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**Good regulatory practices for developing countries – lessons learned in
South Africa from an Appeal under the GMO Act**

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Abstract

South Africa approved the general release of GM maize event Bt11 in 2003. The experience gained in the hearing of an appeal against this approval provides important lessons not only for South Africa but particularly for other countries that are in the process of developing their own regulatory procedures. The appeal process highlighted the need for clear legislation, to prevent differences of legal interpretation; and the need for well-functioning regulatory processes to avoid unintentional procedural irregularities. The gathering of any country-specific data to reach a decision should be considered on a “need to know” rather than a “nice to know” basis.

Key words South Africa Bt maize corn appeal GMO

Introduction

In June 2003 the Executive Council, appointed in terms of the South African Genetically Modified Organisms (GMO) Act, approved an application by Syngenta for the general release of GM Maize event Bt11. An appeal was lodged by Biowatch Trust against this general release, and an Appeal Board hearing was held in September 2004 after a protracted process. The experience gained from dealing with the appeal, which was the

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most comprehensive appeal that has been brought under the GMO Act thus far, provides important lessons not only for South Africa but particularly for other countries that are in the process of developing their own regulatory procedures for dealing with GMOs.

South African GMO legislation

In South Africa, activities involving GMOs are regulated in terms of the Genetically Modified Organisms Act 15 of 1997 (the GMO Act). This Act has been operational since the end of 1999, and South Africa has gained considerable experience in the contained use and release of GMOs during this time. The Act, which is managed by the Department of Agriculture, makes provision for an Executive Council made up of members from relevant government departments, to regulate GMO activities in the country. The Executive Council is supported by an Advisory Committee of knowledgeable people in the field of GMOs. The Act is augmented by Regulations that lay out in more detail the procedures for registration of facilities, applications for and issuing of permits, requirements for publication of proposed releases, and provisions with regard to appeals.

Additional legislation making reference to GMOs includes the National Environmental Management Act (Act No 107 of 1998) (NEMA). This Act requires that the potential impact on the environment, socioeconomic conditions, and cultural heritage, of activities that require authorisation or permission by law and which may significantly affect the environment must be considered, investigated and assessed prior to their implementation. The minimum requirements for investigation, assessment and communication of the potential impact of such activities are laid out in the Act.

NEMA was augmented by the Biodiversity Act (Act No. 10 of 2004), which was published in June 2004. This Act specifically requires that if the Minister responsible for national environmental management has reason to believe that the release of a GMO under the GMO Act may pose a threat to any indigenous species or the environment, then an environmental assessment must be carried out as specified by NEMA before any permit can be issued.

History of GMO releases in South Africa

South Africa has conducted field trials on GM crops since the early 1990s, initially under the Agricultural Pests Act, 1983, following the recommendation of the previous advisory

committee known as SAGENE (South African Committee for Genetic Experimentation), and more recently under the terms of the GMO Act.

Since 1997 a number of permits have been issued for conditional general release or commodity clearance of GM crops, as shown in Table 1 below.

Table 1
General release approvals in South Africa

1a: Type of approval: General release – conditional*

Event	Crop	Trait	Company	Year approved
Bollgard II, line 15985	Cotton	Insect resistant	Monsanto	2003
Bt11	Maize	Insect resistant	Syngenta	2003
NK603	Maize	Herbicide tolerant	Monsanto	2002
GTS40-3-2	Soybean	Herbicide tolerant	Monsanto	2001
RR lines 1445 & 1698	Cotton	Herbicide tolerant	Monsanto	2000
Line 531 / Bollgard	Cotton	Insect resistant	Monsanto	1997
MON810 / Yieldgard	Maize	Insect resistant	Monsanto	1997

Conditional general release provides for use of the event for Importation/exportation, commercial planting, and food and/or feed

1b: Type of approval: Commodity clearance*

Event	Crop	Trait	Company	Year approved
MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Monsanto	2004
MON810 x GA21	Maize	Insect resistant Herbicide tolerant	Monsanto	2003
TC1507	Maize	Insect resistant Herbicide tolerant	Pioneer Hi-Bred	2002
NK603	Maize	Herbicide tolerant	Monsanto	2002
GA21	Maize	Herbicide tolerant	Monsanto	2002
Bt11	Maize	Insect resistant	Syngenta	2002
T25	Maize	Herbicide tolerant	AgrEvo	2001
Bt176	Maize	Insect resistant	Syngenta	2001
Topas 19/2, Ms1Rf1, Ms1Rf2, Ms8Rf3	Oilseed rape	Herbicide tolerant	AgrEvo	2001
A2704-12	Soybean	Herbicide tolerant	AgrEvo	2001

Commodity clearance provides for importation of the event for use as food or feed. Commodity clearances listed above exclude events that obtained general release clearance before commodity clearance

**Information supplied by SA Department of Agriculture*

Release of Syngenta Bt11 maize

The first field trial of Bt11 maize was approved in 1998 under the Agricultural Pests Act, ahead of the implementation of the GMO Act. Field trials were undertaken every year thereafter (separate permits issued annually), including a field trial permit that extended to December 2003.

