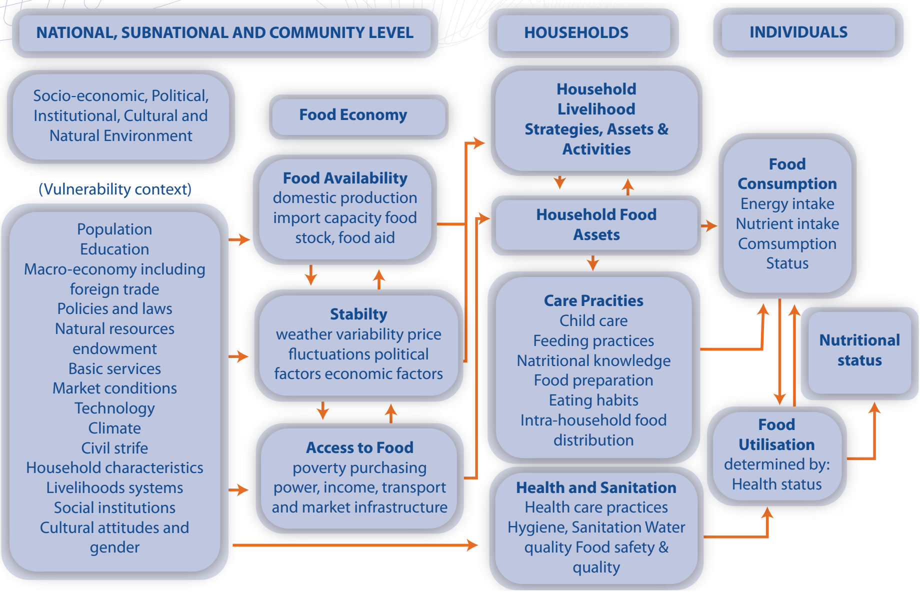

Figure 2.4: Factors influencing nutritional status

Possible role of GMO: For the past 20 years the science of biotechnology has made significant and important advances in recombinant DNA engineering, making it possible to produce transgenic food crops of better quality. In this biotechnological process, genetic material of a given crop is manipulated and modified using a technique known as recombinant DNA technology. This modification process is usually aimed at enhancing desired traits such as increased resistance to herbicides, pests, specific diseases, harsh environmental conditions such as cold spells, heat waves and drought, or improved shelf life or nutritional content. Compared to conventional plant breeding methods, GM technology is less time-consuming and more accurate in acquiring the desired objectives. The product obtained is known as a genetically modified organism (GMO) or a GM food. Great strides have been made in this area which have given rise to a wide range of improved food crops which are now increasingly being cultivated at industrial level in most developed countries and to a lesser extent in some developing countries. In 2006, for example, GMO crops in the US were grown over an area of over 135 million acres, with the total global area exceeding 250 million acres. The current list of GM foods includes corn, potato, pineapple, cocoa bean, yellow squash, sweet pepper, sugar cane, banana, soybean, etc. In South Africa this technology has been used to produce transgenic maize, cotton and soybeans that have traits for insect resistance and herbicide tolerance.

Increasing numbers of research results on GMO are regarded as a reason for the adoption of GMOs in the fight against food insecurity in Africa. These milestone research results show the possibility of increasing crop yields, improving the storage potential of harvested crops, improving the protein content of starchy foods, biofortification of local foods, improving the functional food potential of local foods, etc.

Contrary to the expectations of opponents of GM foods, the results of modern comprehensive profiling of crop composition have shown a very close similarity between GM foods and their conventionally bred counterparts (Catchpole *et al.*, 2005). Reputable organisations such as the WHO and the US National Academies of Science have issued numerous reports on the safety of GM foods. In June 2005, for instance, the WHO released a report entitled *Modern Food Biotechnology, Human Health and Development*, which has affirmed the safety of GM foods. In view of the findings, GM technology has huge potential for resolving the food and nutrition problems in Africa.

