

# Analysis of Malawi's Biosafety Legislation

By Mariam Mayet  
April 2004

## BACKGROUND

The government of Malawi published its biosafety draft regulations in *The Malawi Gazette Supplement* on the 13<sup>th</sup> September 2002<sup>1</sup> ("biosafety law") at the height of the GM food aid controversy when several countries in Southern Africa imposed restrictions on the acceptance of genetically modified food aid from the United States. Malawi accepted the GM food aid, with few restrictions being imposed. At the time of writing, the writer obtained conflicting information as to whether the draft law had been promulgated. However, the writer was able to ascertain that the biosafety law, represents the current biosafety framework.

Malawi is not yet a Party to the United Nation's Cartagena Protocol on Biosafety ("Biosafety Protocol"), nor is it amongst the 123 developing countries participating in the UNEP-GEF Biosafety Capacity Building project.<sup>2</sup> It was however, one of 7 "core target"<sup>3</sup> countries in Southern Africa that participated in a USAID funded biosafety capacity building project, the **Southern Africa Regional Biotechnology Program (SARB)**<sup>4</sup>

SARB is a sub-project of a larger United States Assistance for International Development (USAID) project, managed by the Michigan State University, **Agricultural Biotechnology Support Program (ABSP)**.<sup>5</sup> <sup>6</sup> ABSP's private sector partners include, Asgrow, Monsanto Co. Garst See Company (ICI Seeds Inc), Pioneer Hi-Bred and DNA Plant Technology (DNAP).<sup>7</sup>

The objective of SARB is to "build regional policy and technical capacity supportive of science-based regulation of the development, commercial application and trade in agricultural products derived from modern biotechnology".<sup>8</sup> However, USAID is more forthright on SARB's specific objective, which is to provide the "**regulatory foundation to support field testing of genetically engineered products.**"<sup>9</sup> (own emphasis).

SARB was a three-year project (2000-3), co-ordinated by South Africa's Agriculture Research Council (ARC)-Vegetable and Ornamental Plant Institute. SARB's person in charge of biosafety training is Ms Muffy Koch, a member of the industry lobby group, Africabio in charge of education issues.<sup>10</sup>

The SARB project conducted a number of workshops in several Southern African countries and other communication outreach events and in so doing, specifically targeted decision-makings, scientists and the media.<sup>11</sup> The industry influence at some of these workshops is clearly apparent. For instance, SARB workshops conducted in South Africa were supported by Dr. Donald Mackenzie, Vice President of Agbios, Canada.<sup>12</sup> SARB workshops held in Mauritius were hosted by the Mauritian Sugar Industry Research Institute<sup>13</sup>. These workshops were supported by consultant, Julian Kindelerer

who "added an international flair to the resource team from SARB."<sup>14</sup> NGOs in South Africa have long since held the view that Julian Kindelerer has been associated with drafting of South Africa's weak regime relating to GMOs.<sup>15</sup> This regime has been described by environmental and development lawyers in South Africa, as displaying "a cynical disregard for contemporary international and national environmental principles, as well as for the development imperatives of South Africa"<sup>16</sup>.

## OVERVIEW OF MALAWI'S BIOSAFETY LAW

### GENERAL

1. Malawi's Biosafety law is unspeakably appalling, displaying a flagrant and contemptuous disregard for biosafety. It is the only "biosafety" law that we have seen so far, that mentions or deals with issue of risks posed by GMOs to human health and the environment in its preamble only and not in its operational provisions! The Biodiversity law makes a mockery of the Biosafety Protocol-hard fought by the African Group of countries.

2. Malawi is the first country on the African continent to allow gene therapy for humans to be regulated and allowed at all, in Biosafety legislation. It is also the first country to brazenly produce biosafety legislation that has absolutely nothing at all, to do with biosafety.

