

Critical overview of South Africa's bioprospecting laws



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The African Centre for Biosafety (ACB) is a non-profit organisation, based in Johannesburg, South Africa. It provides authoritative, credible, relevant and current information, research and policy analysis on genetic engineering, biosafety, biopiracy, agrofuels and the Green Revolution push in Africa.

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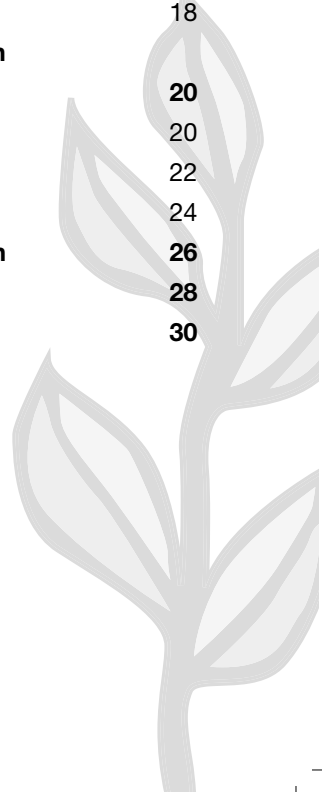
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Acronyms

ACB	African Centre for Biosafety
BABS	Regulations on Bio-Propecting, Access and Benefit Sharing
BSA	Benefit Sharing Agreements
BTF	Bioprospecting Trust Fund
DEA	Department of Environmental Affairs
DG	Director-General
EC-DEAET	Eastern Cape Department of Economic Affairs, Environment and Tourism
EPO	European Patents Office
IBR	Indigenous biological resources
MEC	Member of the Executive Council
MTA	Material Transfer Agreement
NEMBA	National Environmental Management: Biodiversity Act
PAIA	Promotion of Access to Information Act
PAJA	Promotion of Administrative Justice Act



structure of booklet



In this booklet, we provide an overview of the core provisions of the legislative framework governing bioprospecting, access and benefit sharing in South Africa. In particular, we highlight the lack of opportunity for public participation by civil society in the bioprospecting permitting process, problems with accessing information, issues relating to the restricted appeal process, and the apparent conflict between the bioprospecting laws and apartheid provincial legislation. These themes are discussed against the backdrop of the ACB's (at times frustrating) experiences as an NGO seeking to engage in bioprospecting permitting processes on its own behalf or on behalf of affected communities.

legislative framework



Bioprospecting is regulated through the National Environmental Management: Biodiversity Act¹ (NEMBA) and the Regulations on Bio-Prospecting, Access and Benefit Sharing² (BABS regulations).

Chapter 6 of NEMBA regulates bioprospecting³ involving indigenous biological resources (IBRs),⁴ as well as the export of these resources for the purpose of bioprospecting or any other kind of research. It is intended to provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting.

In essence, bioprospecting refers to any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation. The meaning extends to any traditional knowledge or use of traditional knowledge that is researched, modified or used for commercial or industrial exploitation.

The BABS regulations further regulate the permit system set out in NEMBA and set out the contents of, the requirements and criteria for Benefit Sharing Agreements (BSA) and Material Transfer Agreements (MTA).⁵

What activities require a bioprospecting permit?

New activities

NEMBA provides that no person may, without a permit issued in terms of chapter 7, engage in the commercialisation phase of bioprospecting⁶ involving any IBR, or export such resources from South Africa.⁷ An amendment to NEMBA relating to the requirements for the discovery phase of bioprospecting has been promulgated,

but has not yet been put into operation by proclamation.⁸ Once in operation, anyone engaging in the discovery phase of bioprospecting involving IBRs will be required to give notice to the Minister of Water and Environmental Affairs and be required to sign a commitment to comply with legal requirements during the commercialisation phase.

The BABS Regulations have yet to be aligned with this pending amendment, and as the law stands, both the discovery and/or commercialisation phases of a bioprospecting project⁹ may only be carried out with a bioprospecting permit.¹⁰ Anyone intending to export the IBRs, to which the permit application relates, must apply for an integrated export and bioprospecting permit.¹¹

In addition, the NEMBA regulations provide that IBRs may only be exported for research purposes other than bioprospecting with an export permit,¹² which may be issued as an integrated permit.¹³ *'Any other kind of research'* is defined as meaning research other than bioprospecting. It includes the systematic collection, study or investigation of IBR conducted under the auspices of a *bona fide* research institution or organisation to generate scientific knowledge, but excludes incidental surveys and searches.

In summary, the following permits can be granted:

- **Bioprospecting Permit:** for discovery and commercialisation phase of bioprospecting project involving IBRs;
- **Integrated Export and Bioprospecting Permit:** for anyone intending to export the IBRs and
- **Export Permit:** for anyone exporting IBRs for research.

It is relevant to note that the Minister of Environmental Affairs is the issuing authority for bioprospecting permits and for integrated export and bioprospecting permits if the IBRs are being exported for the purposes of bioprospecting.¹⁴ The provincial MEC is designated as the issuing authority for export permits if the IBRs are being exported for research purposes other than bioprospecting, and if the IBRs to be exported are collected, gathered or curated in that province.¹⁵

The Department of Environmental Affairs has explained that the BABS regulations define two phases of bioprospecting projects, namely the commercialisation and discovery phases. Research for purposes other than bioprospecting is defined as a specific activity not as a bioprospecting project. The Department has advised further that activities would have to be examined on a case-by-case basis within their project context to determine where they fit in, but has suggested that activities can generally be categorized as follows:

- Pre-clinical trials: discovery phase or research;



Bioprospecting. <http://www.materialbeliefs.com/events/images/rca-ibe/prospect.jpg>

- *In vitro* and *in vivo* trials: research, discovery or commercialisation phases;
- Isolation: discovery phase or research;
- Market research: discovery phase or research;
- Research funded by institution: discovery phase or research and
- Intellectual Property application: discovery phase or research.¹⁶

The Department of Environmental Affairs has explained that the commercialisation phase would include the propagation, multiplication and cultivation of IBRs for the purposes of developing new products such as drugs, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts.¹⁷

Existing activities

Any party who was involved in a bioprospecting project as at 1 January 2006 was allowed to continue the project, pending the negotiation and implementation of an appropriate BSA. This provision lapsed after a year.¹⁸ However, in terms of the BABS regulations, any person involved in a bioprospecting project at the commencement of the regulations may continue pending the issuing of a bioprospecting permit, but was obliged to submit a bioprospecting permit application within 6 months of 1 April 2008.¹⁹

According to correspondence received by the ACB from the Department of Environmental Affairs, any party who was involved in a bioprospecting project, who failed to submit a permit application before 30 September 2008, 'would be in contravention of the legislation and could be prosecuted and fined according to NEMBA sections 98(2) and/or 101 if this information was provided to DEA'.²⁰ Interestingly, the Department has advised the ACB that by 31 December 2008 it had received 34 permit applications from 12 organisations.²¹ This suggests that some of the applicants may have missed the 30 September 2008 deadline, in which case those parties would have committed an offence and could be prosecuted accordingly.