At present, the quality and yield of different varieties of the principal food crops grown and consumed in sub-Saharan Africa such as cassava, maize, yams, cocoyams, plantains, bananas, groundnuts, Irish potatoes, millet, beans, vegetables and tropical fruits are affected by several constraining factors including diseases of viral and fungal origin, poor soil and climatic conditions. In Cameroon, for example, several factors (Table 2.2) are major constraints in food production.

Table 2.2: Some food crop production constraints in Cameroon

No	Crop	Constraining factor
1	Maize	Soil acidity, aluminium toxicity, striga streak, aflatoxin
2	Cassava	Mosaic, root scale, cooking quality
3	Cocoyam	Root rot, root scale, oxalic acid content
4	Sweet potato	Weevils, virus complex
5	Irish potato	Late blight, bacterial wilt, frying quality
6	Groundnut	Aflatoxin, rosette, pod filling
7	Cocoa	Black pod

Source: Ngeve (2006)

Based on current research trends in and successes with GM technology, these constraints can be eliminated. In addition, the same technology can be used to enhance the nutritional quality of locally grown foods such as protein, iron, zinc, vitamin A, iodine, etc.

From a policy viewpoint, this should not be a matter of choice but compulsory for Africa because the successes so far in resolving food production problems on the continent have largely not been concerned with conventionally grown food crops but with GM crops. If this technology is not used to resolve Africa's food and nutrition problems, the continent will be dependent on world food trade since it is virtually an island in a sea of countries involved in GM food production (Figure 2.5). The prospects for the economies of those countries that find themselves in a situation of dependency are not encouraging.

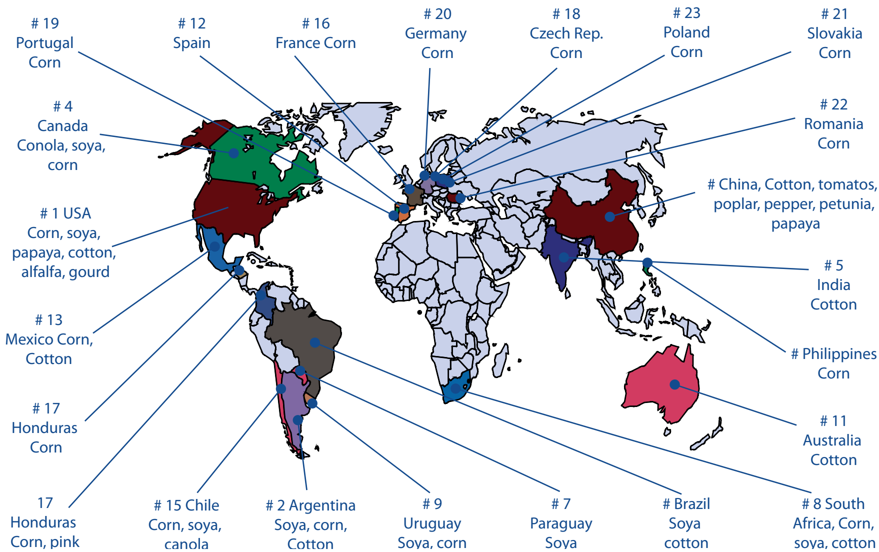

Figure 2.5: Major GMO-producing countries in 2007

In the light of the above, the opportunity now exists for African countries to boldly embrace this technology for the benefit of the huge numbers of people suffering from hunger, undernutrition and malnutrition. GM technology, with an appropriate quality control mechanism (Mbofung, 2006), can go a long way towards improving not only the yield of traditional African food crops but also their safety and nutritional quality.

Specifically, opportunities now exist for:

(a) **Increased food production:** The main causes of reduced crop yield and availability are insect pests and fungal infection pre- and post-harvest. GM maize and sorghum resistant to these conditions can now be produced. The extension of this technology to root and tuber crops, as well as to other cereals commonly grown and consumed in Africa, would go a long way towards boosting food yields. In addition to reducing food crop losses due to pest and fungal attack, GM methods are currently available for food crop production on otherwise infertile soil or in drought-stricken areas. A good part of the farming land in Africa is threatened by the changing climatic and soil conditions. The current success in the development of food crops that are drought resistant presents the opportunity for Africa to exploit land which was previously regarded as unsuitable for food crop production.

