to opinion on the issues raised within their areas of expertise; and
- The government should provide appropriate compensation to SAC members so they have the time to review applications and provide good advice to the EC.

Improve the Appeals Process: Now that several EC decisions have been appealed, those procedures should be clarified and improved. The party appealing a decision of the EC should have the right to present its case orally before the Appeals Board. In addition, when the Appeals Board reaches a decision, it should be immediately provided to the applicant. Finally, the time it takes from the date of the request of an appeal to the decision being provided to the applicant should be much shorter than it currently is.

Clarify How Socio-Economic Considerations are Addressed in the Application Process: Stakeholders acknowledged that socio-economic considerations play a role in the review and approval of a GMO application in South Africa. However, the applicant should have some responsibility and role in their assessment. When a concern is raised that involves such issues, the EC should go back to the applicant to conduct any additional assessment and provide evidence involving the issue raised by the application. The government should provide guidance on how socio-economic considerations will be considered in the decision-making process and how they should be analyzed by the applicant. Socio-economic considerations include a benefits analysis of the proposed product.

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1. See: http://www.dst.gov.za/publications-policies/strategies-reports/reports/dst_biotechnology_strategy.PDF
2. See:http://www.dst.gov.za/publications-policies/strategies-reports/The%20Ten-Year%20Plan%20for%20Science%20and%20Technology.pdf
3. See: http://www.nda.agric.za/docs/NPPOZA/Agricultural%20Pests%20Act.pdf
4. See: http://www.nda.agric.za/docs/NPPOZA/PlantBreeder.pdf
5. See: http://www.nda.agric.za/docs/plant_improvement/exemption.htm
6. See: http://www.info.gov.za/acts/1997/act15.htm
7. See: http://www.info.gov.za/view/DownloadFileAction?id=67850
8. See: http://www.info.gov.za/view/DownloadFileAction?id=70641
9. See: http://www.info.gov.za/view/DownloadFileAction?id=68034
10. See: http://www.info.gov.za/view/DynamicAction?pageid=623&myID=152763
11. See http://www.doh.gov.za/docs/legislation/acts/1972/act54.htm
12. See: http://www.info.gov.za/view/DownloadFileAction?id=63042
13. See: http://www.info.gov.za/view/DownloadFileAction?id=68186
14. See: http://www.info.gov.za/view/DownloadFileAction?id=68196
15. See: http://www.cipro.co.za/legislation%20forms/patents/Patent%20act.pdf
16. See: http://www.info.gov.za/view/DynamicAction?pageid=545&sdate=%202008&orderby=act_no%20desc
    Departments of Agriculture, Health, Environmental Affairs, Trade & Industry, Labour and Science & Technology. The Amendment Act has increased this number to eight with the addition of Forestry & Water Affairs and Arts & Culture.
17. See: http://programs.ifpri.org/pbs/pdf/pbsbrief11.pdf

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Policy Brief

December 2010

THE DISPARITY BETWEEN SOUTH AFRICA'S BIOTECHNOLOGY POLICY LEGISLATION

About AATF

The African Agricultural Technology Foundation (AATF) is a not-for-profit organisation that facilitates and promotes public/private partnerships for the access and delivery of appropriate proprietary agricultural technologies for use by resource-poor smallholder farmers in Sub-Saharan Africa (www.aatf-africa.org) www.aatf-africa.org/wema/

About WEMA

The Water Efficient Maize for Africa (WEMA) project is a public-private partnership coordinated by AATF to develop drought-tolerant African maize using conventional breeding, marker-assisted breeding, and biotechnology and make it available royalty free to small-scale farmers in Sub-Saharan Africa.

Produced by AfricaBio www.africabio.com

South Africa has long recognised the importance of a successful biotechnology industry. The national biotechnology strategy was published in 2001 and in 2007, a ten-year innovation plan outlined an ambitious plan to make South Africa one of the top ten nations in the world in terms of the pharmaceutical, nutraceutical, flavor, fragrance and biopesticide industries by 2018 .