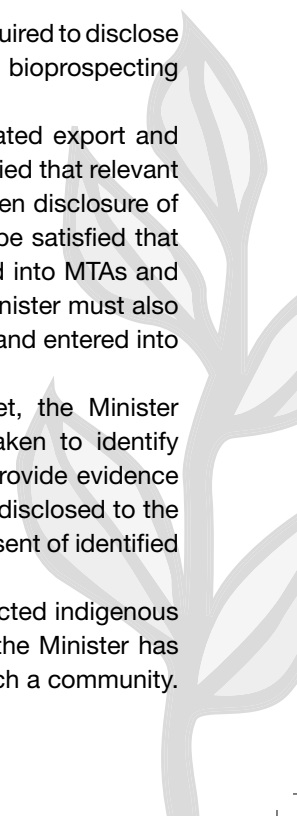
Prerequisites for issuing bioprospecting and integrated export and bioprospecting permits

Before an application for a permit is considered, the applicant is required to disclose to the issuing authority all information concerning the proposed bioprospecting and IBR to be used.²²

In terms of the BABS regulations, bioprospecting and integrated export and bioprospecting permits may only be issued if the Minister is satisfied that relevant stakeholders have been properly identified and that there has been disclosure of relevant information to all stakeholders. The Minister must also be satisfied that the applicant has obtained the prior consent of, and has entered into MTAs and BSAs, with anyone providing or giving access to the IBR. The Minister must also be satisfied that the applicant has obtained the prior consent of, and entered into BSAs with, affected indigenous communities.²³

In order to ensure that these requirements have been met, the Minister may require the applicant to show: what steps have been taken to identify stakeholders; to take further steps to identify stakeholders; to provide evidence that relevant information relating to the bioprospecting has been disclosed to the identified stakeholders and to provide evidence that the prior consent of identified stakeholders has been obtained.²⁴

The question that arises, however, is how stakeholders or affected indigenous communities should assert their rights in circumstances where the Minister has not been informed by the permit applicant of the existence of such a community.



As will be shown below, this problem is compounded by the lack of any mandatory requirement for an applicant to give notice of a bioprospecting permit application, which could leave potential stakeholders in blissful ignorance.

To whom can a permit be issued?

In terms of the BABS regulations, a permit can only be issued to a juristic or natural person registered in terms of South African law, who is a South African citizen or is residing permanently in SA.²⁵ Thus, foreign companies, institutions or individuals must apply jointly with a South African person. This applies to bioprospecting permits, integrated export and bioprospecting permits and export permits.

The applicant is required to disclose whether any other permit applications have been made in respect of the IBR, and if so, whether it was refused, granted or is still pending. If the bioprospecting was preceded by research other than bioprospecting, the applicant is also required to disclose the nature of the research and the activities resulting in the application for a bioprospecting permit.²⁶

The Department of Environmental Affairs has advised the ACB that this regulation is intended to protect IBRs from 'exploitation by unscrupulous non-South African bioprospectors', but recognises that the enforcement of these provisions in the international arena in the absence of an international regime is problematic.²⁷

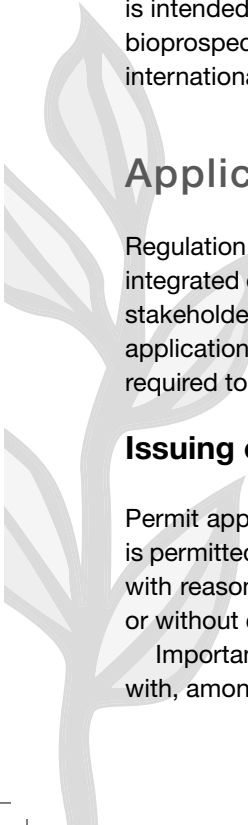
Application procedure

Regulation 10 sets out the permit application procedure for bioprospecting permits, integrated export and bioprospecting permits and export permits. Of relevance to stakeholders is the requirement that any MTA or BSA must be attached to the application. If it was not possible to conclude these agreements, the applicant is required to request intervention by the Minister to negotiate such agreements.²⁸

Issuing of permits and contents

Permit applications must be lodged in the prescribed form. The issuing authority is permitted to request additional information; may require the applicant to comply with reasonable conditions before granting the application; issue the permit with or without conditions or refuse the permit.²⁹

Importantly, the decision of the issuing authority is required to be consistent with, amongst other things:



- the national environmental management principles;
- any applicable international agreements binding on the Republic and
- the Promotion of Administrative Justice Act (PAJA).³⁰

The above provisions are significant. The national environmental principles apply to the actions of all organs of state that may affect the environment and guide the administration of any law concerned with the protection or management of the environment. The principles provide that participation of all interested and affected parties in environmental governance must be promoted³¹ and that decisions must take the interests, needs and values of all interested and affected parties into account. This includes recognising all forms of knowledge, including traditional and ordinary knowledge.³² Any decisions would also have to be consistent with the provisions of the Promotion of Administrative Justice Act, 2000 (PAJA).

The issuing authority is given the discretionary authority to require the applicant to furnish, at the applicant's own expense, an independent risk assessment or expert evidence.³³

In the event that the activity requiring a bioprospecting license is also regulated by another law, the authority empowered under that law and the issuing authority may decide to exercise their powers jointly and issue a single integrated permit instead of a separate permit or authorization.³⁴

A permit can be cancelled if it was issued as the result of misleading or false representations by the applicant or a person acting on the applicant's behalf. It may also be cancelled if the permit holder contravenes or fails to comply with any permit condition, any legal requirement governing the permitted activity, or any foreign law governing the activity.³⁵

The BABS regulations provide further detail regarding the issuing of various permits. Each of these is discussed hereunder.

Bioprospecting Permit

Regulation 11 provides that a bioprospecting permit must be in the prescribed form and must include specified details such as time-period, type, quantity and source of the IBRs involved, as well as mandatory and discretionary conditions as determined by the Minister.

Integrated export and bioprospecting permits

Integrated export and bioprospecting permits may only be issued if the Minister is satisfied that the purpose of the export will be in the public interest, including:

- the conservation of biodiversity in SA;
- the economic development of SA or
- enhancing the scientific knowledge and technical capacity of SA people and institutions.³⁶

These integrated permits must be in the prescribed form and must include specified details such as time-period, type, quantity and source of the IBRs involved, as well as mandatory and discretionary conditions as determined by the Minister.