(b) **Minimum use of chemicals:** Pest-resistant and herbicide-tolerant GM food crops require minimum use of chemicals against pests and weeds. This will also protect the environment from harmful chemicals. Fungal and insect attacks are common problems associated with post-harvest handling of cereals in tropical Africa. The use of chemicals to reduce these effects, in addition to being expensive, can be harmful to humans. Development of pest-resistant and herbicide-tolerant GM varieties of our local crops will minimise the use of toxic chemicals. On a slightly different note, the essential oils of some tropical plants have been advocated as alternatives to chemicals for the post-harvest storage of cereals because of their non-toxicity. For the past ten years we have been exploring the wide plant biodiversity of Cameroon as sources of essential oils with the potential for use against insect and fungal attack on grains during storage. Encouraging results have been obtained, but the difficulty lies with the yields of essential oils produced from the identified plants. GM technology could be used to overcome this difficulty.

(c) **Improvement of local food processing and storage technologies:** The production of decaffeinated coffee entails the use of chemicals. Using GM technology, researchers in Japan have developed a process for the production of low-caffeine coffee. Cassava is a major food crop grown and consumed in Africa, but some high-yield varieties often contain significant levels of cyanogenic glucosides (linamarin and lotaustralin) which on hydrolysis release toxic **hydrocyanic acid** (HCN) which is only eliminated through tedious processing. The food value of these varieties could be improved by developing GM versions with lower cyanogenic glucoside levels. In the same vein, other tropical foods such as taro (*Colocassia esuculenta*) and bean varieties (*Phaseolus vulgaris*) habour natural toxicants which reduce their food value. GM technology could also be applied in the development of non-toxic versions of the same.

(d) **Micronutrient biofortification**: Some of the most disturbing cases of malnutrition in children in Africa are due to the low micronutrient content of the restricted diets they eat. GM foods with improved nutritional content could be used as a remedy for some of these conditions. Rice, which is a widely consumed cereal, is deficient in vitamin A which is important for human health. Scientists have developed a gene for rice crops ("golden" rice) that will contain the lacking vitamin. Other studies on biofortification have succeeded in producing rice with a higher iron content, which was shown to improve the iron deficiency of consumers (Haas *et al.*, 2005). Given the high incidence of micronutrient deficiency in children and pregnant women, GM technology could be used to increase the level of these micronutrients in some commonly consumed foods.

(e) **Improvement of the protein quality and content of local foods**: Some of the important advances made in GM technology include improvement of the nutritional content of GM foods. One of the major nutritional problems facing Africa is protein malnutrition. Improvement of the protein content of foods hitherto focused on maize, and is now being applied to other cereals. "Super sorghum", which is a GMO biofortified version of a popular staple sorghum crop, is currently undergoing greenhouse trials by the Council for Scientific and Industrial Research (CSIR) in South Africa. It is a good example of a big step in the right direction for the alleviation of protein and micronutrient deficiencies in the diets of consumers. This success story is one example of the biofortification of several staple foods consumed in Africa but which are low in nutrient content.

(f) **Production of functional foods**: Plant foods also contain many bioactive substances important to health. These bioactive substances, which are increasingly being shown to be abundant in certain plant species, include carotenoids, vitamins C and E, pigments (beta-carotene, lycopene), polyphenols, etc. They are known to play a role in the prevention of malnutrition and the development of diseases such as cancer and cardiovascular disease, aging, etc. GM technology could be used to enhance the potential of the wide variety of some of our local foods to serve as functional foods. The production in the US of a GM Roma tomato containing three times more lycopene (a red pigment thought to have a role in the prevention of prostate cancer) is illustrative of this idea. Equally inspiring is the creation by researchers in Singapore of a lettuce that synthesises Resveratrol, a molecule of the red grape implicated in the "French paradox" concerning the positive effect of red wine on cholesterol metabolism. Another important research advance has been the creation of a strain of "golden" rice containing very high levels of beta-carotene (pro-vitamin A) by the Swiss Federal Institute of Technology. Since rice is widely consumed, the availability of this strain for food will contribute to the fight against avitaminosis A which affects a high proportion of people in most African countries.

