may appeal against the decision to the Minister. Such an appeal must be lodged within the period and in the manner prescribed and upon the payment of the prescribed fee. In such circumstances the Minister is required to appoint an Appeal Board to hear the appeal.[80] The GMO Act provides further that any member of the Appeal Board must recuse him/herself in the event of a conflict of interest.[81] Unfortunately, the identities of the persons who make up this Appeal Board have not been made public, and a request made by the ACB to the Department for this information was refused.[82] This secrecy compounds the lack of transparency evident in the GMO regulatory process.

The Appeal Board is empowered to make a number of decisions, including confirming, setting aside, substituting or amending any provision.[83] It can refer the matter back to the Registrar for reconsideration by the EC.[84] It also has a wide discretion to make any order it considers fit in order to minimize a significant impact on the environment or human and animal health (after a due consideration of the potential risks and benefits).[85] In making its decision, the EC may consider new scientific or technical evidence or any other information that is, in the opinion of the Appeal Board, directly applicable to the appeal.[86]

Where an appeal is successful, the appeal fee is refunded to the applicant. If it is amended, a portion of the fee as determined by the EC is refunded to the appellant.[87]

The Appeal Board is required to record its full decision in writing, together with reasons for this decision. It is also required to furnish it to the Minister, the Registrar and all parties directly involved in the appeal, and to make it available to the public, within 30 days after the final decision has been taken.[88]

The GMO Regulations provide that an appeal in terms the GMO Act shall, amongst other things, be lodged with the Minister in writing within thirty days from the date on which the appellant was notified in writing of the decision or action concerned, and shall state the grounds on which the appeal is based.[89] The appellant is required to submit a copy of the appeal to the Registrar.[90]

Interestingly, the amended Regulations provide that the Appeal Board may request the appellant and any other party to appear before it to clarify any issue on appeal.[91] In light of the Department's refusal to divulge the identities of the Appeal Board members, it will be interesting to see how the Appeal Board maintains its anonymity in the event that it exercises

its discretion in this regard! The chairperson of the EC is required to give the appellant and any other party at least seven days notice in advance of the date, time and place at which he or she is to appear before the Appeal Board.[92] The chairperson is permitted to request that new scientific or technical evidence or any other information that is, in the opinion of the Appeal Board, directly applicable to the appeal, be lodged with the chairperson in writing within such period as the chairperson may determine.[93]

In the event that the Appeal Board requests the appellant or any other party to appear before it, the chairperson may:

- summon any person who may give material information concerning the subject matter of the appeal or who has any document which has any bearing upon the subject matter of the appeal, to appear before the appeal board to be interrogated or produce that document, and the Registrar may retain for examination any document so produced;
- administer an oath to or accept an affirmation from any person called as a witness at the hearing; and
- call as a witness any person summoned to appear, and interrogate him or her and require him or her to produce any document in his or her possession or custody or under his or her control.[94]

Any person asked to appear before the Appeal Board is permitted to:

- call witnesses during the hearing and to cross-examine other witnesses; and
- notify his or her witness of the date, time and place of the hearing and to ensure their presence at the hearing.[95]

http://www.wellnessuncovered.com/joomla/images/stories/gmo-corn.jpg

The appellant is allowed to present his or her case first and to call witnesses,[96] whereafter any other person requested to appear is allowed to present his or her case and call witnesses.[97] The appellant and any other party is also entitled to legal representation during any appearance before the appeal board.[98]

The Appeal Board is required to provide the Minister and the Registrar with a decision on appeal, together with the reasons therefore, within ninety days from the date that the Appeal Board received the relevant documentation pertaining to the appeal.[99] Once the Minister has made a final decision on the appeal, the Registrar is required to make the decision and reasons available to all parties directly involved in the appeal and the public within thirty days.

While the appeal process has been significantly improved, some obstacles to a fair appeal process remain. One obstacle is the ongoing secrecy surrounding the identities of the members of the Appeal Board discussed above. Another obstacle arises in circumstances where a GMO permit applicant appeals against a permit refusal. While the amended appeal process does not exclude an I&AP from making representations with regard to the appeal, it does not make

provision for such a party to be notified of the appeal or to obtain access to the grounds of appeal.