Export permits for research other than bioprospecting

Export permits may also only be issued if the issuing authority (provincial MEC) is satisfied that the export will be for a purpose that is in the public interest, including:

- the conservation of biodiversity in SA;
- the economic development of SA or
- enhancing the scientific knowledge and technical capacity of SA people and institutions.³⁷

These export permits must be in the prescribed form and must also include specified details such as time-period, type, quantity and source of the IBRs involved, as well as mandatory and discretionary conditions as determined by the issuing authority.³⁸

Protection of stakeholders

NEMBA requires the issuing authority considering a permit application to protect the interests of specified stakeholders before a permit can be issued.³⁹

Two categories of stakeholders are identified, namely:

- any person (including any organ of state or community) providing or giving access to the resources to which the application relates and

- an indigenous community or individual whose traditional uses of the IBR have initiated or will contribute to or form part of the proposed bioprospecting, or whose knowledge of or discoveries about the IBR are to be used for the purpose of bioprospecting.⁴⁰

Where the stakeholder is a person providing or giving access to the resource, the issuing authority may only issue a permit if:

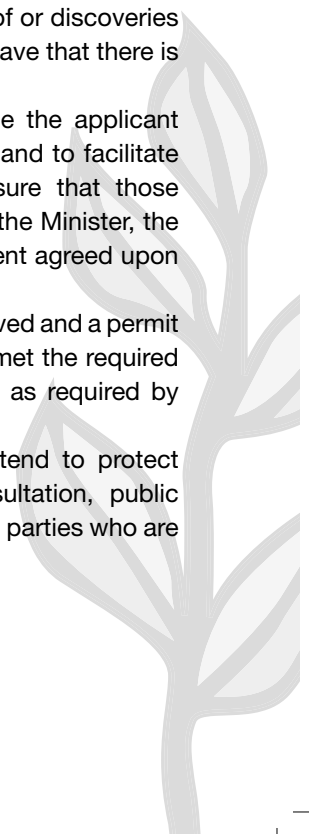
- the applicant has disclosed all material information relating to the bioprospecting to the stakeholder, and on the basis of such disclosure has obtained the prior consent of the stakeholder for the provision of or access to the resource;
- the applicant and stakeholder have entered into a MTA and BSA that provides for sharing by the stakeholder in any future benefits that may be derived from the bioprospecting and
- the Minister approves the BSA and MTA.⁴¹

The same requirements apply where the stakeholder is an indigenous community or individual whose traditional uses of the IBR have initiated or will contribute to or form part of the proposed bioprospecting, or whose knowledge of or discoveries about the IBR are to be used for the purpose of bioprospecting, save that there is no requirement for a MTA.⁴²

The issuing authority is given discretionary power to engage the applicant and stakeholder on the terms and conditions of a BSA or MTA, and to facilitate negotiations between the applicant and stakeholder and ensure that those negotiations are conducted on an equal footing. If requested by the Minister, the issuing authority must ensure that any benefit-sharing arrangement agreed upon between the applicant and stakeholder is fair and equitable.⁴³

The Minister⁴⁴ has advised the ACB that a BSA will not be approved and a permit not consented to if she was not satisfied that the applicant has met the required conditions, including consultation with all relevant stakeholders as required by NEMBA and the BABs regulations.

It is evident from the above that the NEMBA provisions intend to protect the stakeholders defined in the Act. Issues relating to consultation, public participation and access to information by interested and affected parties who are not stakeholders are discussed separately below.



Benefit Sharing Agreement

As has been explained above, the applicant is required to disclose information, obtain the prior consent of stakeholders and enter into a BSA with stakeholders. NEMBA provides that the BSA⁴⁵ must be in the prescribed format and is required to specify:

- the type of IBR;
- the area or source from which the IBR are to be collected or obtained;
- the quantity of IBR that is to be collected or obtained;
- any traditional uses of the IBR by an indigenous community and
- the present potential uses of the IBR.

The BSA is also required to set out the names of the parties, the manner in which and the extent to which the IBR is to be utilized or exploited, and the manner in which and the extent to which the stakeholders will share in any profits that may arise from the bioprospecting. The BSA must also provide for a regular review of the agreement by the parties.

The BSA and any amendment must be submitted to the Minister for approval, and does not take effect unless approved by the Minister.

The BABS regulations go further and provide that before approving a BSA, the Minister must be satisfied that the agreement is fair and equitable to all parties (namely the applicant and the stakeholders).⁴⁶

The Minister is given the discretionary power to also consult with any person competent to provide technical advice on the agreement,⁴⁷ and may also invite public comment on the agreement (provided that no confidential information is made public).⁴⁸ This means that the Minister is not obliged to invite public comment. In correspondence between the Minister⁴⁹ and the ACB, the Minister has stressed that she has the discretion (not obligation) to invite public comment on a BSA provided that no confidential information is made public, and that this provision would be considered when any BSA is considered for approval.

On 2 July 2010, the Department of Environmental Affairs published 'non-confidential' information in the *Gazette*⁵⁰ relating to a BSA between Parceval (Pty) Ltd, Schwabe Extracta GMBH & CO.KG and the Imingcangathelo Development Trust. ACB's concerns that much of the BSA would be regarded as confidential and that a watered down version would be published, proved to be well-founded.

In addition to the names of the parties to the BSA, the information published was limited to the following:

- Imingcangathelo Development Trust intends to cultivate the indigenous biological resource (*Pelargonium sidoides* and *Pelargonium reniforme*) to which the Bioprospecting Permit application relates;
- The Benefit Sharing Agreement provides monetary, non-monetary and in-kind benefits to the Imingcangathelo Development Trust.
- The Benefit Sharing Agreement between the parties is based on access to the resource, not use of traditional knowledge.

Other than clarifying that the BSA is based on access to the resource and not use of traditional knowledge, the information provided is general in nature and already known to the ACB. No information has been published indicating the traditional uses of the IBR by indigenous communities, or regarding the potential uses of the IBR.

The Minister is also given the discretionary power to refuse to approve a BSA unless it makes provision for:

- enhancing the scientific knowledge and technical capacity of persons, organs of state or indigenous communities to conserve, use and develop IBRs or
- any other activity that promotes the conservation, sustainable use and development of the IBR.⁵¹

The BSA must be in the prescribed format, namely Annexure 8 to the BABS regulations. This form indicates that, where an indigenous community representative signs the BSA on behalf of the community a resolution adopted by the indigenous community must be attached. This resolution must confirm that the indigenous community representative has been authorised to enter into the BSA on behalf of the indigenous community, that the indigenous community has full knowledge of the bioprospecting project and that it consents to entering into the BSA.

Material Transfer Agreement

It has been explained above that where a stakeholder is giving access to the IBR, a MTA must be concluded. The MTA is also required to be in a prescribed format, and must specify:

- particulars of the provider and the exporter or recipient of the IBR;
- the type of IBR to be provided or to which access will be given;
- the area or source from which the IBR will be collected, obtained or provided;
- the quantity of IBR to be provided, collected, obtained or exported;

- the purpose for which such IBR are to be exported;
- the present potential uses of the IBR and
- conditions under which the recipient may provide any such IBR, or their progeny, to a third party.

The MTA and any amendment must also be submitted to the Minister for approval and does not take effect unless approved by the Minister.