3. The policy imperatives underpinning this law include:

- Ensuring that research and experiments of GMOs can take place with minimum or no biosafety restrictions being imposed by creating a **special permit** system (section 18);
- Ensuring that genetically modified (GM) food aid is accepted with there being no restrictions placed on the receipt of such food aid through a special **permit system** (section 18);
- Ensuring that GMOs and its products imported into Malawi takes place with minimum or no restrictions being imposed; (section 20);
- Establishing a **licensing system** for a variety of activities concerning GMOs and products of GMOs, including field trials, commercial growing, manufacture, wholesale and dispensing (in the case of GM pharmaceuticals) (section 19). This licensing system does not encompass any **biosafety measures such as risk assessments, environmental risk assessments, risk management, post-release monitoring; the precautionary principle; socio-economic impacts; liability and redress etc.**
- Establishing a decision-making structure for the issue of licences on inappropriate and non-biosafety criteria (sections 22 and 23);
- Completely excluding the public from public participation in regard to the regulation and decision-making concerning GMOs and products of GMOs;
- Trying to appease the public by making it possible for the labelling of GMOs and products of GMOs. (section 26) and by providing for

- measures to control the advertising of GMOs and products of GMOs (section 28);
- Protecting industry information on pain of criminal sanctions (section 38).

## **SPECIFIC COMMENTS**

### **Permitting and Licensing Systems**

1. The law establishes a permitting and a licensing system.
2. Permits are required for scientific activities and emergency supply of food for human beings.<sup>17</sup> However, the purpose of such permits appears to provide the façade of biosafety sanction in order to enable the unrestricted research and experiments to take place in Malawi concerning GMOs and for the unrestricted acceptance of GM food aid. This is so, because the holder of the permit is entitled to request the Minister of Environmental ("Minister") Affairs to exempt it from complying with all or any provisions of the Act and the Minister is given the power, at his or her own discretion to grant such exemption.<sup>18</sup>
3. No other information is given in the law concerning this permitting system. An application for a permit is to be made in a prescribed form. The form that will be prescribed i.e. by way of regulations (secondary legislation).
4. No provision is made for the furnishing of relevant biosafety information when application is made for a permit.
5. Licences are required for the genetic modification of organisms, importation, development, production, testing, release, use and application of GMOs and the use of gene therapy in animals, including human beings.<sup>19</sup>
6. Four different types of licenses are introduced, namely, a "products license", a "manufacturers license", a "wholesale dealers' licence" and a "dispensers licence".
7. A "product licence" is required for the sale, supply or export of GMOs or products of GMOs. It must be noted that although a licence is required for exports from Malawi of GMOs or products of GMOs, the legislation does not apply to exports. Exports have been specifically excluded from the scope of the Law.
8. The production and manufacture of GMOs or products require a "manufacturers licence".
9. The sale and supply of GMOs or products of GMOs require a "wholesale dealer's licence".

10. A retail pharmacy business will require a "dispensing licence" for GMOs or products of GMOs.
11. It appears that the sale and supply of GMOs or products will require 2 licences-a "products" licence as well as a "wholesale dealer's licence". However, the distinguishing characteristics of these licences are not provided in the law.
12. An application for a licence will have to be made in accordance with a form that will be made by regulations.
13. The only information that the applicant is required to furnish when making application for a licence is "a description of products to which the licence will relate". A description of the GMO or product of a GMO is perhaps the most basic information and cannot under any circumstances, suffice as information upon which a biosafety evaluation can be made. If the applicant is only required to furnish a description of the products, on what data will a decision be made as to the risks posed by GMOs to the human health, the environment, biodiversity? Compare this for example, to the requirements of Annex I of the African Model Law on Safety in Biotechnology (African Model Law) which sets out an extensive list of information that an applicant must furnish in order to place before a decision-making authority sufficient data upon an evaluation can be made.
14. Crucially, the biodiversity law does not require a risk assessment to be conducted for any GMO or products for GMOs. There is no provision made in the law for the conducting of risk assessments for any GMO or products.

## **Decision-making**

### **Undemocratic decision-making**

The biosafety law vests all decision-making powers in a single person, namely, the Minister of Environmental Affairs ("the Minister"). As the sole decision-making authority, the Minister is not obliged to consult, as would be expected in a biosafety regime, with any scientific or expert panel in the exercise of his functions and powers. Indeed, the law does not establish any institutional mechanism whereby scientific and other relevant expertise is obtained.