Case Study: Spunta G2 Potato Appeal

This problem is illustrated by ACB"s experience in the Spunta G2 Potato appeal. In 2009, the EC refused to grant the African Research Council (ARC) a permit for the general (commercial) release of genetically modified potatoes. The ACB, who had objected to the permit being granted, discovered through informal channels that the ARC had appealed against the refusal. As a consequence, the ACB wrote to the Minister requesting an opportunity to represent its views in the appeal process. A formal request for a copy of the ARC's appeal document was also made under PAIA. This request was refused on 29 November 2009, with the Department justifying its refusal on the basis that 'the ARC documents in respect of the appeal... is (sic) regarded as confidential as the ARC applicant feels that if the appeal letter is made public now, it may influence the process and/or outcome of the appeal'.[100] The ACB appealed to the Minister against this refusal on 25 January 2010. One of the grounds of appeal was that the information was already publicly available.

Within this context, the ACB's attorney wrote to the Minister asserting the ACB's right to make representations in the appeal process, requesting that the Department's officials be instructed to provide the ACB with the relevant contacts details of the Appeal Board, and requesting the Minister to make her decision on the ACB's PAIA appeal.[101] While no response was received from the Minister, on 26 November 2010 the Director of Biosafety wrote to the ACB advising that the chairperson of the Appeal Board was of the view that:

> 'in order for the ARC appeal to be lawful, reasonable and procedurally fair, the ACB must be given an opportunity to make representations to the appeal board regarding the ARC appeal. The Chairperson appreciates that in order for you to make representations you may require certain information forming part of the ARC appeal process... however... certain of the information contained in the ARC's appeal may be confidential and... the ARC may legitimately object to the provision of this information'.

The ACB was requested to provide a list of the information required to make representations to the Appeal Board, and to provide a comprehensive motivation as to why this information was required. The ACB responded by pointing out that the ACB had not been afforded sight of the documentation founding, forming part of, or supporting the ARC's appeal, and that it was in the dark regarding the grounds of appeal. As a consequence, the ACB requested the ARC's grounds of appeal and any documentation or specialist reports put up to support its grounds of appeal. A motivation was also provided setting out why the dictates of procedural fairness required that this information be furnished.

On 25 February 2011, the Director of Biosafety wrote to the ACB on behalf of the Appeal Board advising that the Appeal Board had met on 7 February 2011, and had decided that the issue of confidentiality did not arise as the documentation comprising the appeal was already in the public domain. A copy of the ARC's eight page grounds of appeal was provided to the ACB, together with an invitation for the ACB to make representations within 21 days.

While the identity of the Appeal Board members remain secret, its decision to recognize the ACB's right to make representations, and to have access to the appeal documentation, is commendable. The Appeal Board also appears to have applied its mind to whether the ARC discharged its onus to justify a refusal on the grounds of confidentiality. The reasonable and fair approach applied by the Appeals Board stands in stark contrast to Department of Agriculture

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information officer's refusal to grant the ACB access to the information on the spurious grounds discussed above. It is also significant that this information was supplied within the GMO permit appeal process, and outside of the context of a formal PAIA application.

2.4 Scientifically based risk assessment

When considering a GMO application, the EC is required to have regard to scientifically based risk assessments.[102] The GMO Regulations prohibit the undertaking of an activity involving GMOs unless a 'suitable and sufficient assessment of the potential adverse effects to the environment, human and animal health and safety has been made'.[103] The Regulations prescribe that such a risk assessment shall be conducted in a scientifically sound manner, taking into consideration recognised risk assessment methods and techniques that are currently applied at national, regional and international level. The Regulations go further to stipulate that any risk assessment shall entail, as appropriate, the following steps:

- Identification of any potential adverse effect resulting from the novel genotypic and/or phenotypic characteristics of the GMO;
- An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the potential receiving environment to the GMO;
- An evaluation of the consequences should these adverse effects be realized;
- An estimation of the overall risk posed by the GMO based on the evaluation of the likelihood and consequences of the identified adverse effects being realized.[104]

This risk assessment is to be conducted on a case-by-case approach and shall include the consideration and evaluation of all available relevant scientific information, including expert advice of, and guidelines developed by, relevant international organizations.[105] The applicant is required to provide the data on which the risk assessment was based together with the application, to the registrar.[106] To a large extent this accords with Annexure III to the Biosafety Protocol.