The BABS Regulations provide that the parties to a MTA include both categories of stakeholder. On the face of it this appears to be a case of sloppy drafting of the regulation, as NEMBA does not require a MTA in respect of the second category of stakeholder, namely where the stakeholder is an indigenous community or individual whose traditional uses of the IBR have initiated or will contribute to or form part of the proposed bioprospecting, or whose knowledge of or discoveries about the IBR are to be used for the purpose of bioprospecting.⁵²

The MTA is required to be in the form of Annexure A to the BABS regulations.⁵³

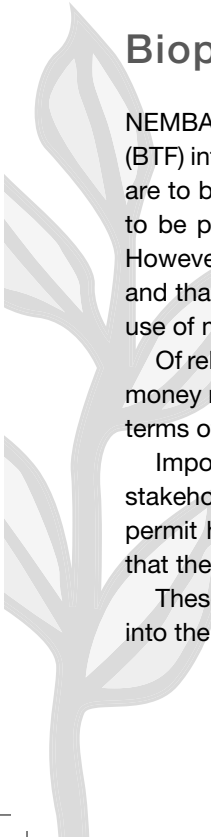
Bioprospecting Trust Fund

NEMBA makes provision for the establishment of a Bioprospecting Trust Fund (BTF) into which all monies arising from BSA and MTA that are due to stakeholders are to be paid and from which payments to or for the benefit of stakeholders are to be paid.⁵⁴ The administration of the BTF is beyond the scope of this paper. However, it is relevant to note that each BSA will be regarded as a trust instrument, and that the Director-General (DG) is responsible for the safekeeping and proper use of money received, and may charge a reasonable fee.⁵⁵

Of relevance to stakeholders is that the DG is obliged to advise the parties of any money received in respect of the BSA and the amount due to each stakeholder in terms of the BSA. This money must be distributed in accordance with the BSA.⁵⁶

Importantly, the permit holder must notify the DG when money due to stakeholders (as specified in the BSA) will be transferred or paid into the BTF. The permit holder must also notify the stakeholders entitled to the monetary benefit that the funds were so transferred or paid.⁵⁷

These provisions should provide transparency regarding any payments made into the BTF insofar as stakeholders who are parties to the BSA are concerned.



Exemptions

The Minister is given authority (subject to following the prescribed consultative process)⁵⁸ to exempt, by notice in the Gazette, any specified IBRs or activities relating to that IBR, or to declare that the permitting requirements do not apply to certain categories of research involving IBRs or commercial exploitation of IBRs.⁵⁹

The following activities relating to indigenous biological resources have been exempted⁶⁰ from the permitting requirements of NEMBA:

- research other than bioprospecting, provided that the research is conducted within the borders of South Africa and the research is not conducted for the purposes of commercial or industrial exploitation;
- the export of *ex situ* indigenous biological resources for purposes of research other than bioprospecting, provided the exporter has entered into an export agreement and notified the issuing authority thereof;
- the trade of commercial products purchased from a bioprospector, provided that the bioprospector has complied with the Regulations on Bioprospecting, Access and Benefit-sharing;
- the keeping, breeding, cultivation, moving, trading and use of wildlife not directed at the development and production of:
 - products such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts;
 - or new plant varieties and products;
- the collection, use, propagation cultivation or trade of indigenous biological resources for domestic use or subsistence purposes;
- the artificial propagation, multiplication or cultivation of flora species for the local and international cut flower and existing ornamental plant markets and
- aquaculture or mariculture activities involving fresh water and marine species producing specimens for consumption purposes.

The Department of Environmental Affairs has indicated that traditional healers and herbalists are exempt from applying for bioprospecting permits only for subsistence / direct use or other traditional practices, but that those 'selling medicinal plants for commercial purposes must apply for a bioprospecting permit



Pelargonium Sidoides. http://betula.br.gov.br/research/COLLECTIONS/LIVING/LIVCOL/img_large/6005002099629_2005016773_1.jpg

if using indigenous biological resources to develop new products for commercial exploitation, whether alone or in partnership with a third party'.⁶¹

Appeal

NEMBA also provides a mechanism for any permit applicant aggrieved by a permitting decision (including a cancellation) to lodge an appeal with Minister within 30 days.⁶² The Minister may appoint an appeal panel, which in turn can decide the appeal. Records of the proceedings and decision must also be kept.⁶³

The BABS regulations expand upon the appeal provisions and stipulate that the applicant may appeal any decision to:

- refuse a permit;
- impose conditions that are in addition to mandatory conditions or
- cancel a permit.⁶⁴

An appeal must be lodged with the Minister within 30 days of the applicant receiving notification of the permitting decision.⁶⁵ Stakeholders who have an interest in the appeal must be provided with a copy of the appeal and must be notified that they have 15 days from the date of notification to lodge submissions

in relation to the appeal with the Minister.⁶⁶ The appeal must include the grounds of appeal and identify stakeholders who have an interest in the appeal. Proof that a copy of the appeal has been served on these identified stakeholders must accompany the appeal.⁶⁷

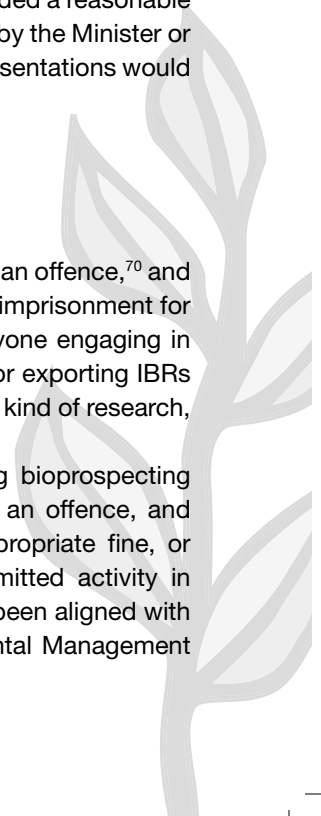
While these provisions give the permit applicant the right to appeal, they do not give members of the public or interested and affected parties the right to appeal against a decision to grant a permit. In such cases, the only remedy available to an aggrieved party would be that of judicial review.

And while the appeal provisions of the BABS regulations afford specified stakeholders the opportunity to be furnished with a copy of the appeal and to lodge submissions, they do not extend this opportunity to interested and affected parties who may be aggrieved by the decision (and who, for example, may have also submitted representations during the permitting phase of the administrative decision-making process). However, as has been pointed out above that the decision of the issuing authority is required to be consistent with the provisions of PAJA.⁶⁸ Any interested and affected party would need to show that the appeal decision was an administrative action that materially and adversely affects their rights or legitimate expectations, and assert their right to be afforded a reasonable opportunity to make representations.⁶⁹ On the face of it, a failure by the Minister or appeal panel to afford such parties the opportunity to make representations would be administratively unfair and could be set aside on review.

Offences and penalties

NEMBA provides that any person contravening s81(1) is guilty of an offence,⁷⁰ and is liable upon conviction, to a fine not exceeding R10 million, or imprisonment for a period not exceeding 10 years, or both.⁷¹ This applies to anyone engaging in the commercialisation phase of bioprospecting involving IBRs, or exporting IBRs from South Africa for the purpose of bioprospecting or any other kind of research, without a permit.

