12 Clamart Road, Suite 3
Richmond
2090
South Africa
www.biosafetyafrica.net

SUBMISSIONS TO THE DEPARTMENT OF ENVIRONMENTAL AFFAIRS AND TOURISM ON THE NATIONAL ENVIRONMENTAL MANAGEMENT: BIODIVERSITY ACT, 2004,: REGULATIONS ON BIOPROSPECTING, ACCESS AND BENEFIT SHARING

By Mariam Mayet and Anouk Verheijen
Mariam@biosafetyafrica.net

INTRODUCTION

The African Centre for Biosafety (ACB) is a non profit organisation, based in Johannesburg South Africa. It provides authorative, credible, relevant and current information, research and policy analysis on issues pertaining to genetic engineering, biosafety and biopiracy in Africa. The ACB is active in playing an effective role in protecting Africa's biodiversity, traditional knowledge, food production systems, culture and diversity, from the threats posed by genetic engineering and biopiracy.

We are grateful to the Department of Environmental Affairs and Tourism (DEAT) for providing the public with opportunities to engage with the protection of South Africa's rich biological resources. The ABS Regulations represent a critical legal mechanism in order for Chapter 6 and related provisions of the National Environmental Management: Biodiversity Act, 2004, to come into effect. Together, these pieces of legislation enable South Africa to implement its obligations and enforce its rights under the United Nation's Convention on the Conservation and Sustainable Use of Biological Diversity (CBD).

On the whole, the Regulations published on the 16 March 2007, by way of Government Notice 329 of 2007, is a marked improvement on earlier drafts, particularly with regard to the creation of more transparent and processes. Nevertheless, we believe that room for improvement does exist.

Our comments are presented in two parts. The first deals with general comments framed under the title "Biopiracy, rights and recourses" and the second, with specific, technical comments.

With regard to the former set of general comments, these are concerned with the legal lacuna that exists between the time South Africa ratified the CBD and the coming into effect of the ABS legal regime in South Africa. Whilst we are cognizant of the fact that laws cannot be enacted/enforced retroactively, we do believe that some legal responsibility does lie on the shoulders so to say, of the South African government, stemming from its international obligations under the CBD. Linked to this, is a general concern about legal and other assistance that should be placed at the disposal of communities where acts of biopiracy have been committed, especially with regard to challenging patents granted in the United States and the European Union, after the coming into effect of the CBD.

ACTS OF BIOPIRACY AND RIGHTS OF RECOURSE

Recently, the ACB successfully tracked two cases of dubious acquisitions of South Africa's endemic medicinal plant species P*elargonium sidoides* (*P. sidoides*) and *Pelargonium reniforme* (*P. reniforme*) in respect of which 3 patents have been filed based on traditional knowledge, pursuant to the marketing of medical remedies Europe and the United States directly derived from these species. *P. reniforme* is indigenous to a wide geographical area in South Africa (Western Cape, Eastern Cape, Kwa-Zulu Natal) and is found at altitudes ranging from near the sea level to 2300m, while the *P. sidoides* predominantly occurs within the Eastern Cape (particularly in areas around Alice, Fort Beaufort, Peddie and Grahamstown.

Both species are traditionally used by the Zulu, Basotho, Xhosa and Mfengi people in South Africa for their ability to treat various symptoms of upper respiratory tract infections and gastrointestinal problems, as well as for treatment of several other infections including cough, fever, tuberculosis, sore throat, fatigue and weakness of the body. Both species are key ingredients in medical remedies sold in Europe and the United States by Murdock Madaus Schwabe (MMS), a private natural products company, deeply involved in bio-prospecting activities around the world.

A German Company ISO Arneimittel, owned by Murdock Madaus Schwabe has submitted three patent applications, in 2002, 2004, and most recently, November 2006. Of the three patents applications submitted (all are based on the **use of extracts** of both species), the most recent patent submitted in Germany (DE20040324395) in November 2006 is directly based on the traditional use of the Perlagonium species, whereas the previous patent applications make more general claims, but crucially, still duplicate traditional uses. These patents were granted in April 2003 and May 2005 respectively.