### **Decision-making for licences**

The Minister is obliged to take into account certain factors before he or she **grants** a licence. These include the safety of GMOs or products.<sup>20</sup> However, the Minister will not be able to evaluate the application for risks to human health based only on information about the description of the GMO or product in question in the absence of a risk assessment. Furthermore, there is no obligation on the Minister to consider adverse impacts on the environment, biodiversity or socio-economic impacts.

Several other criteria are set out that the Minister must take into account before granting a licence. These include the efficacy and quality of GMOs and products of GMOs. These are not considerations normally taken into account in a biosafety assessment and evaluation. In fact, these issues are not relevant for the purposes of a biosafety assessment and evaluation.

The Minister is also obliged to take into account, the operations and procedures proposed by the applicant. However, what these would and should entail is left entirely to the discretion of the applicant and is thus a typical example of self-regulation by industry//permit holder.

The balance of the criteria set out in the law do not deal with the risks posed by GMOs and products to human health, the environment and biodiversity, but is rather, concerned with the premises where operations will take place; equipment to be used, the keeping and maintenance of records; storage etc.

The biosafety law also contains a peculiar provision: it allows the Minister to grant a licence only if he is satisfied that the applicant *if the applicant is a fit and proper person to engage in such activities.*<sup>21</sup> Why this issue should be a decisive factor and not the adverse impacts of GMOs on human health and the environment is a mystery!

Where the Minister imposes conditions on licences, these may also be varied at the instance of the applicant if the Minister is satisfied that the variation will not adversely affect the safety, quality and efficacy of GMOs or products thereof.<sup>22</sup> If conditions are imposed, they should be complied with. These provisions epitomise the essence of the law: the facilitation of the uptake of GMOs in Malawi.

### **Refusal of licences**

The only grounds upon which an application for a licence can be refused contemplated by the biodiversity law is when the Minister does not consider the applicant to be a fit and proper person.<sup>23</sup> This is really out of place in a biosafety regime where considerations of safety are of paramount importance. The grounds for refusal should be based first and foremost on full and complete biosafety data and information as to the risks involved, information regarding potential socio-economic impacts and the precautionary principle.

### **Biosafety Fund**

A Biosafety Fund is established to fund the administration of the Act. The acceptance of voluntary contributions or donations is specifically provided for.<sup>24</sup> This means that industry is allowed to make contributions toward the funding of the legislation.

Minister is also empowered to impose a levy on gross net income accruing to any person or class or persons money.<sup>25</sup> This provision on the face of it appears to be imposing a levy, but it can function as an incentive for the government to issue licences in order to obtain funding for the administration

of the Act. The more licences are granted, the more levies may be imposed, the more money there is to grant more licences for GMO approvals.

### **Public Participation**

No explicit or clear provisions exist in the biodiversity law dealing with public participation. Although the Minister is obliged to conduct an inquiry, including a public inquiry, into any matter requiring investigation under the Act, the Minister has the power to exercise this function, at his sole discretion.

The fact remains, however, that the public is not included in the administration of this legislation. For instance, there are no provisions regarding access to information by the public regarding applications for permits and licences and the right to object to such applications. There is also, no obligation whatsoever placed on the Minister to take into account the views of the public of affected communities before making a decision.

### **Criminalising disclosure of information**

The biodiversity law makes it a criminal offence for any person employed under the Act to disclose **any** information acquired in relation to the financial or business affairs of any person, undertaking or business.<sup>26</sup> This provision goes well beyond the ordinary statutory protection of confidential business information. It is "confidential business information" that usually is protected by legislation not "any information relating to business affairs". To criminalise the disclosure of such a huge bulk of information in one foul swoop, to protect industry is extremely disturbing!

### **Labelling of GMOs and products**

The Biosafety Law does provide for the labelling of GMOs and products<sup>27</sup>. However, these provisions will only be operational once regulations are made to give effect to them.

## **CONCLUSION**

While it is acknowledged that the ultimate responsibility for this law must be placed firmly at the door of the Malawian government, the influence of the SARB project on Malawi's decision-makers and scientists in the production of this astonishingly bad piece of legislation cannot be ignored.