The BABS regulations provide that any person undertaking bioprospecting involving IBRs or exporting IBRs without a permit is guilty of an offence, and is liable upon conviction to imprisonment for 5 years, an appropriate fine, or both.⁷² The same applies to any person performing the permitted activity in breach of any permit conditions.⁷³ The regulations have not yet been aligned with the amendments made to NEMBA by the National Environmental Management Amendment Act 14 of 2009.



consultation, public participation and access to information by non-stakeholders



Consultation and public participation

As discussed in *Protection of Stakeholders* above, Chapter 6 of NEMBA affords the defined stakeholders (namely those giving access to the IBR, or whose traditional uses, knowledge or discoveries have initiated, will contribute to, form part of, or are to be used for bioprospecting purposes) protection. This protection includes disclosure of all material information to the stakeholder, obtaining the stakeholder's prior informed consent and requirements relating to MTA and BSA.

What does this mean for the NGOs and other interested and affected parties who do not fall within the defined categories of stakeholder?

While NEMBA includes provisions for consultation and public participation, these requirements are limited by the operation of s99. This section provides that 'before exercising a power which, in terms of a provision of this Act, must be exercised in accordance with this section and s100, the Minister must follow an appropriate consultative process in the circumstances' and must 'allow public participation in the process in accordance with section 100'.⁷⁴ This means that the NEMBA consultative and public participation process is obligatory only where the section giving rise to the statutory power being exercised states that the power must be exercised in accordance with s100.

The operation of this provision is illustrated by various sections, which stipulate that before publishing various notices, the Minister must follow a consultative process in accordance with sections 99 and 100. These requirements are found in sections dealing with listing threatened national ecosystems or species, identification of threatening processes, restriction of activities involving threatened or protected species, and invasive species.⁷⁵

In contrast, there are no requirements in the bioprospecting, access and benefit sharing provisions of NEMBA stating that the statutory powers referred to must be

exercised in accordance with s99 and s100. Consequently, there is no obligation on the issuing authority to follow the consultation and public participation process set out in s100 of NEMBA. The BABS regulations do not remedy this situation. No provision is made for public comment on permitting applications or appeals, while the Minister may, but is not obliged to, invite public comment on BSAs (provided that no confidential information is made public).⁷⁶

However, this does not mean that interested and affected parties cannot assert a right to be heard in the permitting process. As has been mentioned above, any decision taken in terms of NEMBA must be consistent with the provisions of PAJA.⁷⁷

S3 of the PAJA stipulates that administrative action, which materially and adversely affects the rights or legitimate expectations of any person, must be procedurally fair. While fairness depends on the circumstances of each case, PAJA provides for adequate notice, a reasonable opportunity to make representations, a clear statement of the administrative action, adequate notice of any right of review or internal appeal, and adequate notice of the right to request reasons. The administrator may only depart from the abovementioned requirements if it is 'reasonable and justifiable in the circumstances'.

S4 of PAJA stipulates that where administrative action materially and adversely affects the rights of the public, the administrator must decide whether to hold a public inquiry, follow a notice and comment procedure or follow both procedures. Where empowered to follow a procedure which is fair but different, the administrator must decide whether to follow that procedure, or to follow another procedure that gives effect to s3 of PAJA.

Thus, provided that an NGO, community based organisation or other interested and affected party could show that a bioprospecting permitting decision materially or adversely affected their rights or legitimate expectations, the issuing authority would be required, under PAJA, to follow a procedure that complies with the provisions of s3 of PAJA.⁷⁸ Where the decision materially or adversely affects the rights of the public, the issuing authority would have to comply with the requirements of s4 of PAJA.

In practice, the Department of Environmental Affairs seems to have recognized that civil society is entitled to make representations. With regard to submissions made by the ACB in relation to the Alice community not having been consulted with regard to *Pelargonium* bioprospecting permits, the Minister informed the ACB that its 'concerns for the community have been noted, and will be taken into consideration at the appropriate time of evaluation of any benefit sharing agreement pertaining to *Pelargonium* species that may be submitted for my consideration'.⁷⁹

Access to information

It has been pointed out above that one of the protections afforded to stakeholders by NEMBA is the requirement that the applicant discloses all material information relating to the bioprospecting to stakeholders. The BABs regulations also give the Minister discretion to invite public comment on BSAs, provided that no confidential information is made public.

Unfortunately, NEMBA and the BABs regulations do not require disclosure of information relating to bioprospecting to interested and affected parties who are not stakeholders. The lack of publicly available information relating to bioprospecting permit applications makes it very difficult for civil society groups to make meaningful representations.

The ACB has been working with the Alice community in the Eastern Cape of South Africa for some years. This community has a long established practice of utilizing extracts from *Pelargonium* for medicinal purposes and the ACB has attempted to assist the community in asserting its rights as one of the traditional knowledge holders relating to these IBRs. A commercial product (Umckaloabo) based on this IBR is currently sold by a German company, Schwabe Pharmaceuticals. The company also held several European Patents over the product, which was recently retracted following objections submitted by the ACB to the European Patents Office (EPO) and at least one patent was revoked by the EPO.

In the course of this work, the ACB has made numerous efforts to engage in bioprospecting permitting process relating to *Pelargonium*. These efforts have included, amongst others, informal and formal requests for information relating to any bioprospecting permit applications submitted in respect of *Pelargonium Sidiodes* and *Pelargonium Reniform*.

On 5 February 2009 the ACB wrote to the Department of Environmental Affairs requesting information relating to bioprospecting permit applications, including information on how many permits had been issued for *P. Sidiodes* and *P. Reniform*, and how many permits had been applied for. A reply was received on 22 July 2009. While this letter dealt with various issues, it is relevant to note that the Department confirmed that three permit applications had been received for *P. Sidiodes* and *P. Reniform*. The names of two applicants (namely Parceval Pharmaceuticals (Pty) Ltd and Gowar Enterprises) had already been supplied to the ACB by this time following formal PAIA requests. The Department directed the ACB to make another formal PAIA application in order to be provided with the name of the third applicant. Regarding the information relating to the permit applications, the Department requested further details on what information was



Pelargonium Reniforme. <http://img87.imageshack.us/i/letztenfotosschrebergareo5.jpg/>

required so that it could recommend the most appropriate method to facilitate access. Regarding the assertion that the information was already in the public domain, the Department responded that the information sources cited did not pertain to the bioprospecting applications, but rather to scientific, conservation and /or utilization of *Pelargonium*.

The ACB submitted formal PAIA requests for details included in the bioprospecting permit applications by Gowar Enterprises⁸⁰ and Parceval Pharmaceuticals.⁸¹ In reply, the Department of Environmental Affairs wrote to the ACB on 20 May 2009 advising that it had consulted with Gowar Enterprises and Parceval Pharmaceuticals, and that:

'The affected parties refused the request for disclosure of the information pertaining to their submitted Bio-prospecting permit applications, citing sections 36(1), 37(1) and 43(1) as reasons to refuse access to the records. Based on the provisions in PAIA and refusal by the third parties, I refuse to grant you access to the requested documents.'⁸²

In response to this refusal, the ACB instructed its attorney to write to the Department, pointing out that the Department was required to provide adequate reasons for the refusal, and that a mere reiteration of the wording of the enabling legislation did not constitute reasons.⁸³

The Department responded to this request by furnishing detailed reasons.⁸⁴ While it is beyond the scope of this publication to deal comprehensively with these reasons, it is germane to note that the Department relied on the definition of confidential business information as contained in the BABs regulations.