In its promotion of biotechnology, South Africa has established structures across the country to enhance biotechnology research and innovation. Four of the most important of these are CapeBiotech, BioPAD, LIFElab and PlantBio, referred to collectively as the Biotechnology (Regional) Innovation Centers. All of these structures have been incorporated into the recently established Technology Innovation Agency or TIA.

The Technology Innovation Agency, (TIA) aims to improve coordination and allow an integrated approach for the promotion of innovation, including in biotechnology. It has also been established as a public funding agency that will ensure that local research and development is converted into commercial products and services. Its primary objectives are to stimulate the development of technology-based products, services and enterprises; develop a technology base for the South African economy and facilitate the development of human capital for innovation.

Current legislation relevant to biotechnology in South Africa is as follows:

- Agricultural Pests Act, 1983 (Act No. 36 of 1983)[1]
- Plant Breeders' Rights Act, 1976 (Act No. 15 of 1976)[2]
- Plant Improvement Act, 1976 (Act No. 53 of 1976)[3]
- The Genetically Modified Organisms Act, 1977 (Act No. 15 of 1997)[4]
- Genetically Modified Organisms Amendment Act, 2006 (Act No.23 of 2006)[5]
- The National Environmental Management Act, 1998 (Act No. 107 of 1998) (NEMA)[6]
- The National Environmental Management: Protected Areas Act, 2003 (PAA)[7]
- The National Environmental Management: Biodiversity Act, 2004 (NEMBA)[8]
- The Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972)[9]
- Regulations governing the labeling of foodstuffs obtained through certain techniques of Genetic Modification[10]
- Promotion of Access to Information Act, 2000 (Act No.2 of 2000)[11]
- Promotion of Administrative Justice Act, 2000 (Act No.3 of 2000)[12]

- Patents Act, 1978 (Act No. 57 of 1978) [13]
- Intellectual Property Rights from Publicly Financed Research and Development Act, 2008 (Act No. 51 of 2008)[14]

Various organisations and programs are active in funding research and development, building research capacity and transferring technology, although not for biotechnology alone. For example, the National Research Foundation is the major body responsible for funding research and human resource development at higher education institutions, national institutions and other councils. In addition, the Department of Trade & Industry's Technology and human resources for industry programme provides funding to innovative research programs that involve an industry partner.

The Disparity

In the development of the GMO Act, a central concept was the formation of an Executive Council (EC) that could make a recommendation to the Minister of Agriculture on any application submitted to the Registrar for a permit to develop, produce, use or apply genetically modified organisms (GMO's) in South Africa. A unique feature of the EC was its composition - it was officially composed of representatives from each government department directly involved in the import, evaluation and use of GMOs . It was hoped that in this way an executive body representing the wide range of government interests, would act as a single vehicle for the discussion and resolution of differences in departmental interests and so streamline the process of evaluating and judging an application. Unfortunately, developments have shown this concept to have been too optimistic. Since the implementation of the GMO Act a number of departments have independently enacted their own legislation on GMOs which has complicated the approval process.

A further complicating factor has been the highturnover of staff in the government sector which has had a negative effect on the time taken to evaluate and approve applications and handle appeals. For example, the Council for Scientific and Industrial Research (CSIR) was involved in a project to develop vitamin enriched sorghum using genetic modification (GM). Initially, the application for a permit for greenhouse trials for GM sorghum was denied but on appeal a favorable response was eventually received – 18 months later! A similar delay was also recorded in the case of an appeal lodged for work on GM cassava.

The damage caused by these slow responses has had many negative outcomes. One of the most important was that most of the R&D for the GM sorghum project has now been moved to Kenya where approval for GM sorghum greenhouse trials was obtained within three months. This case shows that South Africa (which has the most expertise and capacity in plant biotechnology in Africa) is likely to loose the advantage for carrying out projects that involve applications for permits under the GMO Act due to the uncertainty of the regulatory goal posts and the lengthy process each application requires.