In February 2002 a commodity clearance permit was issued as shown in Table 1, on the basis of data submitted demonstrating the safety of Bt11 maize for food and feed use.

In September 2002, Syngenta submitted an application for conditional general release of Bt11 maize. This application was submitted in tandem with an application for further field trials in the 2002/3 growing season, and notification of both applications was published in the press in October 2002 as required by the GMO Act. Certain errors which came to light in the original press notice were corrected in a later notice in December 2002.

The field trial application received fast-track approval on the basis that it represented a continuation of trials that had received previous approval, while the general release application was reviewed by a subcommittee of the GMO Advisory Committee.

In May 2003 the Advisory Committee confirmed its recommendation that Syngenta's application for conditional general release should be approved, and in June 2003 the Executive Council authorized the issuing of a general release permit.

Background to the appeal

An NGO, Biowatch Trust, registered concerns with the Department of Agriculture at the stage when the public notices were published in October 2002. The Trust representatives pointed out some errors in the public notices and additionally expressed concern that the application for general release was being considered while field trials were still being conducted. The Registrar of the GMO Act responded in a letter sent to Biowatch during January 2003 in which it was stated that:

“Although both applications have been submitted at the same time, the trials being conducted in the 2003-growing season will be completed before a decision has been taken on the general release application.”

In October 2003 the Biowatch Trust, having earlier learned that general release of Bt11 maize had been approved, and having received written confirmation of this from the Department of Agriculture during September, lodged an appeal with the Department of Agriculture. The appeal sought to set aside the permits for both field trials and general release, and to suspend the importation of Bt11 maize. Pending the outcome of the appeal, it also sought suspension of the operation of the authorisations granted to Syngenta.

The grounds for the appeal as finally submitted (an amended appeal was drafted following the provision of additional information to Biowatch by the Department of Agriculture, at the request of the Appeal Board) were on alleged deficiencies in Syngenta’s application, and in particular in the risk assessment submitted by Syngenta, which were alleged to have been inadequately addressed by the Advisory Committee and/or the Executive Council in making their decisions. The deficiencies primarily concerned the environmental safety of Bt11 maize and to a lesser extent human health and food/feed safety issues. Specific issues included:

- possible effects of the maize on non-target organisms and the build-up of Bt toxin in soil;
- the lack of results from specifically South African field trials, and a lack of South African data in general, including data on South African production lines;
- the development of an adequate pest resistance management strategy and the fact that the proposed strategy had insufficient scientific backing;
- the levels of expression of the *pat* gene in the maize plants and the related possibility that this might encourage illegal use of the herbicide glufosinate ammonium;
- consideration of the scientific literature in general (as opposed to the literature provided by Syngenta);
- possible adverse effects of Bt11 maize on human health; and

- sociological and/or economic factors such as farming practice amongst farmers in South Africa.

Other concerns related to the incorrect information published in the press notices regarding the release, and that inadequate information was provided regarding the location of areas where field trials were to take place.

Finally, Biowatch also raised issues regarding the requirements for environmental assessment under NEMA.

The appeal process

As provided for in the GMO Act, an Appeal Board was appointed in January 2004 by the Minister of Agriculture to consider the appeal. The appeal hearing was initially postponed at the behest of the Appeal Board due to the fact that Biowatch had not been provided with the reasons for the Executive Council's decision and certain documents which formed part of Syngenta's application. Without these reasons and documents, the Appeal Board was of the view that Biowatch could not properly prepare for the appeal. Once these documents had been supplied, Biowatch was invited to submit an amended appeal, which was received in April 2004.