The BABS regulations define “confidential information” as information which if disclosed may be detrimental to the commercial or financial interests of a party to a benefit-sharing agreement. It includes: information about research being or to be carried out including details of species to be collected and areas in which specified species are to be collected; financial, commercial, scientific or technical information, including trade secrets and indigenous knowledge, if the disclosure of that knowledge may be detrimental to the relevant indigenous community. It excludes information that has already been disclosed through publication in a scientific journal or if the parties consent to its disclosure.⁸⁵

The Department⁸⁶ asserted that the permit application form (BABs regulations Annexure 2, parts 1 and 2) required the applicant to provide information in response to questions 21 and 36 of part 1 and Question 4 of part 2 which it viewed as information falling within the definition of confidential business information in the BABs regulations. It was asserted that question 21 required the applicant to provide information on the species to which the permit applies, the locality details of the areas in which specified species are to be collected and technical information on the part of the organism to be collected. It was asserted further that questions 36 and 4 required the applicant ‘to furnish information which may include financial, commercial, scientific or technical information, which may include trade secrets.’ Other grounds for the refusal were also asserted.⁸⁷

While it is acknowledged that some of the information provided by applicants could be *bona fide* commercial confidential information, it is difficult to see how all of the information should be regarded as commercially confidential. It seems absurd, for example, to regard information on the species to be collected as confidential, as it is common knowledge that Gowar and Parceval were dealing

with *P. Sidiodes* and *P. Reniform*. A provincial collector's permit⁸⁸ also in the ACB's possession, indicates that *P. Sidiodes* and *P. Reniform* was to be collected by Parceval's project partners in the Seymour and Balfour areas.

The definition of 'confidential information' as contained in the BABS regulations are to be censured for being too wide, and for failing to balance the competing interests of bioprospecting permit applicants and interested and affected parties. The withholding of entire permit applications on the basis that they contain some confidential information is, it is submitted, an unreasonable limitation on the right of access to information.

Synthesis

Given that all bioprospecting and export permit applications require the same kind of information to be furnished, it is highly likely that the Department will also refuse all future access to information requests relating to bioprospecting permitting applications on the basis that they contain confidential business information. The only exception to this might be in the unlikely event that the permit applicant consents to the disclosure of the information.

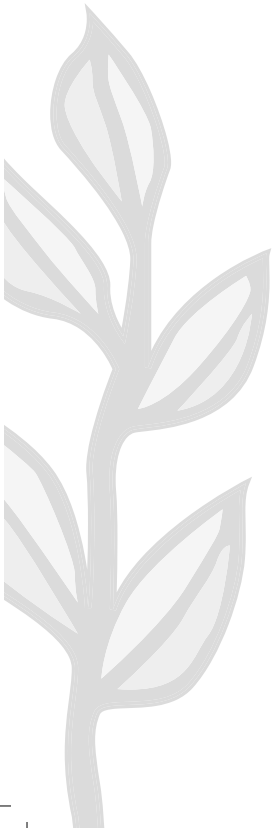
This leaves civil society and other interested and affected parties in a very difficult position when it comes to public participation. NEMBA and the BABS regulations do not require the applicant or issuing authority to give public notice of any bioprospecting permit application. Should an interested and affected party become aware of a permit application through some other means, no information contained in the permitting application would be made public due to the application forms containing confidential business information. Applying the same reasoning, it is also unlikely that a copy of any permit granted will be made public.

On the face of it, the provisions of NEMBA and the BABS regulations institutionalise unfair administrative processes insofar as interested and affected parties who are not stakeholders are concerned. These provisions could well infringe upon the constitutional right to just administrative action⁸⁹ and the minimum requirements for fair administrative action as set out in s3 and s4 of PAJA.

The wide definition of confidential information arguably also infringes unjustifiably upon the constitutional right of access to information.⁹⁰ In addition, it is submitted that the Department of Environment's blanket refusal to provide any information contained in the bioprospecting permit applications cannot be the correct approach to take, as it is unlikely that all the information contained therein would fall within the definition of confidential business information. It is submitted

that it would be reasonable for the issuing authority to delete or blank out *bona fide* confidential information in the permit applications forms when providing access to this information. It is relevant to note that the Constitutional Court has indicated that government authorities are obliged to pass on information in their possession, save only for material that could reasonably be withheld in order to protect certain prescribed interests, and has stated that:

‘The government’s duty was to act as impartial steward, and not to align itself either with those who had furnished the information or with parties seeking access to it. It was important that the objectivity not only be present, but be seen to be present in circumstances where the information related to questions of general public interest and controversy, and there was no lawful ground to withhold it. This required objectivity and distance in respect of any competing private interests that might be involved. The greater the public controversy, the more the need for transparency and for manifest fidelity to the principles of the Constitution, as ultimately given effect to by PAIA.’⁹¹



potential conflict between nemba and provincial legislation



Some aspects of the trade relating to bioprospecting are regulated under relevant Provincial Laws. The Department of Environmental Affairs has, for example, pointed out that local harvesters are required to apply for harvesting / collection permits from Provincial Authorities. The Department has indicated that ‘Provincial Authorities are primarily responsible for conservation and sustainable use of indigenous biological resources and are governed by specific Provincial Legislation and ordinances. Provincial Authorities may decide to only issue harvesting permits to applicants who collaborate with, or provide, indigenous biological resources to a Bioprospecting Permit Holder’.⁹²

The Department has also pointed out that packaging and labelling companies exclusively involved in these activities are not required to apply for a bioprospecting permit, but would be required to comply with Provincial legislation and stipulated collecting / harvesting permit conditions.⁹³

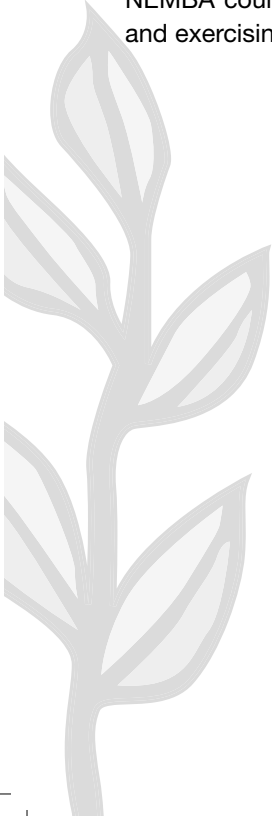
As mentioned above, the ACB was successful in revoking, in its entirety, a patent granted to Schwabe Pharmaceuticals pertaining to the extraction method used for *Pelargonium*. A potential undermining of NEMBA came to light when the CEO of Schwabe asserted in an affidavit in proceedings before the EPO that the Eastern Cape Department of Economic Affairs, Environment & Tourism (EC-DEAET) had issued a collection permit to Schwabe’s co-operation partners on 29 September 2009, and that this permit was based on an application submitted by Schwabe and another South African partner for a permit under NEMBA.⁹⁴

The ACB was able to obtain a copy of the permit⁹⁵ which authorised the Siyazama Project in terms of the Ciskei Nature Conservation Act, 1987 to collect live material specimens from *P. Sidiodes* and *P. Reniform* in the Seymour and Balfour areas. The permit authorised the Siyazama Project to sell collected material to Parceval and stipulated that ‘No plant material may be sold to any other person / company other than Parceval (PTY) LTD as they are the only party that have complied with the Bio-prospecting and Benefit Sharing Regulations’.