CONCLUSION

In conclusion, current advances in GMO technology present exciting opportunities to contribute towards the resolution of the African food and nutrition security problem. This of course will be possible only within the framework of a properly set out biotechnology policy with sufficient financing for the training of the right people, the construction of and equipment for the necessary laboratories and the carrying out of rigorously planned, results-oriented GM food research for safe and sustainable food and nutrition security. The need for a concerted effort cannot be overemphasised. Failure to take the bull by the horns in this process may leave Africa and its people at the mercy of some Western adventurers with respect to GM foods.

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3

Transgenic Plants with Virus Resistance: Opportunities and Challenges for Africa

Dr Augustine Gubba

TRANSGENIC PLANTS WITH VIRUS RESISTANCE: OPPORTUNITIES AND CHALLENGES FOR AFRICA

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1. Introduction

The use of genetically modified (GM) technology and its products in Africa is still in its infancy. South Africa, which has biosafety regulations in place, is the only country on the continent that is commercially producing GM crops. However, countries such as Egypt and Burkina Faso have recently reported growing GM crops on a commercial basis. The GM crops that are produced on a commercial basis have been limited to maize (*Zea mays* L.), cotton (*Gossypium hirsutum* L.), soybean (*Glycine max* L.) and oilseed rape (*Brassica napus* L.). These four crops have been transformed for the two traits of insect resistance and herbicide tolerance. There is a need in Africa also to develop GM crops with other important traits. This presentation will focus on the trait of plant disease resistance, specifically resistance to plant virus infection. Compared to other pathogens, such as bacteria and fungi, viruses have very simple structures and genomes, and for that reason GM crops with resistance to viral infection can easily be produced.

2. Examples of viruses of economic importance in African agriculture

For a long time viruses have been known to be major limiting factors in the production of Africa's major food and commercial crops. The literature abounds with examples of the detrimental effects of viruses on many different crops grown on the African continent (Figure 3.1). Maize streak virus (MSV) (*Zea mays* L.), discovered in 1901, is a major pathogen of maize (Wambugu, 1999; Bosque-Perez, 2000). The virus has rendered the production of maize in some parts of Africa virtually impossible. The twin threat of cassava mosaic virus disease (CMD) and cassava brown streak virus disease (CBSD) has had devastating effects on the production of cassava *(Manihot esculenta* L.) in East and Central Africa (Gibson *et al.*, 1996; Legg & Tresh, 2000; Hillocks *et al.*, 2001; Tresh & Cooter, 2005). The hopelessness of farmers trying to eke out a living from their heavily diseased crops is a common feature in all production areas. In the recent past, banana bunchy top virus (BBTV) has emerged as a major threat to banana (*Musa paradisiacal* L.) production, putting at risk the food security of more than 70 million people in 15 countries in sub-Saharan Africa who depend on banana for their livelihood and food supply (FAO, 2001). Infected banana plants produce little or no fruit.

Bean (*Phaseolus vulgaris* L.) is a major source of dietary protein for cash-poor farmers who constitute a large majority of people in Africa. The seed-borne viruses, bean common mosaic virus (BCMV) and bean common mosaic necrosis virus (BCMNV) continue to be serious threats to bean production on the continent (Mukeshimana *et al.*, 2003). Potato virus X (PVX), potato virus Y (PVY) and potato leafroll virus (PLRV) singly or in combination, result in substantial yield losses in potato (*Solanum tuberosum* L.) production in all areas of production. Sweet potato (*Ipomea batatas* L.) is among the most important food staples grown in sub-Saharan Africa, particularly East Africa. Efforts to control sweet potato disease virus (SPDV), a result of the synergistic interaction between sweet potato feathery mottle virus (SPFMV) and sweet potato chlorotic stunt virus (SPCSV) which results in up to 95% reduction in tuber yield of potato (*Ipomea batatas* L.) throughout Africa, are being pursued in earnest (Gibson *et al.*, 2003).