It should also be noted that guidelines were published in 2004 dealing with, amongst other things, the methodology for and content of risk assessments.[107]

It will be recalled that a GMO permit application includes the above scientifically based risk assessment, and that the regulation 9(5) notice is required to provide information to the public on how to access this application.

Interestingly, the Regulations stipulate that a lack of scientific knowledge or scientific consensus shall not be interpreted as indicating a particular level of risk, an acceptable risk or an absence of risk.[108] While this 'neutral' formulation of the precautionary approach seems at odds with the expression of the approach set out in the 1992 Rio Declaration on Environment and Development,[109] its wording is very similar to the formulation used in Annexure III of the Biosafety Protocol. The intention seems to have been to leave subjective concerns about the impact of LMOs outside of the risk assessment process, with the exception being that socio-economic may be taken into account where there may be an impact on indigenous and local people. 'International regulation of GMOs thus reflects a rationalist faith in the objective application of scientific principles.'[110] It has been suggested that this approach 'may be out of step with recent scientific developments, in particular 'sustainability science', which is regarded as a multidisciplinary approach combining scientific, economic, legal and other disciplinary understandings and knowledge.[111]

2.5 Risk Management

When considering a GMO application, the EC is required to have regard to proposed risk management levels.[112]

Every application is required to include measures to manage the potential risks of the proposed activities.[113] In making its decision on authorization, the EC is required to determine the appropriateness of the risk management or control mechanisms, measures or strategies proposed by the permit applicant.[114] The regulations do not prescribe what the content of these risk management measures should be, but stipulates that they may include:

- containment and confinement of GMOs;
- movement of GMOs;
- storage and inventory of GMOs;
- disposal of residual or excess GMOs;
- harvest and/or disposal of GMOs after completion of the activity;
- cleaning of any equipment used during the activity;
- monitoring for compliance to permit conditions;
- restriction of unlawful access to GMOs; and
- management and maintenance of records and reports.

This information must be made available to the EC, Registrar or any inspector within the period specified by the Registrar.[115]

The Biosafety Protocol deals with Risk Management in Article 16. Amongst other things, this article provides that each state party shall 'endeavour' to ensure that any LMO (whether imported or locally developed) has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

2.6 Socio Economic Considerations

The EC is obliged to determine whether a person applying for a GMO permit must also submit an assessment of the socio-economic considerations of such activities in accordance with the

provisions of NEMA.[116]

It will be recalled that the GMO Act provides that the EC shall determine whether the applicant must submit an assessment of the socio-economic impact considerations of the activity concerned.[117] While no clear criteria are established to guide the EC in making this decision, it is nevertheless a determination that the EC is obliged to make.

The GMO Regulations are not prescriptive about the content of such an assessment, stipulating instead that such an assessment may include (but is not limited to) information on the impact of the activity on the following:

- continued existence and range of diversity of the biological resources;
- access to genetic and other natural resources previously available;
- cultural traditions, knowledge, and practices;
- income, competitiveness or economic markets; and
- food security.[118]

Where such a social impact assessment is submitted, these are relevant considerations that the EC would have to take into account when deciding upon a GMO permit application.

http://www.rikenresearch.riken.jp/images/figures/hi_4208.jpgjpg

The Biosafety Protocol deals with socio-economic assessments in Article 24. This article provides that in making decisions on importing LMOs, state parties may take socio-economic considerations into account. In accordance with this discretion, the amended GMO Act makes it the EC's responsibility to make a determination on whether or not a socio-economic impact assessment is required. The regulations go further by providing some guidance on the minimum content of any socio-economic impact assessment that the EC determines should be undertaken.