The appeal process has also highlighted a number of short comings within the regulatory system:

- The intentions of the GMO Act (and its regulations) and National Environmental Management: Biodiversity Act (NEMBA) is seemingly being misinterpreted, leading to unpredictable "off-the-cuff policy" changes with no scientific basis.
- Biosafety objectives are ostensibly not fully understood – risk assessment (the backbone of biosafety) is an iterative process intended to explore a best fit containment/confinement measure, applying the best science available at the time, for the specific crop and trait.
- A lack of understanding of the progression of biotechnology – development of a GM crop hinges primarily on the biosafety data collated through the various stages, namely, greenhouse and field trials. Denying a greenhouse trial, even in its centre of origin, is tantamount to imposing a ban on research.

While the South African system on GMOs is functioning and has resulted in the official approval of various activities involving GMOs over the past 10 years, many stakeholders believe it could be improved. As a result, the South African biosafety regulatory system was evaluated in 2008 by a number of key stakeholders. This evaluation included a review of operating procedures and authorizing legislation as well as a series of stakeholder interviews. The evaluation resulted in several recommendations to improve the operations and allow it to become more efficient and effective.

For example:

The Executive Council Should Provide a Formal Decision Document to Applicants and the Public: Currently, the Executive Council (EC) decides permit applications by consensus and informs the applicant of its decision by having the Registrar issue a permit to the applicant and then places notice that a permit has been issued on its website. The EC does not write down the basis of its decision in an official government decision document that could be released to the applicant or the general public.

Executive Council should memorialize its decision on GMO applications in a document accessible to the public: That document should explain the basis for the decision and would be available for use in any appeal of an adverse decision. Such a document would provide feed back to applicants about the issues pertinent to their application and also inform other developers about issues that were of concern to the EC.

Increase the Transparency of the Work of the Biosafety Regulatory System: If a biosafety regulatory system is transparent; it is more understandable to the different stakeholders (applicants, government officials, and the public at large) and can be more efficient. It can also result in decisions that garner more public confidence.

Provide for More Efficient Communication between the EC and Others: Under the current procedures the EC communicates any questions or issues it has to applicant or its science advisors through written correspondence from the Registrar. The EC should be allowed to invite the applicant to answer questions at its meetings. In addition, the chairperson of the expert review committee or a member of the Science Advisory Committee (SAC) knowledgeable about the particular issues raised by an application be present at the EC meeting to answer any scientific questions from EC members. The applicant could be allowed to orally present its application to the Registrar if the Registrar believes that would be helpful to performing its duties.

Improve Forms and Provide Additional Guidance: To both improve transparency and to make the biosafety regulatory system more efficient for both applicants and regulators, current forms needed to be revised. Current forms should be made user friendly and should be relevant to the specific application. For example, a commodity form should not request environmental information that is needed for a general release GMO. Guidance should be provided on new GMO applications, such as on stacked gene applications or pharmaceutical crops. In addition, more specific guidance would be helpful on the various studies needed for different applications. The regulatory system could allow the applicant to ask questions in advance of submitting an application for a novel type of GMO, such as nutritionally enhanced product, so that the application can be complete when it is finally submitted.

Ensure that the Executive Council Gets the Needed Expert Advice for Reviewing Applications: Applications and their corresponding risk assessments raise issues where the EC needs independent expert advice. The current SAC and its advisory panels perform this important function but stakeholders believe the process for obtaining expert advice could be improved with the following changes:

- The SAC should match the reviewers with the particular issues raised by an application (including the use of non-scientists such as an economist when an application raises economic or trade issues);
- The reviewers should be allowed to meet and achieve a consensus opinion on the issues raised by the application and then forward it to the EC (as opposed to the current process of providing the EC with a summary of the different reviewer opinions);
- The report of the experts should be standardized;
- When an application raises issues that go beyond the expertise of the three reviewers, all SAC members should be given the opportunity