All three patent applications have been submitted and granted well after the coming into effect of the CBD entered into force. Certainly, the CBD is binding on South Africa for more than a decade.

Despite our extensive enquiries, we have not been able to find any evidence of the existence of ABS agreements with its essential element of Prior Informed Consent (PIC) of both the South African government and crucially, the communities whose knowledge has been exploited.

It is entirely possible that the communities in South Africa, whose knowledge has seemingly been misappropriated, are completely in the dark.

The communities involved are desirous of seeking justice and enforcing international law. The question is, how does it do so? What legal remedies

will the South African put at the disposal of these communities to ensure that the CBD is complied with? Must these communities go to the way side because the South African government has dragged its feet in putting in place legislation to "domesticate" its obligations under the CBD.

In any event, there are no provisions in the ABS regulations that will make legal and other assistance available to communities whose traditional knowledge has been unlawfully appropriated. This is a fatal flaw of the Biodiversity Act, read together with the Regulations, because it is crafted around legal acquisitions that are to be regulated via a permit system.

We would encourage the South African government establish a mechanism to track, trace and monitor cases of biopiracy and have a corresponding support system to challenge patents granted in violation of international law. In addition, the government needs to explore the realm of legal and other interventions that may be put at the disposal of the state and affected communities in the event of a biopiracy case being discovered.

SPECIFIC COMMENTS ON ABS REGULATIONS

Definitions

1. The definition of "indigenous knowledge" makes reference to "biotechnology" twice, without providing a corresponding definition for "biotechnology". We urge DEAT to clarify this.
2. The definition of "bioprospecting" is very wide and includes research, yet in various places, double definitions seem to have been created for instance, benefit sharing agreement speaks of research or bioprospecting whereas "research" is already included in the definition of "bioprospecting";
3. The Regulations do not define "indigenous community" why is this so?
4. A very wide definition has been created for biological resources, which is good, but it does include for instance timber being exported. It may well be necessary to **differentiate use** of the biological resource-something even the CBD has failed or avoided doing.

Linkages with IPR systems

We urge that the ABS regulations make linkages between the ABS/permit system and the patent system, for instance, exclusions from the benefit sharing agreement of patents on the resource. This is essential to ensure that South Africa does not lose control over our resources. There are some examples concerning Teff in Ethiopia that may be looked at for further discussion and guidance.

Issues concerning communities

1. We are concerned that the regulations do not make any provision for legal assistance to be made available to indigenous communities in order to assist them in negotiating Benefit-Sharing Agreements. We are of the opinion that state lawyers should be made available, pro bono to communities in need of such assistance.
2. A clearer link must be made between ownership rights by indigenous communities to the resource and their rights to grant access to the resource, for the sake of legal certainty and clarity.
5. The regulations do not stipulate the time frame within which the money paid into the trust fund will be transferred to stakeholders. At the very least, the phrase "within a reasonable period of time" should be inserted.
6. The regulations should clarify the situation with regard to the use of traditional knowledge that is freely in the public domain. The question is this: are bio-prospectors free to use any indigenous knowledge if it is already part of the public domain either by earlier research publications or because knowledge is wide- spread and therefore commonly held? If so, then a bio-prospector is not forced to seek the PIC from the relevant community nor enter into a benefit-sharing agreement with communities holding this knowledge? We believe this critically important issue not to have been adequately captured in the regulations.
7. The regulations recognize that indigenous knowledge is sometimes held by only a distinct part of a community (for example traditional healers). However, the regulations do not adopt a consistent approach to this issue. Greater care should be taken to ensure consistency throughout the drafting of the Regulations.
8. It is essential that copies of the proposal, reports and other relevant publications be translated in local language if communities so require, as ensuring access to information and greater transparency.

Confidential Information

The provisions dealing with confidential information as these make it possible for everything to be declared CI puzzle us. We believe that the term Confidential **Business** Information should be used instead as being more appropriate and connoting a specific legal interpretation.