The economic impact of tomato spotted wilt virus (TSWV) is huge mainly due to its extremely broad host range and worldwide distribution (Rosello *et al.*, 1996). It possesses one of the largest host ranges of any plant virus, with over 1 090 plant species in over 100 families cited (Peters, 2003). The virus infects many different vegetable crops and reduces the marketable value of produce. With an estimated crop loss of over US$1 million for several crops, TSWV ranks among the ten most detrimental plant viruses worldwide (Goldbach & Peters, 1994). Zucchini yellow mosaic virus (ZYMV) occurs wherever cucurbits are grown and infected plants have very poor fruit set.

In West Africa, the production of cocoa (*Theobroma cacao* L.) has been under threat from cocoa swollen shoot virus (CSSV) for over 70 years and the search for virus-resistant cacao varieties is still on (Posnette & Todd, 2008). Côte d' Ivoire, Ghana, Nigeria and Togo record combined loses of over 500 000 tons/year. In the citrus-producing countries, infections of trees with citrus tristeza virus (CTV) have resulted in millions of infected trees being felled, leading to severe financial losses for the affected farmers (Bar-Joseph & Marcus, 1989). Control of CTV continues to be a challenge.

Figure 3.1: (a) Maize streak virus (MSV) on maize (*Zea mays* L.); (b) Cassava mosaic disease (CMD) on cassava (*Manihot esculenta* L.); (c) Banana (*Musa paradisiacal* L.) infected with banana bunchy top virus (BBTV); (d) Healthy banana

It is evident that the damage associated with viral diseases to different crops translates into major financial losses for the affected farmer and in most cases the losses are a real threat to food security. Given that the strategies that have been commonly used to control or manage plant viral diseases have not been very effective, there is an urgent need to look at alternative methods that can complement the existing strategies. To this end, the concept of pathogen-derived resistance (PDR) as described by Sanford and Johnson (1985) to produce genetically modified plants with virus resistance offers exciting possibilities.

2.1 Transgenic Papaya (*Carica papaya* L.) with Virus Resistance

One of the very few transgenic crops with virus resistance that have been commercialised is papaya (*Carica papaya* L.). Papaya with resistance to papaya ringspot virus (PRSV) is now grown on a commercial basis by farmers on the Hawaiian islands (Gonsalves, 1998). These beautiful islands have a compelling story to tell on how GM technology was used to save the local papaya industry from total collapse due to infection by PRSV. The Hawaii papaya story can be used as a model to address the many virus problems that have affected African farming communities for a long time.

At the height of the PRSV problem, abandoned papaya orchards were a common feature of the landscape in the main papaya-growing areas, and this bore testimony to the devastating effects the virus was having on the papaya industry. Efforts to control the virus using resistant papaya cultivars and cross-protection had failed dramatically. Local scientists looked at the concept of PDR for providing a lasting solution to the problem. To this end, the coat protein (CP) gene of PRSV was used in the transformation of papaya (Cai *et al.*, 1990; Fitch *et al.*, 1992). The resultant transgenic plants showed resistance to PRSV under greenhouse conditions (Tennant *et al.*, 1994).

Following a series of field tests, and having met the stringent environmental and biosafety requirements, transgenic papaya was eventually commercially released in 1998 (Gonsalves, 1998). Using GM technology, the papaya industry in Hawaii was transformed from the seemingly hopeless state at the height of the PRSV problem to where the industry today is back to its former glory (Figure 3.2). Today, transgenic Rainbow papaya is being exported to mainland US and Canada.

Figure 3.2: (a) Papaya orchards before GM technology intervention; (b) Papaya orchards after GM technology intervention

3 Lessons from the Hawaii papaya story

The fact that the local farmers and the scientific community in Hawaii came together to solve an economically important viral disease problem shows that there is no need to involve a multinational company in such projects. The participation of multinational companies in such projects always attracts the opponents of GM who use the opportunity to portray the technology in a negative light. The papaya story is a model of how GM technology can be harnessed to solve a viral disease problem and help save a whole community from total financial ruin. This model can be adapted to suit specific environments.