2.7 Environmental Impact Assessment (EIA)

Under the amended GMO Act, one of the powers and duties conferred on the EC is an obligation to determine whether a person applying for a GMO permit must also submit an assessment of the impact on the environment of such activities in accordance with the provisions of the National Environmental Management Act 107 of 1998 (NEMA).[119] The new EIA regulations under NEMA stipulate that a basic assessment is required for the release of GMOs into the environment in circumstances where an assessment is required under the GMO Act or the National Environmental Management: Biodiversity Act 10 of 2004 (Biodiversity Act).[120]

The amended GMO Regulations provide that an applicant may be required to conduct an EIA in accordance with section 78 of the Biodiversity Act, and that the EC may on a case-by-case

approach make a recommendation to the Minister of Environmental Affairs on whether an environmental impact assessment will be required.[121]

This last provision is presumably intended to be aligned with the Biodiversity Act, which provides that, if the Minister (of Environmental Affairs) has reason to believe that the release (trial or general release) of a GMO into the environment under a permit applied for in terms of the GMO Act may pose a threat to any indigenous species or the environment, no permit for such release may be issued unless an EIA has been conducted in accordance with the requirements of NEMA. In such circumstances the Minister is required to convey his or her belief referred to the authority issuing permits in terms of the GMO Act before the application for the relevant permit is decided. This issuing authority is the EC.

Based on the above, it is clear that the Minister of Environmental Affairs can trigger an EIA by informing the EC, before a permit application is decided, that he or she has reason to believe that the release of a GMO into the environment may pose a threat.

What is unclear is how this aligns with the duty conferred on the EC under the amended GMO Act to make a determination on whether or not an EIA under NEMA is required. On the face of it, the EC must make this determination regardless of whether or not the Minister of Environmental Affairs informs the EC in accordance with s78 of the Biodiversity Act. It remains to be seen whether or not the EC interprets its powers and duties in this manner. However, in circumstances where a GMO permit is issued and it is evident from the reasons provided by the EC that it has not made such a determination, the decision would be open to challenge on administrative appeal or review.

2.8 Notification of Accidents

The new GMO Regulations make provision for notification of accidents involving GMOs An 'accident' is defined in the GMO Act as any incident involving an unintentional environmental release of GMOs that is likely to have an immediate or delayed adverse impact on the environment or on human or animal health within the Republic; or the unintentional transboundary movement of GMOs that is likely to have an immediate or a delayed adverse impact on the environment or on human or animal health.[122]

Importantly, it is the user concerned that is under an obligation to notify the registrar both verbally and in writing, and to supply the registrar with the specified information. The 'user' is defined as meaning any person who conducts an activity regarding GMOs, and 'activity' is defined as meaning any activity with GMOs, including the importation, exportation, transit, development, production, release, distribution, use, storage and application of genetically modified organisms.

The information that must be submitted in the notification includes, but is not limited to:

- available relevant information on the estimated quantities, identity and relevant characteristics and/or traits of the genetically modified organism;
- information on the circumstances and the estimated date of the release;
- information on the use of the GMO within the originating Country;
- any available information about the possible adverse effects on the environment, human and animal health and safety; and
- information on emergency measures already taken, as well as alternative short-term, medium-term and long-term risk management measures that could be taken to avoid or mitigate adverse effects on the environment, human and animal health and safety;

http://www.abc.net.au/reslib/200710/r193400_731667.jpg

The EC is empowered to instruct the Registrar to appoint a panel to enquire into and report on the causes of such accident.[123]

Where an unintentional transboundary movement is likely to have an adverse impact on the conservation and the sustainable use of biological diversity or human and animal health and safety in any affected or potentially affected State, the EC is required to instruct the Registrar in writing to notify such States, the Biosafety Clearing House and, where appropriate, any relevant international organisations, of the unintentional transboundary movement and to provide them with the stipulated information.[124] This intention of this provision appears to implement South Africa's notification obligations under Article 17 of the Cartagena Protocol in the event of unintentional transboundary movements.

While the obligation to notify the Registrar of accidents involving GMOs extends to both unintentional releases within South Africa and in respect of unintentional transboundary movements, the amended Regulations do not impose a requirements on the user or the EC to notify potentially affected parties within South Africa (such as neighbouring farmers, public interest NGOs etc.).

2.9 Biosafety Clearing House

The amended GMO Regulations require the Registrar to communicate the following information to the Biosafety Clearing House (BCH) created under the Biosafety Protocol:

- The GMO Act and accompanying Regulations;
- Any guidelines developed;
- Any bilateral, regional or multilateral agreement or arrangement, including any agreement on contingency plans regarding unintentional transboundary movements;
- Summary of the science-based risk assessment according to the format determined by the registrar;
- Final decisions regarding the:
  i. importation and trial release of a GMO;
  ii. transit of a specific GMO;
  iii. use of a GMO as food, feed or for processing,
  iv. conditional general release or general release of a GMO;
- The reconsideration of any decision taken;
- Simplified procedures regarding the intentional transboundary movement of a GMO, as approved by the EC;
- Notice of an unintentional transboundary movement;
- Notice of an illegal transboundary movement.

