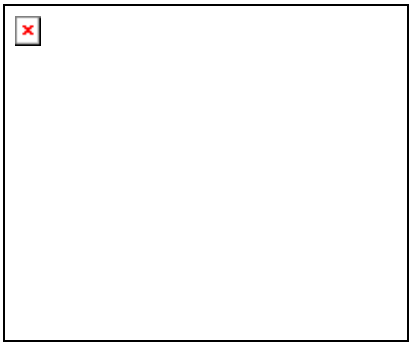
OBJECTIONS TO THE APPLICATION MADE BY THE COUNCIL FOR SCIENTIFIC AND INDUSTRIAL RESEARCH (CSIR)

IN RESPECT OF CONTAINED USE OF GENETICALLY MODIFIED SORGHUM

TO THE NATIONAL DEPARTMENT OF AGRICULTURE, SOUTH AFRICA

BY



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BACKGROUND

Sorghum

Sorghum, a grass of east African origin, is said to have present as early as 8000 years ago. The timing of the emergence of the domesticated sorghum, *Sorghum bicolor* from the wild species progenitor is disputed with dates ranging from 3700-4900 years ago to not much before 2000 years ago.[i] Four main groups can be identified within the sorghum family: grain sorghums such as milo, grass sorghums cultivated for pasture and hay, sweet sorghums (also known as Guinea corn) used in the production of sorghum syrups and broomcorn (for brooms and brushes).[i] Sorghum was introduced into the western hemisphere in the early sixteenth century, and is now an important crop in the United States and Mexico.[ii]

Sorghum bicolor is an important source of food and fodder in the semi-arid tropics of the world[iii] and is used in the production of alcoholic beverages[i] and is a staple food for more than 500 million people in more than 30 countries.[iii] Industrially, sorghum can be used for vegetable oil, waxes and dyes.[iii]

Florence Wambugu

Kenyan scientist Florence Wambugu built her pro-GE reputation during her time working for Monsanto on its GM virus-resistant sweet potato project. Post-Monsanto Dr Wambugu became the first Director of the AfriCentre of the International Service for the Acquisition of Agri-biotech Applications (ISAAA) a U.S.-centred, GM promotion and 'technology transfer' agency funded by AgrEvo, Bayer, Cargill, Dow, Monsanto, Novartis, Pioneer and Syngenta to name a few. The AfriCentre had as its main aim, the introduction of GM into Sub-Saharan Africa, establishing in the process, several pro-GM fronts, such as the African Biotechnology Stakeholders' Forum (ABSF), of which she is the Vice Chair, and the African Biotechnology Trust. At the beginning of 2002, Dr Wambugu established African Harvest Biotechnology Foundation International (AHFBI) which has a pro-GE communication program funded by CropLife International an organization led by companies such as BASF, Bayer, Dow, DuPont, Monsanto, and Syngenta.[iv]

Florence Wambugu's reputation is built on the Monsanto-developed virus-resistant sweet potato. Forbes reported that the results of Kenyan sweet potato trials were astonishing with double the yields.[v] The Toronto Globe and Mail claimed even greater yields.[vi] The FAO listed the sweet potato project as an example of successful technology development.[vii] In contrast, Kenya's Daily Nation,[viii] the New Scientist[ix] and The Guardian[x] all exposed the sweet potato trials as a failure with transgenic crop yields much lower than non-transgenic tubers and with the plants susceptible to viral attack, the very thing it had been created to resist.

Wambugu claimed that the aim of the trials was really to test the extent of the problems faced at a very early stage in the project. At no point were the claims of the Kenyan Daily, Guardian or the New Scientist ever refuted. To add insult to injury, Wambugu has claimed that conventional breeding research had proved powerless to develop varieties resistant to these viruses' and that 'the time and money spent actually developing GM varieties are less than for conventional varieties'.[vi] This, despite reports of a successful conventional breeding programme in Uganda, which had already produced a new virus-resistant variety with raised yields by roughly 100%.[xi]

The Bill and Melinda Gates Foundation's Role in the Development of Genetically Engineered (GE) Sorghum