In May 2004, the Appeal Board considered an application by Biowatch for the suspension of the operation of the authorisations granted to Syngenta, pending the outcome of the appeal. This application was dismissed, primarily because the Appeal Board was not convinced that any potential environmental harm or health risks would be exacerbated between the hearing of the interim application and the finalization of the appeal. Thereafter, Syngenta launched an urgent application in the High Court to prevent the Appeal Board hearing taking place. The Court postponed the hearing of this application but ordered Syngenta not to distribute its Bt maize for the following planting season prior to the finalisation of the appeal.

The Appeal Board decided that it should consider the appeal as a "wide appeal", which involves a complete re-hearing and re-determination of the decision taken by the Executive Council, with or without additional evidence or information. Thus, in its deliberations the Appeal Board was not confined to the information available at the time of the Executive Council's decision, but could consider new information which had been made available to it and decide the matter afresh. In effect, this meant that the Appeal

Board need not concern itself with the intricacies of the decision in terms of which a permit was issued to Syngenta, but rather whether, in light of the information now available to the Appeal Board, the authorization given to Syngenta should be confirmed or revoked.

In light of Biowatch's grounds of appeal, the Appeal Board therefore had to ascertain whether Syngenta had satisfied the requirements set out in the GMO Act and other applicable legislation (including NEMA), i.e. to ensure that the potential risks of harm to the environment and human health posed by the use and consumption of Bt11 maize were addressed sufficiently for it to be granted a permit for the general release and import of the maize. These matters were considered at the appeal hearing in September 2004 where a final decision was reached.

Findings of the appeal board

The Appeal Board decided to dismiss the appeal, but specified some amendments to the conditional general release permit issued to Syngenta. The main considerations that led it to this conclusion are summarized below.

Firstly, having dismissed claims of other procedural irregularities, the Appeal Board considered issues regarding irregularities in the public notices. While accepting that there were irregularities, particularly in the notification of trial release, the Appeal Board determined that the public had been made aware of the intended release of the maize and no decision had been taken to grant permission for release before the public had had an opportunity to comment on the proposed release. It was therefore felt that there was no justification to set aside the permit on this basis.

Secondly the Appeal Board considered whether the requirements of NEMA had been fulfilled. NEMA states that an environmental assessment should be carried out when the activity has the potential to **significantly** affect the environment. The Appeal Board reached the decision that there was insufficient evidence either in the public-domain literature or in other literature that was presented to the Board during the hearing, to support a finding that the introduction of Bt11 maize would affect the environment to any greater extent than is already happening with current agricultural practices. Accordingly, the Appeal Board was of the view that the effect on the environment of the introduction

of Bt11 maize cannot be regarded as “significant”, and thus an environmental assessment is not necessitated.

Moreover, the Appeal Board also considered that there are insurmountable problems associated with the gathering of adequate data sets on environmental effects of Bt crops under limited field-trial conditions, making an environmental assessment based on field trial data effectively meaningless. Support for this conclusion is provided by Conner *et al* (2003) who state that “based on available data to date, we estimate it will take decades for current GM crops to have appreciable ecological consequences, if any, on a single agricultural site. Furthermore, it will take centuries for any appreciable ecological consequences, if indeed they exist, to occur on a more global scale”. Additionally Hilbeck *et al* (2000) point out that due to large variability when measuring environmental effects, sample sizes and replications must be large, often pressing logistical limits, and that such variability severely constrains statistical power. In particular it was noted that adequate data on possible ecological effects (which would necessitate studies on a variety of types of organisms and in different habitats) should not be a requirement for the issuing of a permit, although long term studies should be undertaken to monitor whether or not these effects might happen.

Thirdly, the Appeal Board gave consideration to the adequacy of the original risk assessment and the decision by the Executive Council to authorize the general release, in light of the concerns raised by Biowatch. The Appeal Board determined that the original risk assessment compiled by Syngenta complied with the requirements of the GMO Act and with international norms, given that the objective is not to guarantee zero risk, but to ensure that there are minimal risks. It was also considered that the review committee and the Executive Council had considered all salient points concerning both human health (including food safety) and the environment in reaching a decision to issue a permit. This included issues raised by Biowatch regarding possible illegal herbicide use as a result of expression of the *pat* gene, and (as evidenced by conditions in the permit) the need for ongoing monitoring of insect resistance to support the resistance management strategy.

It was recognized that in reaching a decision to issue a general release permit, the results of South African field trials did not play a major role, because the main purpose of performing such field trials was to verify the results obtained during the development and commercial introduction of Bt11 elsewhere, as well as to develop specific Bt11 cultivars

adapted to the agricultural conditions in South Africa. The agronomic performance and efficacy of the product contribute to a risk-benefit analysis, but do not materially support the risk assessment *per se*. To contribute to the data gathered under local conditions, the Appeal Board added certain conditions to the permit issued to Syngenta requiring additional data-gathering over the long term to support the conclusion of minimal risk.