4 The way forward for Africa

PDR has been demonstrated to be very effective in controlling/managing an important viral disease. It is important that the use of PDR should occupy a prominent position on the African agricultural research agenda. There is an urgent need to initiate projects that address the numerous viral disease problems that African farmers are currently facing and have been facing for a very long time.

4.1 Development of Transgenic Plants with Virus Resistance in Africa

It is pleasing to note that different laboratories across the continent are using GM technology to develop transgenic crops with virus resistance on a routine basis. The first all-African produced modified plant in the form of transgenic maize with resistance to MSV has been developed (Shepherd *et al.*, 2007). This maize is at present being evaluated under containment. Other projects underway on the continent include:

(a) Transgenic cucurbits and potato with resistance to several viruses being developed in Egypt.

(b) Transgenic sweet potato with resistance to SPDV being developed in Kenya, Uganda and South Africa.

(c) Transgenic cassava with resistance to CMD and CBSD being developed in Uganda and Kenya. Confined trials of cassava transformed for resistance to CMD are now being conducted in Uganda.

As the number of scientists with training in molecular biology, tissue culture and virology increase, there is likely to be a concomitant increase in the number of projects on developing transgenic crops with virus resistance. Against this background, the future for the development of GMOs in Africa looks promising.

4.2 Opportunities and Challenges

Given the many virus disease problems in Africa that need urgent research attention, many opportunities exist for using GM technology. However, there are many challenges that have to be addressed before these opportunities can be exploited. First, it is important for individual countries to have biosafety regulations in place so as to create environments in which GMO research can take off. Second, it will also be necessary to identify centres of research excellence on the continent that can spearhead the research. Such centres must have a molecular biologist, a virologist and a tissue culture specialist to lead the research. Third, substantial amounts of money will be needed to fund this expensive research. The money will be used to buy equipment and consumables, and build facilities in which the research will be conducted.

5 Conclusion

GM technology in the form of GMO plants with virus resistance could be the key to unlocking the potential of African agriculture by, among other things, addressing and solving the numerous viral disease problems that have hampered the economic production of Africa's major food and commercial crops. Lessons learnt from the Hawaii transgenic papaya project can be used as a model to develop GMOs with virus resistance by the various National Agricultural Research Services (NARS) and universities across the continent. The long-suffering farmer will have a brighter future.

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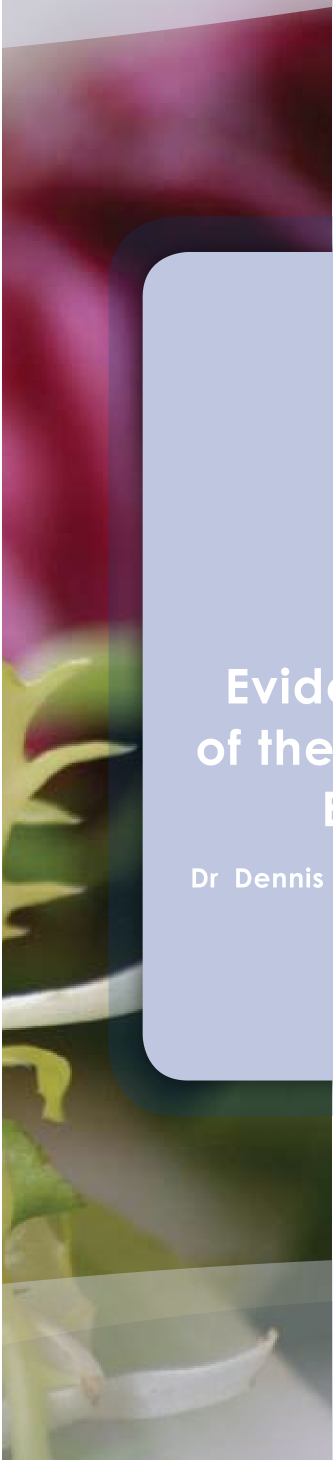

4

Challenges for GM Technologies: Evidence-based Evaluation of the Potential Environmental Effects of GM Crops

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CHALLENGES FOR GM TECHNOLOGIES: EVIDENCE-BASED EVALUATION OF THE POTENTIAL ENVIRONMENTAL EFFECTS OF GM CROPS