Wambugu sits on the Science Board of the Grand Challenges in Global Health, the initiative created by the Bill and Melissa Gates Foundation (BMGF).[xii] Wambugu's African Harvest Foundation, in collaboration with DuPont Crop Genetics Research (Pioneer HiBred International) has been granted $16.9 million by the BMGF to conduct research on Nutritionally-Enhanced Sorghum for the Arid and Semi-Arid Tropical Areas of Africa. This project has been given the moniker, the Africa Biofortified Sorghum (ABS) Project. Already under this grant, in partnership with the Council for Scientific and Industrial Research in South Africa, a genetically engineered new variety of sorghum containing increased levels of the amino acid lysine has been produced.[xiii]

The Africa Bio-Fortified Sorghum (ABS) Project

The stated aim of the ABS Project is to "develop sorghum with improved food quality by enriching it for essential amino acids (part of the protein component of the diet), and later by increasing its content in essential vitamins (vitamin A and E)"[xiv] and to do so by the application of genetic modification. The outcome of this project would be the development of a Super Sorghum.[xiv]

THIS APPLICATION

Application to the Department of Agriculture, South Africa for Contained Use of GM Sorghum

An application was submitted to the South African Department of Agriculture to conduct laboratory and greenhouse experiments on GM sorghum. This application was denied in an Executive Council (EC) decision taken at a council meeting in 15 June 2006. The EC is a statutory body established by the Genetically Modified Organisms Act comprising six government departments (science and technology, agriculture, trade and industry, health, labour, and environmental affairs and tourism). The recommendations of the EC to the CSIR were that "the experiment be conducted on a non-indigenous species with no wild relatives in South Africa", and that a level 3 containment facility be used to conduct the experiment.[xv] Further the EC cited concerns regarding the risks "pertaining to possible impact as a result of gene flow on bio-diversity".[xv] Derek Hanekom, the deputy science and technology minister said in August 2006 that the South

African government might well reconsider its stance if the CSIR could demonstrate to the council that the sorghum is suitably contained.[xvi]

In September 2006, an application was re-submitted in the name of the CSIR Biosciences to conduct an assessment of GM sorghum that has been engineered to express a high-lysine storage protein from barley.[xvii] The African Centre for Biosafety (ACB), in response to an application to the Department of Agriculture for details of the application, has been given a non-CBI version of the application. This version excludes several portions of the application which have been designated CBI.[xvii] Crucially, the molecular characterization information, risk assessment data (annex 5) and reference list has been omitted. This new application provides for the use of a level 3 containment facility.

Description of the Sorghum Modification from Available Information

For the purposes of this discussion, all references in parentheses refer to the relevant sections and/or pages in the application.[xvii] The GM sorghum event under discussion here has been given the identifier ABS1.[xvii] Sorghum line P898012 was transformed by *Agrobacerium*-mediated transformation with a binary vector containing HT12, alpha hordothionin barley protein and *bar* genes.[xvii] Hordothionin is a barley seed protein which carries 5 out of 45 lysine residues. A mutated form, of *Hordeum vulgare* alpha-hordothionin protein, developed by molecular modelling contains 12 lysine residues and has been designated H12.[xviii] ABS1 contains this mutated form under the control of the maize gamma zein promote and terminator. No copy number details are available.

Glufosinate-ammonium salt (or phosphinothricin), often referred to as just glufosinate, is a broad-spectrum contact herbicide that behaves sufficiently like the amino acid glutamate to enable it to disrupt the conversion of glutamate to glutamine. It disrupts the enzyme mediated reaction by inhibiting glutamine synthetase activity in susceptible plants, resulting in reduced glutamine production. Glutamine synthetase also regulates ammonia levels by detoxification and disruption of the enzyme activity results in elevated ammonia levels.[xix] The *bar* (bialaphos resistance) encodes the phosphinothricin-N-acetyltransferase enzyme which catalyses phosphinothricin acetylation effectively rendering it inactive and thereby enabling transformed plants to withstand phosphinothricin based herbicide applications. It is unclear under what promoter and terminator control the *bar* gene is in ABS1.

Part 3 Chapter 4 Sections 64 (1) (b) and (c), Section 65 and Section 68 (1) (b) and (c) (ii) which appear to be detail of the molecular description and characterisation have abeen designated confidential business information (pages 7 and 8). No details of the full Zhao reference (page 9) have been included in the information pack we have received. The Zhao reference apparently makes the claim that no vector backbone was integrated into the genome.