Finally, the Appeal Board gave consideration to Biowatch's contention that sociological and/or economic factors such as farming practice amongst farmers in South Africa were not adequately addressed. The regulations under the GMO Act state that the Executive Council "may" in performing its function of approving or refusing an application for the release of GMOs "consider the socio-economic impact that the introduction of a GMO may have on a community living in the vicinity of such introduction". The report of the review committee stated that no socio-economic concerns were identified. Moreover, Biowatch was also unable to identify specific concerns. In light of this, as well as the fact that there is a body of evidence to suggest that Bt maize may have significant health benefits for small scale farmers by reducing associated infection with toxin-producing fungi, as well as reducing unsafe use of agrochemical sprays (Munkvold *et al*, 1999; Bakan *et al*, 2002; Gressel *et al*, 2004), the Appeal Board considered that socio-economic impacts are more likely to be of a positive than of a negative nature.

Modifications to the permit

The Appeal Board specifically modified conditions in the permit that related to ongoing monitoring. It was considered that monitoring of target and non-target organisms should continue on a long term basis. To support Syngenta's claims of product efficacy (i.e. to look at to the benefit side of the risk-benefit equation), monitoring of the effects on target pests should include larval dispersal and intercrop movements, larval survival, yield effects and internal plant damage, as well as a comparison with the other Bt event currently in the South African market, MON810.

In passing it should be noted that the consideration of benefit as well as risk in decision making represents a clear difference between many developing countries and the Western world. The inclusion of a risk-benefit analysis has a major impact on decision-making, enabling regulators to consider potential benefit in their discussions (Morris and Koch, 2002).

Some lessons learned

The value of field trials

In South Africa, field trials in the country must precede any application for general release. As noted above, field trials on Bt11 maize were undertaken annually from 1998 until the conditional general release approval. On each occasion, permission for such field trials was obtained in terms of the GMO Act.

From the perspective of Syngenta, it appears as though the purpose of the field trials was largely to test the agronomic performance of certain maize cultivars, in order to obtain the data for registration of those cultivars. From the perspective of the Executive Council and the Advisory Committee under the GMO Act, the response to a field trial application involves an evaluation of the safety of that particular trial. To date, the reviewers have not been requested to focus their attention on the data that should be gathered during the course of field trials in order to facilitate the next stage of release. The inclusion of this as a standard consideration would preclude a repeat of the situation where the local field trial results were effectively irrelevant in the decision making process.

Owing to resource constraints in the office of the Registrar of the GMO Act, there is not always adequate follow-up to ensure that written reports on completed field trials are received from the companies, are adequately scrutinized, and are passed on to relevant parties within the biosafety structures. This is essential to ensure that whatever data have been gathered are given due consideration in subsequent decision making.

In an ideal situation, it would be hoped that from the start of field trials with any GM event, consideration would be given by all parties to the nature of the data that should be gathered locally to proceed with confidence to general release at a later date. This constitutes the stepwise approach to risk assessment (UNEP, 1995). At this stage the majority of applications received by developing countries involve GM crops developed elsewhere in the world. Industry-supplied data, on which the safety evaluation is based, will therefore also have been gathered elsewhere in the world. The applicability of the data to a different country should be carefully considered, and the need for any additional country-specific data should be defined and where possible gathered during the course of the field trials.

Building competence in risk assessment in developing countries

It is essential that all parties involved in the regulatory process receive adequate training in the theory and practice of risk assessment and risk management. Moreover, to ensure a comprehensive review of a specific application, it may be necessary to bring to bear a range of skills. Mechanisms need to be put in place to allow for additional expertise to be included in the advisory and decision making processes as required. In the evaluation of the Syngenta application, the review subcommittee could have been strengthened by the inclusion of additional expertise in entomology and ecology. Morris & Koch (2002) provide examples of the range of expertise that may be required for an evaluation. Particularly in developing countries, individuals with the required knowledge may not be readily available, and in all probability although they may be experts in their field, they will not have the domain knowledge concerning GMO issues.