These notification requirements appear to implement South Africa's obligations in respect of providing information to the BCH created under the Biosafety Protocol.

In 2009, the ACB wrote to the Minister of Agriculture complaining of South Africa's non-compliance with its obligations to report abovementioned information to the BCH. When no responses were forthcoming, the ACB lodged a complaint with the Compliance Committee under the Biosafety Protocol. Unfortunately, the Compliance Committee declined to consider the complaint on the basis that only State parties to the Convention on Biological Diversity (CBD) could lodge complaints.

Notwithstanding this, the amended GMO Regulations clearly impose a statutory duty on the GMO Register to communicate the specified information to the BCH. Should the GMO Registrar have failed to report this information in the period since the coming into effect of the GMO Regulations, the GMO Registrar would be vulnerable should an I&AP apply to the High Court of South Africa for an order (mandamus) directing the GMO Registrar to comply.

3. Protection of Information Bill, 2010

Other legal developments worth noting include the development of the Protection of Information Bill, which at the time of writing was before Parliament for consideration. The Act proposed in this Bill is intended to provide a coherent approach to the protection of State information, and to the classification and declassification of such information. It is also intended as a framework to allow the State to respond to espionage.[125] It objectives include harmonizing the proposed Act with the provisions PAIA.[126]

The Bill has, however, drawn much criticism from interest groups. It has been reported that both civil society and legal experts view the Bill as a threat to democratic transparency and criticize it for being inconsistent with the South African Constitution.[127]

Of concern to NGOs working in the field of GMOs, the Bill includes provisions dealing with 'commercial information', which could become classified as 'confidential', 'secret' or even 'top secret'.[128] Disclosure of such information is criminalized, meaning that anyone who disclosed such information could be sentenced (upon conviction) to imprisonment for a period ranging from three to twenty five years (depending on the classification of the commercial information). It is also relevant to note that all matters subject to mandatory protection under s34 to 42 of PAIA are considered to be matters of national interest, regardless of whether or not they are classified. Disclosure of such information is also criminalized under the Protection of Information Bill.[129]

It has been reported that the ad hoc committee on the Protection of Information Bill has recently made a number of recent concessions, including the removal of commercial information as potentially classifiable. It has also been reported that the term 'national interest' has been removed as a criteria for barring access to information.[130] It remains to be seen whether, and how, the final amended version of the Protection of Information Bill will reflect these concessions.

However, an ongoing problem with the proposed Act is that it contains no provision for information to be disclosed if it is in the public interest.[131] This sets it apart from PAIA, which provides for a public interest override. As a consequence, the Protected Information Bill could clash with these provisions, which are designed to promote government accountability and transparency. A spokesperson for the civil society coalition's Right2Know campaign points

out that '[t]he Bill continues to impose criminal sanctions on the legitimate disclosure of state secrets in the public interest... [t]he penalties are still applied to society at large and are outrageously high'.[132]

4. Nagoya-Kuala Lumpar Protocol

The international legal framework relating to GMOs (which are referred to as living modified organisms in international instruments) is comprised primarily of the Convention on Biological Diversity (CBD) and the Biosafety Protocol. It has been pointed out above that the GMO Amendment Act was promulgated in part to give effect to the provisions of the Biosafety Protocol. Negotiators of the Protocol were unable to reach agreement on the issue of liability and redress, which lead to an enabling clause being included in the final text of the Protocol (Article 27). In terms of this Article, a process was to be adopted to elaborate on international rules and procedures relating to liability and redress for damages arising out of transboundary movements of LMOs.