MAIN CONCERNS

Potential Adverse Impacts of ABS1 as Stated in the Application

The application states that:

- No growth retarding activity or toxicity was detected (page 8)
- No antimicrobial activity was detected (page 8)
- There are no known toxic or allergenic effects related to insertion of the modified gene (page 8)
- The HT12 protein does not have any known hazards for human health because it's source is barley (page 9)
- The only possible concerns are potential sensitivity to pollen (page 9)
- There is no health and safety need to wear protective clothing or use other safety measures (page 9)[xvii]

The statements made regarding toxicity are not supported by any referenced research and it is unclear how this conclusion has been reached by the applicant.

Gene Flow

The lack of sophisticated methods for targeted insertion, especially in higher organisms.[xx] necessitates more rigorous research into possible position effects prior to the granting of any release of transgenic organisms into the environment. Further, if transgenes behave just like naturally occurring genes, then they have the potential to be inherited in the same way and persist indefinitely in cultivated or free-living populations. Any mixing of native and transgenic plants whether by dispersal, improper handling etc., can result in the spread of transgenes. The consequences, both ecological and evolutionary of crop-to-crop gene flow are only now beginning to be investigated in any meaningful way and the possible exposure of non-target organisms, including humans to novel proteins cannot be discounted.[xx]

The evolution of antibiotic resistance, for example, is an indicator of the frequency of gene transfer, given that antibiotics have been used in medicine only for about 50 years.[xxi] The intentional modification of plants could through horizontal gene transfer result in the unintentional modification of other organisms. What the possible impacts of such gene transfer might be is not known. There are several reported cases in the literature of both the persistence and transfer of gene sequences after ingestion of GM products. Polymerase chain reaction (PCR) has been used to demonstrate the presence of large fragments of M13 phage DNA, which had been fed to mice, in the faeces and bloodstream and in white blood cells[xxii] Research published by the UK government in 2002 has shown that bacteria in human intestines had in fact taken up a novel gene from

processed food containing GM Soya.[xxiii] It has been reported that people with ileostomies (i.e. who make use of a colostomy bag) are capable of acquiring and harbouring DNA sequences from GM plants in the small intestine.[xxiv] Recombinant DNA fragments and Cry1Ab protein was also found in the gastrointestinal contents of pigs fed genetically modified corn[xxv].

In February 2005 Schmidt and Bothma reported on a crop-to-crop gene flow risk assessment study which was conducted with *Sorghum bicolor* subsp. bicolor to estimate the impact of transgenic sorghum in (South) Africa.[xxvi] This study was funded by the Agricultural Research Council at which Bothma is employed. The field trial was conducted at on the 4000-ha ARC research farm Roodeplaat close to Pretoria. A central sorghum field (30 x 30 m) was planted with male fertile donor plants and surrounded by eight arms planted with male sterile recipient plants at a distance of 13 to 158 m from the central field. Gene flow was found to be high within the first 40m and whilst low beyond this point, regardless gene flow was detected even at the 158 m point. In South Africa we have the presence of fully fertile crop wild relatives and the weedy relative johnsongrass [S. halepense (L.) Pers.], which may form hybrids with crop sorghum. The authors concluded that the fact that gene flow takes place and the presence of these weedy and wild relatives provides strong evidence that introgression of genetically modified- (GM)-sorghum into crops and crop wild relatives will take place once GM-sorghum is deployed.[xxvi]

Genetic modification: degree of certainty

In general, genetic modification by the application of recombinant DNA technology is characterised by scientific uncertainty. This stems from several factors including the inherent imprecision of currently employed recombinant DNA techniques, the use of powerful promoter sequences in genetic constructs and the generation, as a result of genetic modification, of novel proteins to which humans and animals have never previously been exposed.[xxvii] None of the current transgene insertion techniques permit control over location of the insertion site or the number and orientation of the genes inserted.[xxviii] The extent of unintended effects arising out of genetically engineering food plants are only now being truly realised and current risk assessment protocols do not measure for these unintended effects. Indeed, the technologies for measuring these effects are still being developed.[xxix] Additionally, the gaps in the knowledge regarding composition and functioning of the genomes that are often subjected to genetic manipulation and ill-designed experiments compound such scientific uncertainty.[xxvii]

A recent study on transgenic peas from Australia illustrates how even the same gene in two different plant species can have different health effects because the transgenic protein may be modified differently in each plant. Peas expressing a gene for R-amylase inhibitor-1 from the common bean were generated to protect the seeds from damage by inhibiting the R-amylase enzyme.[xxx] This transgenic bean is harmless in beans but displayed immunogenicity to mice when expressed in peas.