For relatively inexperienced reviewers of any GMO application, there can be a temptation to be so overwhelmed by the vast amount of information provided by the company presenting the application that it is difficult to determine what, if any, additional information might be needed to reach an informed decision. However, specific questions may arise requiring further investigation locally (to be determined on a “need to know” rather than a “nice to know” basis). For instance, differences in local conditions (such as insect species composition, soil types, climate etc) may have an impact on the risk assessment. Increasingly, data on potential secondary ecological effects arising from the introduction of a GMO are being required. The reviewers should carefully consider how much of such information is in fact in the category of “need to know” to demonstrate minimal risk in the introduction of the GM crop, bearing in mind that conventional agriculture already has a far from neutral impact on the environment.

Although it has generally not been the case in South Africa, where there is a lack of regulatory capacity in developing countries, there may be a tendency to take a highly precautionary or even preventative approach to safety assessment (Paarlberg, 2000). In particular, where the motives of private companies are greeted with suspicion, there may be a tendency to discount most of the written evidence presented by the applicant, and to require more detailed in-country safety testing. Under these circumstances, the “nice to know” attitude can prevail, and since it is impossible ever to reach the end of the questions that can be asked, the net results are high costs and a regulatory impasse,

resulting in potential beneficiaries being denied the opportunity to utilize the technology or (as in the case of Zambia) to receive food aid. . As pointed out by Paarlberg (2000a), “to avoid errors of under-regulation, (developing countries) may be making a mistake of overregulation”.

Legislative ambiguities

The appeal process highlighted the need for clear legislation, to prevent differences of legal interpretation.

Some ambiguities in the GMO Act led to the questions:

Does the filing of an Appeal suspend decisions taken?

In the case where significant risk has been identified, the suspension of a permit would seem the most logical course of action. However, if this were to be the automatic result, it could be used as a delaying tactic by parties intent on derailing the process. A case-by-case approach appears logical, recognizing that this may in itself extend the timelines and impose further administrative burdens. Consideration could be given to suspending certain decisions and not others.

Can the Appeal Board consider new evidence?

In the case of wide appeal, this is certainly allowed, but a competent decision could equally be reached either with or without additional evidence. However this should be clearly stated and the manner in which any evidence/information is to be presented (i.e. orally or in writing) must be set out. Obviously the public domain literature is equally available to all parties (including members of the Advisory Committee, the Executive Council, and the Appeal Board), although only a representative sample of the literature was presented by Syngenta in their original risk assessment, and similarly by both Syngenta and Biowatch at the Appeal Board hearing. Given that the reviewers and the Appeal Board members were selected because of their domain knowledge, it is to be expected that they would have read widely on the topic at hand and cannot be expected to reach conclusions based only on the specific documents officially presented to them.

Did Syngenta have the right to respond to the Appeal?

The GMO Act and regulations at this stage do not make provision for the respondent to respond to the appeal or to make submissions in regard thereto. Provision should be made

to allow for a response to the allegations made in the appeal, in order to ensure that all parties receive a fair hearing.

What exactly were the required time frames for the hearing of the Appeal?

The time frames in the Regulations require that an Appeal should be heard within 30 days after it has been lodged. However this is ambiguous in that it is not clear when an appeal is “lodged” with an Appeal Board (the appeal is in fact lodged with the office of the Minister and the Appeal Board is only constituted thereafter). Moreover, the fact that Biowatch was permitted to submit an amended appeal some months after the submission of the original appeal further complicated the time frames. The Appeal Board determined that the appeal could only have been considered to be lodged with the Board once all submissions had been made and all evidence submitted to it. Any time limit imposed on the finalisation of an appeal must take cognisance of the fact that the process that will be followed in each appeal may vary. An appeal hearing, where both parties appear and make oral representations to the Appeal Board will clearly be a longer process than one in which no oral representations are made.

What exactly are the powers of the Appeal Board?

Owing to the somewhat vague wording of the GMO Act, and (since this was the first major appeal to be heard) the lack of precedent to follow, the Appeal Board found itself in the difficult position of having to determine its own powers and procedures as it went along. Certain improvements in the Act would for instance, empower the Appeal Board to substitute (rather than simply amend) the decision or action forming the subject of the appeal; to grant a temporary interdict or other temporary relief; or to make costs orders.

It is clear that countries in the process of developing their own legislation should take note of the need to provide sufficient detail in the legislation to facilitate its later implementation.

What exactly should be contained in the public notices?

The South African regulations to the GMO Act state that public notices should provide a full description of the GMO that the applicant proposes to release, and a description of the proposed release, including the area and the environment in which the release is to take place. Guidelines providing fuller details of the requirements only came into effect early in 2004; their earlier publication would have provided considerable clarification.