The process adopted in terms of Article 27 culminated in the agreement of the Nagoya-Kuala Lumpur Supplemental Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (the Supplemental Protocol) after six years of negotiations. The Supplementary Protocol will only enter into force 90 days after the fortieth country ratifies the agreement.[133]

The Supplementary Protocol is limited to liability and redress where damage has been caused by the transboundary movement of LMOs. This includes situations where damage has resulted from the authorized use of LMOs, as well as damage arising from any unintentional or illegal transboundary movements.[134] The Supplementary Protocol also applies to damage that occurs within the national jurisdiction of State Parties, and provides that State Parties will be permitted to use criteria set out in their domestic law to address such damage.

While the amended GMO Act and Regulations do contain provisions relating to unintentional transboundary movements of GMOs,[135] these provisions give effect to similar provisions contained in the Biosafety Protocol. Once the Supplementary Protocol comes into force and is binding on South Africa, the South African government need to assess whether the existing liability measures are sufficient, failing which it will need to promulgate enabling legislation to give effect to provisions of the Supplementary Protocol. Some of the provisions are expressed in mandatory terms and require the parties to take particular action. For example, parties will be obliged to require the appropriate operator,[136] in the event of damage, to immediately inform the competent authority, evaluate the damage, and take appropriate response measures.[137] Parties will also be required to provide, in their domestic law, for rules and procedures that address damage. Other provisions are expressed in discretionary terms. For example, the competent authority 'may' implement appropriate response measures;[138] the parties 'may' assess whether response measures are already addressed by their domestic law on civil liability; the parties 'may' provide time limits relating to response measures,[139] and 'may' also provide for financial limits for the recovery of costs and expenses related to response measures.[140]

5. Conclusion

While the amended GMO Act and Regulations contain a small number of improvements, the amendments fall short in a number of respects. While the public notice provisions have been improved, no guidance is given on the mechanism to be used to afford I&APs access to a copy of the GMO permit application (this could result in I&APs being forced to continue using the onerous PAIA process). In addition, the limited 30 day commenting period is retained, no provision is made for publishing permit applications on a

website, and no guidance is provided on how the public will be informed of a permit application where no local newspapers are in circulation in the area in question, or where illiterate persons could be affected.

Problems with commercial confidentiality are likely to continue, although this problem could be averted by the EC and the Registrar exercising their constitutional and statutory obligation to make a decision on what information is bona fide confidential, and by requiring the permit applicant to discharge its onus of justifying any limitation claimed.

The appeal process has also been improved. However, no provision is made for I&APs to be informed of an appeal or to be granted access to the grounds of appeal. Recent experience in the Spunta G2 Potato appeal has, however, been encouraging. The Appeal Board has shown an understanding of the requirements of procedural fairness, and has recognized the ACB's right to make representations within the appeal process, and to obtain a copy of the permit applicant's grounds of appeal. It can only be hoped that the EC and the GMO Registrar will adopt a similar practical and rational approach.

The issue of EIAs in relation to the commercial or trial release of GMOs into the environment is also uncertain. While the Minister of Environmental Affairs can trigger the requirement for an EIA to be conducted in terms of section 78 of the Biodiversity Act, the GMO Act also requires the EC to make a determination regarding whether or not an EIA or socio-economic impact assessment is required. The amended GMO Act does not seem to be aligned with NEMA or the Biodiversity Act in this respect.

With regard to notification of accidents involving GMOs, the notification requirements do not provide for potentially affected neighbouring communities or the public to be informed about accidents involving GMOs.

While the amended GMO regulatory regime contains provisions relating to liability relating to transboundary movements, the South African government will, once the Supplementary Protocol is ratified, need to assess whether its domestic law relating to civil liability sufficiently covers liability and response measures in the context of transboundary damage.