It is alarming to the ACB that the harvesting and collection of *Pelargonium* can be authorised by a provincial department in accordance with provincial legislation (in this case old-order apartheid legislation) at a time when a bioprospecting permit application made under NEMBA and the BABs regulations has not yet been decided. This seems to undermine the purpose and intent of the relevant provisions of NEMBA and the BABs regulations.

In addition, it appears strange to the ACB that EC-DEAET created a virtual monopoly for Parceval (and thus Schwabe) by stipulating that the plant material collected could only be sold to Parceval. The reasoning that Parceval was the only party to have complied with the BABs regulations also seems flawed, as while Parceval has applied for a bioprospecting permit, this permit had not been granted (unless, of course, Parceval had submitted its bioprospecting permit application under the transitional provisions and before the 30 September 2008 cut-off). On the face of it, this condition also seems *ultra vires*, as the Ciskei Nature Conservation Act does not give the issuing authority the statutory power to make such conditions.

The potential conflict between provincial legislation and the provisions of NEMBA could, however, be avoided by the authorities invoking s92 of NEMBA, and exercising their powers jointly in order to issue a single, integrated permit.



conclusion



Despite being intended to provide for fair and equitable sharing by stakeholders in benefits arising from bioprospecting, NEMBA and the BABS regulations fail to achieve this objective for all stakeholders.

This situation arises because the legislation imposes a duty on the issuing authority to protect the interests of specified stakeholders only before issuing a permit. Any stakeholders who do not fall within this specified group receive no protection under the regime.

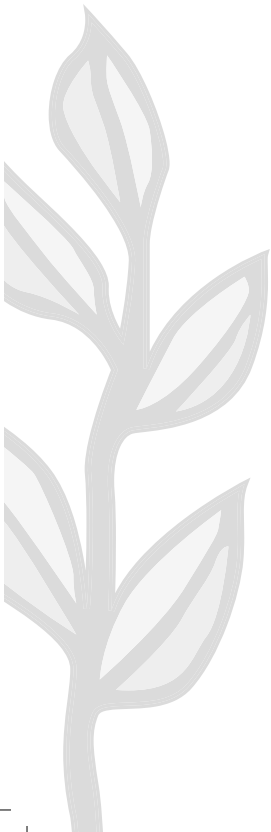
This problem is compounded by the legal regime not imposing any mandatory requirement for applicants to give public notice of bioprospecting permit applications, leaving excluded stakeholders in ignorance of the application and failing to provide them with an opportunity to make a case for inclusion (for example through written representations). The powers exercised by the issuing authority are also not subject to the general public participation and consultation provisions contained in NEMBA. Consequently, the legal regime fails to promote the participation of all potentially interested and affected parties, or to ensure that their interests, needs and values are taken into account. It arguably also infringes upon the rights of potentially interested and affected parties to be heard in the administrative decision-making process relating to bioprospecting permit applications.

While NEMBA and the BABS regulations do require the disclosure of all material information to identified stakeholders, there is no similar requirement for disclosure of information to interested and affected parties who fall outside of this limited category. Experience has shown that requests for information made under PAIA are consistently refused on the basis that the information falls within the meaning of confidential information. This has precluded civil society and other interested and affected parties from accessing sufficient information to enable them to make effective representations in bioprospecting permitting processes. It has also precluded civil society from determining whether permit applications made in respect of existing bioprospecting activities were submitted before the relevant cut-off date. Therefore, it is not known how many of the 34 existing

activity permit applications received by the Department of Environmental Affairs were submitted after the 30 September 2008 deadline.

While NEMBA and the BABS regulations give the permit applicant the right to appeal, and afford identified stakeholders an opportunity to make representations relating to such an appeal, it fails to give members of the public or interested and affected parties the right to appeal against a decision to grant a permit. Excluded stakeholders are also not afforded an opportunity to make representations on any appeal lodged by the permit applicant. In such circumstances, any aggrieved person or community would have to rely on the provisions of PAJA to assert their rights to fair administrative decision-making.

To date, authorities acting under provincial legislation and NEMBA respectively have failed to utilize the statutory provisions authorizing them to exercise their powers jointly and issue a single integrated permit. This has resulted in the anomalous situation arising where provincial permits for the collection of IBRs are granted at a time when bioprospecting applications have not yet been granted.



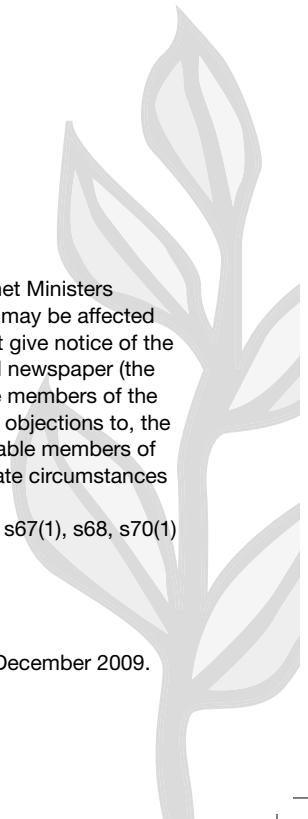
references

- 1 10 of 2004.
- 2 GNR.138 of 8 February 2008, GG No. 30739.
- 3 NEMBA defines “bioprospecting” in relation to IBR as meaning any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, including:
 - (a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application;
 - (b) the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; or
 - (c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation.
- 4 Section 80(a). An ‘indigenous biological resource’ is defined in s80(2) as including:
 - any indigenous biological resources as defined in paragraph (b) of the definition of “indigenous biological resource” in section 1, whether gathered from the wild or accessed from any other source, including any animals, plants or other organisms of an indigenous species cultivated, bred or kept in captivity or cultivated or altered in any way by means of biotechnology;
 - any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any animals, plants or other organisms referred to in subparagraph (i); and
 - any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source which, through the use of biotechnology, have been altered with any genetic material or chemical compound found in any indigenous species or any animals, plants or other organisms referred to in subparagraph (i) or (ii).Excluded from this definition is:
 - genetic material of human origin;
 - any exotic animals, plants or other organisms, other than exotic animals, plants or other organisms referred to in paragraph (a) (iii); and
 - indigenous biological resources listed in terms of the Treaty on Plant Genetic Resources for Food and Agriculture.
- 5 R2.
- 6 “**commercialisation phase of bioprospecting**” is defined in NEMBA as meaning any research on, or development or application of, indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is sufficiently established to begin the process of commercialisation;
- 7 s81(1)(a)&(b).
- 8 s81A of the National Environmental Laws Amendment Act 14 of 2009. This section provides that: (1) No person may, without first notifying the Minister, engage in the discovery phase of bioprospecting involving any indigenous biological resources; (2) A notice referred to in subsection (1) must be in such form and must contain such other particulars as may be

prescribed; (3) A person involved in the discovery phase of bioprospecting must sign a prescribed commitment to comply with the requirements at the commercialisation phase of bioprospecting.”.