Lack of unambiguous specification of requirements leaves the way open to subsequent debate, and if public notification of an application is not correctly carried out at the start, there is the potential to jeopardize the validity of the entire process thenceforth.

How should a socio-economic assessment be performed?

Internationally, there is lack of clarity on both the validity of a socio-economic assessment and on the methodology that should be followed to carry it out. Approaches such as the Sustainable Livelihoods Framework have been proposed (Falck-Zepeda *et al*, 2002), but the methodology to be followed should be described in regulations or guidelines. As long as this remains a somewhat nebulous concept, its value will be questioned. Moreover, there is some doubt as to whether socio-economic assessment is in line with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the World Trade Organization, which requires decision making based on scientific principles.

The legislative framework

As a general guide, the relationship between all legislative instruments that relate to GMOs should be clearly defined (in South Africa this includes the GMO Act, NEMA and the Biodiversity Act). The mechanisms for determining that an application filed under the GMO Act should be referred for an environmental assessment under NEMA are not well laid out, and depend in large part on input from the representative of the Department of Environment Affairs and Tourism who sits on the Executive Council.

Care should be taken not to frame legislation in a way that makes it difficult or impossible to implement later on. This is particularly important for developing countries, where tight time frames and high administrative hurdles will almost certainly lead to subsequent procedural irregularities. Such irregularities open the door for NGOs and the public to challenge the process, regardless of actual safety concerns.

On the other hand, lack of clearly specified requirements potentially paves the way for companies to pay lip service to the regulatory requirements without contributing materially to the body of biosafety data in the country concerned.

Regulatory capacity

The appeal process highlighted the need for well-functioning regulatory processes to avoid unintentional procedural irregularities. Capacity constraints either in government or in the scientific community can jeopardize the regulatory process particularly if legally binding time frames are not adhered to.

Particularly important is the training, experience and recompense of those involved in risk assessment, to ensure their appropriate and timely response to any application. In South Africa, members of the Advisory Committee and its sub-committees generally receive a level of financial compensation for the activities they undertake, and provision for this is made under the GMO Act. This was not however the case for members of the earlier advisory committee, SAGENE, which functioned on a voluntary basis. For developing countries, the costs of the regulatory processes should not be overburdening, but at the same time it may be necessary to remunerate individuals for their participation, in order to ensure timeous delivery.

The importance of comprehensive documentation

In considering the merits of the Advisory Committee's recommendations and the decision by the Executive Council to issue a general release permit, the Appeal Board placed considerable reliance on the documentary evidence available. In this regard they were hampered by the fact that reports from members of the Advisory Committee and the Executive Council tended to focus primarily on issues that were raised as concerns. If a report did not mention an issue, it was not possible to tell if this was because it had not been considered at all, or because a particular reviewer had considered the matter and was satisfied that there were no risks. This shortcoming highlighted the need for documentation to record all the risks that were considered (even where the risk may be negligible) during the review of an application, and for full reasons to be provided to justify any decision reached.

In the circumstances of an Appeal, it is important to be able to demonstrate that the risks have been adequately assessed in accordance with the requirements of the legislation. Any gaps in the documentation have the potential to lead to later questions and concerns, and it is therefore clearly not adequate in this regard for any individuals involved in the review or approval process to merely state that they see no problems with the application.

Additionally, it is important that reviewers should provide an indication of any literature that they have accessed to support their conclusions (over and above the information provided by the applicant) to demonstrate that they have given full consideration to all relevant data.

Time and costs of the appeal process

In South Africa, as in many developing countries, resource constraints in the public service may result in processing delays, inadequate documentation and communication, and procedural problems. The Appeal process highlighted areas for improvement, and in that regard was to be welcomed. However, the time and money involved in the Appeal hearing, and the resources that were tied up, were bound to have a negative impact on the smooth running of the office of the Registrar of the GMO Act. Considering that this office had to provide logistical support and information through the various steps of the process (filing of first appeal, provision of additional information to Biowatch, submission of revised appeal, interim relief hearing, full appeal hearing) and had to provide all relevant documentation to the Appeal Board members on an ongoing basis, the administrative burden and costs were large.

Where there is a lack of capacity or insufficient funding to adequately assess risk or to ensure that regulatory processes are strictly adhered to, developing countries in general may find that any irregularities open the door for decisions to be challenged by individuals or organizations that are concerned about the introduction of GMOs. The appeal process is not only time consuming but costly for all concerned, and may unnecessarily tie up scarce resources.

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