Uncertainty is a key element of the Biosafety Protocol (Cartagena Protocol on Biosafety to the Convention on Biological Diversity.[xxxi] The lack of sufficient relevant scientific information and knowledge regarding the extent of potential adverse effects allows the Precautionary Principle referenced in the Biosafety Protocol to be triggered. The precautionary principle states "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be use as a reason for postponing cost-effective measures to prevent environmental degradation".

Herbicide use and GM crops

ABS1 is designed to tolerate glufosinate applications. One of the draw cards, as claimed by seed companies for the use of GM seed is the benefit of reduced herbicide use. Research in support of this claim is by and large carried out by the developers of GM seeds in field scale evaluations. Trends in the degree and extent of herbicide applications with the advent of GM crops are only now emerging. In the USA, planting of GM crops has led to a substantially greater use of herbicides than non-GM crops with significant year on year increases particularly for GM Soya and maize. Between 2001 and 2003, the planting of GM crops resulted in 73 million pounds more agrochemicals being applied in the USA[xxxii]. Benbrook examined agrochemical use on GM crops,[xxxii] including most recent impacts (since 2002). His data is in agreement with USDA estimates for earlier years. He observed that 'proponents of biotechnology claim that GE varieties substantially reduce pesticide use. While true in the first few years of widespread planting it is clearly not the case now'. Further he found that there is now 'clear evidence that the average pounds of herbicides applied per acre planted to herbicide tolerant (HT) varieties have increased compared to the first few years of adoption. Herbicide tolerant crops have increased pesticide use an estimated 70 million pounds over the last eight years.

Herbicide Tolerance and Effects on Non-Target Species

The main environmental concern related to introducing herbicide resistance into transgenic plants is the development of weed populations that are resistant to particular herbicides, the so-called superweeds.[xxxiii] These weeds may then be able to successfully outcompete other non-herbicide–resistant weeds.[xxxiv] This may result in increased use of herbicides in greater volumes and varieties with possible negative impacts on soil and groundwater.[xix] Glufosinate in particular is defined as being persistent, mobile in soil and highly soluble in water. The large scale cultivation of glufosinate resistant crops will result in an increase in the use of glufosinate with concomitant negative environmental impacts. The full impact of glufosinate on groundwater can only really be determined by long-term monitoring programmes.

LEGAL ISSUES IN RESPECT OF ABS1

Biosafety Reform Still Pending

The Department of Environmental Affairs and Tourism (DEAT) carries an onerous responsibility: it is the government agency tasked with the function of ensuring that

South Africa's international obligations under pertinent multilateral environmental agreements are honoured-such as the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. It also has incurred serious obligations to protect South Africa's biodiversity and exercise fair administrative decision-making based on the precautionary principle when it takes decisions as member of the Executive Council: Genetically Modified Organisms Act. In this regard, DEAT's constitutional and legislative mandate (in terms of NEMA, the Biodiversity Act) has led it into various proactive biosafety projects including the development of an Environmental Risk Assessment Framework for GMOs, and more recently, the launch of a new Biosafety Research Strategy with a vision for ***"Biosafety Challenge Managed"*** and the mission described as follows: ***"By 2010 the South African society experiences an effective system to manage GMO released into the environment…..By 2010 a stronger science basis for decision-making in the context of GMOs released into the environment in South Africa."***

This reform is underpinned by the general acceptance by the DEAT that the current regulation of GMOs in South Africa is woefully inadequate. Indeed, independent scientists and government officials alike are extremely concerned about the environmental impact of the multitude of GMOs released into the environment since 1989 and the scarcity of independent scientific research.

The ACB and other groups have been engaging with DEAT constructively through the attendance of numerous stakeholder meetings and have made comprehensive and lengthy written and oral submissions. The ACB is also committed to contributing towards the development of roadmap for DEAT's new biosafety research strategy.

To date, we have raised a number of serious concerns, which have a direct bearing on the current application, and which we reiterate for the purposes of this objection:

1. The need for regulations to be developed pertaining to permits regarding GMOs that may have wider socio-economic implications for resource poor farmers concerning *inter alia,* landraces and heritage crops;
2. The urgent need for discreet regulations that clearly delineate "no go" options based on the precautionary principle in respect of GMOs and activities concerning GMOs where risks are not tolerated at all. This is an extremely pertinent issue in the context of the current application involving transgenic sorghum, taking into account that Africa is the centre of origin of sorghum where a large number of sexually compatible weeds, wild relatives, strains and races of cultivates sorghum occur; and
3. linked to (b) above, the need for a precautionary approach to permit applications such as GM sorghum which not only results in the permit being denied but results in the banning of any activity relating to the GMO. This is particularly pertinent in the case with the current application and the ABS1 project, which is meant to proceed to field trials and commercial release.