References

1 Keetch, Green & Webster, *The Regulation of GMOs in South Africa* www.africabio.com
2 Act 2 of 2000.
3 M Mayet, *Regulation of GMOs in South Africa – Details and Shortcomings*, African Centre for Biosafety, (2007)
4 Act 23 of 2006.
5 GN R. 3 *GG32966* of 24 February 2010.
6 GNR. 120 GG *32966* of 26 February 2010, as amended by GNR. 175 *GG33007* of 12 March 2010.
7 This includes officers nominated from the Departments of Agriculture; Science and Technology; Environmental Affairs and Tourism; Health; Labour; Trade and Industry; Arts and Culture; and the Department of Water Affairs and Forestry.
8 Section 3(c).
9 Section 4.
10 Section 7(3).
11 Section 9(1)(a).
12 Section 9(2)(d).
13 Extension permits are permits issued for activities relating to GMOs for which permits have been issued previously. In terms of s9(3) of the amended GMO Act, the Registrar may (subject to such terms and conditions laid down by the EC) issue an extension permit for an activity in respect of GMOs for which a permit has been issued.
14 Section 9(1)((a)-(e).
15 Section 9(2)(b).
16 Section 9(2)(c).
17 Section 10(1).
18 Section 11(1)(b).
19 Section 11(1)(c).
20 Section 11(1)(d).
21 Section 11(2).
22 R2(1).
23 R2(2). Contained use is defined in the amended GMO Act as meaning the development, production, cultivation, use, application, storage, movement, destruction or disposal of GMOs within a facility, installation or other physical structure, including a greenhouse, that are controlled by specific measures, including physical barriers or a combination of physical barriers together with chemical or biological barriers or both, that effectively limit contact of the GMOs with humans, animals and the external environment and their impact on humans, animals and the external environment.
24 R3(4).
25 R3(3)(a)-(d). This includes an assessment in accordance with the provisions of the National Environmental Management Act, 1998 (NEMA) and any other applicable laws.
26 R3(5).
27 R3(6).
28 R3(7).
29 R3(8).
30 R3(11).
31 These objections can be viewed on http://www.biosafetyafrica.org.za/index.php/GM-Applications/menu-id-100023.html .
32 This includes the common law concept of the 'right to be heard', and the minimum requirements for fair administrative decision making set out in the Promotion of Administrative Justice Act, 2 of 2000 (PAJA). For a discussion on these principles and laws, see ACB's publication *Public Participation in the Context of Patent Laws in South Africa*, 2008.
33 3 of 2000.
34 Section 3(4). In deciding whether to depart from the grounds of fairness as set out in section 3(2) of PAJA, the administrator must take into account relevant factors, including: (i) the objects of the empowering provision; (ii) the nature and purpose of, and the need to take, the administrative action; (iii) the likely effect of the administrative action; (iv) the urgency of taking the administrative action or the urgency of the matter; and (v)the need to promote an efficient administration and good governance.
35 Section 3(5).
36 PAJA, s3(2)(i).
37 Legal standing in environmental matters is extended by s32 of the National Environmental Management Act, 107 1998 (as amended).
38 PAJA, s3(2)(ii).
39 PAJA, s3(2)(iii).
40 PAJA s3(2)(iv).
41 PAJA s3(2)(v).

42 R9(1).
43 R9(2).
44 R9(3).
45 R9(5).
46 Pole, A *Public Participation in the Context of GMOs in South Africa*, November 1997 (unpublished research prepared for and on behalf of the NEAF).
47 GN R1420 of 26 November 1999, as amended by GN R.828 of 21 June 2002, GN R.576 of 2 May 2003, GN R495 of 23 April 2004, GN R.478 of 27 May 2005, GN R.130 of 17 February 2006, GN R.41 of 26 January 2007.
48 R6 of the 1999 GMO Regulations.
49 R9(6).
50 R9(7).
51 This right was recognized by a full bench of the Cape High Court in E*arthlife Africa (Cape Town) v Director-General: Department of Environmental Affairs & Tourism and another [2006]* 10 BCLR 1179 C.
52 Article 23(2).
53 Section 18(1).
54 Section 18(2)(a)-(c). These exceptions include if the disclosure of information is necessary for the proper application of the provisions of this Act; if it is for the purposes of any legal proceedings under this Act; when ordered to do so by any competent court; or if the official is authorised to do so by the Minister. These exceptions correlate largely with the information identified in the Biosafety Protocol as not being considered confidential – see Article 21(6)(a)-(d).
55 Section 18(2).
56 Section 18(3).
57 2005 (4) (SA) 111 (T).
58 Ibid, at paragraph 39.
59 Ibid, paragraph 54.
60 Ibid.
61 Ibid, paragraph 56.
62 R9.
63 107 of 1998, as amended. GN R. 543 of 18 June 2010: *Environmental Impact Assessment Regulations, 2010*, r54(3)(iv).
64 EIA Regulations, r54(7).
65 Ibid, r17.
66 Section 11.
67 S25.
68 S26.
69 Refusal notice from Department: Environmental Affairs & Tourism dated 22 June 2009 in response to ACB application for access to bioprospecting permit applications by Gowar Enterprises (PAIA25005) and Parceval Pharmaceuticals (PAIA 25006).
70 S36(2)(a)-(c) and s36(3).
71 S37(1).
72 S37(2).
73 Section 5.
74 Section 6.
75 Schedule to PAIA.
76 See section 14 of the National Environmental Laws Amendment Act, 2008: Proclamation No. 65, *GG 32580* of 18 September 2009.
77 Promotion of Access to Information Bill, GN 43 *GG 33960* of 24 January 2011.
78 Ibid, background note section 2.6(a).
79 Section 1 of the Promotion of Access to Information Bill, proposed substitution of s6 of PAIA.
80 Section 19(1).
81 Section 19(2)(c).
82 Email from Department of Agriculture, Fisheries and Forestry to ACB dated 18 February 2011, stating that '*Details regarding the appeal board members remains confidential, however any specific communication to the appeal board can be channeled via our offices*'.
83 Section 19(4)(a).
84 Section 19(4)(b).
85 Section 19(4)(c).
86 Section 19(4)(d).
87 Section 19(5).
88 Section 19(6).
89 R11(1).
90 R11(2).