I have written elsewhere of the ever-present danger that "biosafety" projects funded by USAID would threaten to influence weak biosafety regulation on the African continent.<sup>28</sup> This Malawian Biosafety Law appears to vindicate those fears.

Mariam Mayet is with the African Centre for Biosafety  
E-mail: mariammayet@mweb.co.za

- 
- <sup>1</sup> Biosafety Bill 2002, B. No.13, 13 September 2002.
- <sup>2</sup> <http://www.unep.ch/biosafety/devcountries.htm>
- <sup>3</sup> The other 6 countries include Mauritius, Mozambique, Namibia, South Africa, Zambia and Zimbabwe.
- <sup>4</sup> USAID Fact Sheet *SARB: Southern African Regional Biosafety Program*  
<http://www.usaid.gov/press/facsheets/2003/fs030623.html>
- <sup>5</sup> USAID Launches Biotechnology Initiatives with Africa” programs foster improved regulation, research, development  
<http://www.biotech-info.net/USAID.html>
- <sup>6</sup> ABSP Biosafety  
<http://www.ija.msu.edu/absp/biosafety.html>
- <sup>7</sup> ABSP Biosafety  
<http://www.ija.msu.edu/absp/partners.html>
- <sup>8</sup> Thompson, G. J, Koch, M, & Brink, J.A., *Southern Africa Regional Biosafety Program (SARB)*  
[www.afr-sd.org/Agriculture/Biotechnology/SA%20Reg%20Biosafety%20SARB.PDF](http://www.afr-sd.org/Agriculture/Biotechnology/SA%20Reg%20Biosafety%20SARB.PDF)
- <sup>9</sup> USAID Fact Sheet *SARB: Southern African Regional Biosafety Program*  
<http://www.usaid.gov/press/facsheets/2003/fs030623.html>
- <sup>10</sup> <http://www.africabio.com>
- <sup>11</sup> Thompson, G. J, Koch, M, & Brink, J.A., *Southern Africa Regional Biosafety Program (SARB)*  
[www.afr-sd.org/Agriculture/Biotechnology/SA%20Reg%20Biosafety%20SARB.PDF](http://www.afr-sd.org/Agriculture/Biotechnology/SA%20Reg%20Biosafety%20SARB.PDF)
- <sup>12</sup> ABSP Biosafety  
<http://www.ija.msu.edu/absp/partners.html>
- <sup>13</sup> MSIRI is a statutory body funded by the global cess on sugar production by all cane growers. It employs 150 scientists and technicians and is governed by a Board of Directors comprising of 7 representatives of millers, growers and the Chamber of Agriculture and 3 governmental representatives. See  
<http://webmastersiri.intnet.mu/Engsite/webpage/biotechhome.htm>  
See also, by Appasawmy, S. GMO Legislation - The Mauritian Paradox Apr 2, 2004, GENET-news archives  
<http://www.genet-info.org>
- <sup>14</sup> ABSP Biosafety  
<http://www.ija.msu.edu/absp/partners.html>
- <sup>15</sup> See further, Mayet, M. August 1999 *Critical Review of Existing Legislative Framework for Genetic Engineering In South Africa* Biowatch South Africa. And Mayet, M. February 2000 *Srutinising the Legalities of Genetic Modification in South Africa: Food Safety, Public Participation and the Conservation and Sustainable Use of Biological Diversity*. Biowatch South Africa. Found at  
<http://www.biowatch.org.za>
- <sup>16</sup> Biowatch condemns South Africa’s genetic engineering laws, March 10, 2000  
<http://www.wildnet africa.co.za/wildlifene ws/2000/02/228.html>
- <sup>17</sup> Section 18(1).
- <sup>18</sup> Section 18(3).
- <sup>19</sup> Section 17.
- <sup>20</sup> Section 22(a).
- <sup>21</sup> Section 23.
- <sup>22</sup> Section 25.
- <sup>23</sup> Section 23(3).
- <sup>24</sup> Section 7(1)(d)
- <sup>25</sup> Section 8.
- <sup>26</sup> Section 38.
- <sup>27</sup> Section 26.
- <sup>28</sup> Mayet, M., Africa-the new frontier for the GE industry  
<http://www.twinside.org.sg/>