- 9 The **“commercialisation phase of a bioprospecting project”** in the BABS regulations has the same meaning as ‘commercialisation phase of bioprospecting’ in NEMBA. The **“discovery phase of a bioprospecting project”** is defined in the BABS Regulations as meaning any research on, or development or application of, indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is not sufficiently clear or known to begin the process of commercialisation;
- 10 R4(1).
- 11 R4(2).
- 12 R5(1).
- 13 R5(2).
- 14 R6(1).
- 15 R6(2).
- 16 Letter from DG, Department of Environmental Affairs, to ACB dated 22 July 2009.
- 17 Letter from DG, Department of Environmental Affairs, to ACB dated 22 July 2009.
- 18 s105.
- 19 R22.
- 20 Letter from DG, Department of Environmental Affairs, to ACB dated 22 July 2009.
- 21 Letter from the Minister of Water and Environmental Affairs to ACB dated 8 December 2009.
- 22 s81(2).
- 23 R8(1). ‘Indigenous community’ is defined in r1 as meaning any community of people living or having rights or interests in a distinct geographical area within the Republic of South Africa with a leadership structure and:
 - (a) whose traditional uses of the indigenous biological resources to which an application for a permit relates, have initiated or will contribute to or form part of the proposed bioprospecting; or
 - (b) whose knowledge of or discoveries about the indigenous biological resources to which an application for a permit relates are to be used for the proposed bioprospecting;
- 24 R8(2).
- 25 R9.
- 26 R9.
- 27 Letter from DG, Department of Environmental Affairs, to ACB dated 22 July 2009.
- 28 In accordance with section 82(4)(b) of NEMBA.
- 29 s88(2).
- 30 s88(3).
- 31 National Environmental Management Act, 1998 (NEMA), s2(4)(f).
- 32 NEMA, s2(4)(g).
- 33 s89.
- 34 s92.
- 35 s93.
- 36 R12(1).
- 37 R13(1).
- 38 R13(2).
- 39 S82(1)
- 40 S82(1).
- 41 s82(2).

- 42 s82(3).
 43 s82(4).
 44 Letter from the Minister of Water and Environmental Affairs to ACB dated 8 December 2009.
 45 s83.
 46 R17(3)(a).
 47 R17(3)(b).
 48 R17(3)(c).
 49 Letter from the Minister of Water and Environmental Affairs to ACB dated 8 December 2009.
 50 GN 677 of 2 July 2010 GG 33348 *National Environmental Management Biodiversity Act (10/2004): Bio-prospecting Benefit Sharing Agreement, p3.*
 51 R17(4).
 52 R16(1). See also s82(3) of NEMBA.
 53 R16(3).
 54 s85.
 55 R19.
 56 R19(4).
 57 R18.
 58 s86(2). See also s99 and s100 for details of the consultative process required.
 59 s86(1).
 60 GNr.149 GG3079 of 8 February 2008: *Notice of Exemption in terms of section 86.*
 61 Letter from DG, Department of Environmental Affairs, to ACB dated 22 July 2009.
 62 s94.
 63 s95.
 64 R14.
 65 R15(1).
 66 R15(2).
 67 R15(3).
 68 S88(2).
 69 PAJA, s3.
 70 s101.
 71 s102.
 72 R20(b) and r21.
 73 R20(b).
 74 s99(1) and s99(2)(c). The Minister is also required to consult relevant Cabinet Ministers (s99(2)(a)) and with the MEC for Environmental Affairs of any province that may be affected by the exercising of power (s99(2)(b)). s100 provides that the Minister must give notice of the proposed exercise of power in the *Gazette*, and in either a national or local newspaper (the latter if only a specific area may be affected). The notice in turn must invite members of the public within 30 days of publication to make written representations on, or objections to, the proposed exercise of power, and must contain sufficient information to enable members of the public to submit meaningful representations or objections. In appropriate circumstances oral representations or objections may be allowed.
 75 S63, read with s52(1), s53(1), s56(1) and s57(1) and S79, read with s66(1), s67(1), s68, s70(1) and s72.
 76 R17(3)(c).
 77 s88(3).
 78 s100.
 79 Letter from the Minister of Water and Environmental Affairs to the ACB, 8 December 2009.
 80 PAIA request dated 23 February 2009, ref. DG25005.



- 81 PAIA request dated 23 February 2009, ref. DG25006.
- 82 Letter from Deputy Director-General: Biodiversity and Conservation to ACB dated 20 May 2009.
- 83 Letter from Adrian Pole Attorneys to the Deputy Director-General: Biodiversity and Conservation dated 17 August 2009.
- 84 Letter from Deputy Director-General: Biodiversity and Conservation to ACB's attorney dated 14 September 2009.
- 85 R1.
- 86 Letter from Deputy Director-General: Biodiversity and Conservation to ACB's attorney dated 14 September 2009.
- 87 The Department also indicated that information on the agronomical infrastructure, the cultivation and harvesting of the biological resource, their research methodology, and chemical analysis of the biological resource was protected under s36(1)(a) and deemed to be sensitive information under s36(1)(b) of PAIA. It was asserted that the disclosure of the information contained in the application 'may threaten the relationship between the parties to the application and various collaborating parties', and that as a consequence the information officer must refuse access. The Department also relied on s37 of PAIA (requiring the information officer to refuse access if the disclosure would constitute an action for a breach of confidence owed to a 3rd party in terms of an agreement) and s43 of PAIA (requiring the information officer to refuse access if the record contains information about research being or to be carried out). The Department also took the view that the request did not qualify for the provisions of mandatory disclosure in the public interest provided for in s46 of PAIA, arguing that the disclosure of any information in the public interest as contained in the permit applications did 'not clearly outweigh the harm contemplated in any of the cited provisions'. The Department also indicated that notice was given to the permit applicants in terms of s47 of PAIA, and that both had provided written representations motivating why the requests should be refused. Gowar Enterprises was reported to have indicated a willingness to discuss and disclose certain information to ACB 'should they contact the permit applicant once the permit application process has been concluded'.
- 88 Permit No. CR 60/11/09.
- 89 Constitution of the Republic of South Africa, 1996, s33.
- 90 Ibid, s32. See also s39 and the Promotion of Access to Information Act, 2000, s9(b).
- 91 *Biowatch Trust v Registrar Registrar Genetic Resources and Others* 2009 (10) BCLR 1014 (CC), at 1032.
- 92 Letter from DG, Department of Environmental Affairs, to ACB dated 22 July 2009.
- 93 Letter from DG, Department of Environmental Affairs, to ACB dated 22 July 2009
- 94 Affidavit by Dr. Rainer Oschmann, signed at Karlsruhe on 13 November 2009.
- 95 Permit No. CR 60/11/09, valid from 30 November 2009 to 31 January 2010. This permit was subsequently purportedly extended to March 2010 through a signature attached to an undated letter from the Siyazama Project to DEAET. A new permit was subsequently issued on 6 April 2010, Permit No. CR 26/04/10, valid to 31 January 2011.