91 R11(3).
92 R11(4).
93 R11(5).
94 R11(7)(a).
95 R11(7)(b).
96 R11(7)(c).
97 R11(7)(d).
98 R11(8).
99 R11(11).
100 26 November 2009 letter from the Department of Agriculture to the ACB.
101 22 April 2010 letter from Adrian Pole Attorneys to Minister Joemat-Pieterrson.
102 Section 5(c)(i). Before the Biosafety Protocol was agreed in 2000, a divergence in views emerged between developed and developing states on the issue of risk assessment. Developed states that were keen to facilitate trade in living modified organisms (LMOs), and in particular members of the 'Miami Group', favoured the 'sound science approach.' This approach sought to ensure that risk assessments were based on scientific data, and wanted to exclude other issues such as socio-economic impact assessments. The Miami Group also favoured a minimalist approach to documentation and labeling. Developing countries, on the other hand, considered scientific data alone to be insufficient to assess the full range of potential impacts, and favoured a multidisciplinary approach to risk assessment. See Boyle *et al* 'International Law and the Environment', 2009 (3rd Edition) Oxford University Press, p644.
103 R4(1).
104 R4(3).
105 R4(4).
106 R4(5).
107 *Guideline Document for Work with Genetically Modified Organisms*, GN 1046 *GG 26422* of 11 June 2004.
108 R4(6).
109 Principle 15 of the Rio Declaration states as follows: In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.
110 Boyle *et al* 'International Law and the Environment', 2009 (3rd Edition) Oxford University Press, p646.
111 Ibid.
112 Section 5(c)(i).
113 R7(1).
114 R7(2).
115 R7(4).
116 Section 5(a).
117 S5(a).
118 R5.
119 Section 5(a).
120 GN R544 of 18 June 2010, Appendix 1, listed activity 25.
121 R6.
122 Section 1 GMO Act.
123 R10(2).
124 R9(4).
125 Section 1, Memorandum on the objects of the Protection of Information Bill, 2010.
126 Section 2(j).
127 *Mail & Guardian*, 21 January 2011, *Secrets Bill has 'not been defanged'*, accessed online at http://mg.co.za/printformat/single/2011-01-21-secrets-bill-has-not-been-defanged on 7 February 2011.
128 See section 15.
129 Section 38. If found guilty of an offence, the person concerned would be liable to a fine or imprisonment for a period of not less than three years but not exceeding five years (or both).
130 Op cit note 113.
131 Ibid.
132 Ibid.
133 Article 18.
134 Article 3.
135 See for example the s5(h) to (l) of the amended GMO Act and r10(4) of the Regulations.
136 Defined as meaning any person in direct or indirect control of the LMO which could, as appropriate and as determined by domestic law, include, inter alia, the permit holder, person who placed the LMO on the market, developer, producer, notifier, exporter, importer, carrier or supplier.

137 Article 5.
138 Article 5.
139 Article 7.
140 Article 8.