We thus urge the EC to reject the application until the DEAT has completed its biosafety reform process. A positive ruling in favour of the applicant on this precedent setting application, will severely undermine the DEAT's process and bring the entire regulation concerning GMOs into disrepute.

In this regard, we reiterate our demands that DEAT must ensure that appropriate regulations are drafted for all activities involving GMOs and for all types of GMOs that pose unacceptable risks to indigenous and heritage crops in South Africa and beyond its borders in other countries in Africa. Contamination by transgenic sorghum of wild and weedy relatives in South Africa and/or its neigbours will be in violation of South Africa's national and international obligations and will bring South Africa into disrepute on the continent for tainting Africa's heritage.

Public Participation Still Pending by Work of NEAF

The engagement of the public, public consultation and public participation in the context of the regulation of GMOs have been singled out as requiring urgent attention by different sectors of the South African society, including, civil society groups opposed to GMOs, the academic fraternity, farmer groups, parliamentarians, officials within the South African government, and the private sector. The National Environmental Management Advisory Forum (NEAF) is in the process of conducting research with a view to making several recommendations to the Minister of Environment to institute legal reform to remedy the current problems. Until such time as the Minister intervenes, civil society groups will continue to remain outside the process, particularly regarding decision- making and contained use applications.

In the circumstances, we reiterate our previous grave concerns regarding the extent to which the public is excluded from the process, including applications for contained use.

Disregard for Biowatch Court Ruling Concerning Access to Information

The NGO Biowatch South Africa has successfully brought an action against the National Department of Agriculture regarding access to information. Nevertheless, we as civil society continue to be denied the information to which Judge Dunn clearly ruled we are entitled to. The ACB scientist has been unable to assess the application at all, as the bulk of the pertinent information has not been provided at all.

Despite the positive ruling in Biowatch's favour and despite the expensive legal action it has instituted, the public are denied complete and accurate information in order to ensure that adequate safety is being ensured.

CONCLUSIONS REGARDING THE APPLICATION

The molecular description and characterisation information has been designated CBI which has prevented us from making an assessment of the changes to the Sorghum to

yield the transgenic ABS1. The risk assessment data could not be assessed at all as it appears that the bulk of the pertinent information is contained in Annexures copies of which we have not been provided. Any engagement by the public with the applicant needs to be made on the basis of complete and accurate information being made to the public. Without basic information relating to the GE events, the public cannot have confidence that adequate safety is being ensured.

In light of the responses by the applicant it is our contention that this application cannot be adequately assessed. The information provided is sketchy at best. Claims are made regarding no toxicity or possible harmful impacts of ABS1 on the biosystem without reference to any literature. The basis of these claims is therefore in question. The impression gained from the applicant's responses is that any possible impacts of the release of the transgene are negligible – this is a view not supported by the published literature. At a minimum, the literature indicates that a great deal more investigation has to be carried out on the impacts of transgenes before their release into the environment. The long review process of similar applications by the EU bear out these concerns.

The EC decision of 15 June 2006 requested that the applicant characterise sorghum species in South Africa with particular regard to examining sexual compatibility, geographic distribution, climatic requirements and importance to bio-diversity, including nutritional characterisation of the different species of sorghum in S.A. There is no evidence in this application of such a study having been carried out.[xv]

The opportunities for outcrossing to cultivated sorghum and to wild relatives of sorghum are said by the applicant to be highly unlikely (page 2) because of the level 3 containment facility that is proposed for the release. The South African Sorghum gene flow study[xxvi] raised very serious concerns of introgression of GE-sorghum into wild relatives which need to be addressed. Ultimately, ABS1 is being developed for commercial release and will have to undergo field trials. If the original objection of the EC made on 15 June 2006 was based on concerns regarding containment and possible adverse effects on local varieties, any further development or re-consideration of the application must be forestalled by this concern.[xv] Containment now will not negate these concerns for field trials and the risks to local varieties will remain.

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