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Abstract

The human population in Africa has undergone a rapid increase in the last decade and this, coupled with problems such as erratic rainfall, prolonged droughts and agricultural pest problems, has resulted in severe food insecurity. Advanced agricultural technologies, including the use of genetically modified organisms (GMOs), could play a role in enhancing agricultural productivity in Africa. However, despite the apparent potential of GMOs to improve agricultural production, there is still a significant debate regarding the extent of the risks posed by GM crops. A number of concerns pertaining to the possible impacts of these crops have been raised and they include food safety, animal/human health, environmental, agricultural and socioeconomic issues. Even though potential impacts range from negative through to positive, the potential negative impacts are the most pronounced in the perceptions of policy-makers and the general public in Africa. Given the many concerns, there is a great need for accurate, credible scientific and technical

information, appropriate biosafety regulatory systems, policies, legal instruments, and decision-making processes to enable the assessment (and deployment) of GMOs in a rational, scientifically based manner. This paper reviews some of the concerns that have been expressed regarding GM crops and outlines some of the key principles of biosafety that are relevant to their safety assessment and sound decision-making in the context of their potential environmental impacts.

1 Introduction

Population projections estimate that, during the past decade, the human population in Africa has increased from 820 million to over 1 billion (DESA UN, 2009). This, coupled with problems such as erratic rainfall, prolonged droughts and agricultural pest problems, has resulted in severe food insecurity (Mataruka, 2009). The total number of undernourished people in the world reached 963 million in 2008, nearly 15% of the world's population (OECD-FAO, 2009), and it is predicted that the number of people living in hunger will soon surpass the 1 billion mark (FAO, 2009a). Sub-Saharan Africa is the most food-insecure region in the world, and many countries on the continent have seen significant increases in food imports while domestic food production has failed to keep pace with rising food demand (FAO, 2009b).

Paarlberg (2008) attributes the high poverty and hunger levels in Africa to low levels of land and labour productivity: "For farmers in Africa today, productivity is low and poverty high because far too little science has been brought to farming. Currently, only 4% of Africa's farmland is irrigated, less than 30% is planted to improved seeds, and average fertiliser use is only 9 kg per hectare, compared to 117 kg per hectare in the industrialised world." To enhance land and labour productivity, he proposes that African farmers must utilise improved technologies such as improved draft animals, fertilisers and insect- and disease-resistant crop varieties. This brings into sharp focus the role that advanced agricultural technologies, such as genetically modified organisms (GMOs), could play in improving agriculture for socioeconomic development in Africa. Concerns pertaining to the use of GM technology will increasingly play a role in shaping the structure of agricultural production over the medium term (OECD-FAO, 2009).

The global area under GM crop cultivation is rapidly increasing. By 2008, GM crops (mostly herbicide-tolerant) were cultivated on up to 125 million ha worldwide (James, 2008). These crops have been demonstrated to enhance agricultural productivity and have the potential to address some of the challenges facing agricultural production in Africa. For example, under rain-fed irrigation, *Bt* maize (expressing genes that encode insecticidal proteins from the bacterium *Bacillus thuringiensis*) increased maize production in South Africa by 11% (James, 2008); in Burkina Faso, *Bt* cotton cultivation resulted in a two-thirds reduction in pesticide usage and 15% higher yield (Vitale *et al.*, 2008).

Despite the apparent potential of GM crops to improve agricultural production, there is still significant debate regarding the risks posed by the technology. For the potential benefits of GM crops to be realised, it is necessary that they be assessed (and deployed) in a rational, science-based manner. Several African countries have therefore put in place policies and regulatory frameworks to support the responsible and safe use of biotechnology, assure public confidence, encourage local biotechnology innovation based on local priority needs, and help mitigate against any possible adverse effects on human health and the environment. This paper reviews some of the concerns that have been expressed regarding GM crops (drawing on examples from insect-resistant [IR] and herbicide-tolerant [HT] crops) and outlines some of the key principles of biosafety that are relevant to their safety assessment and sound decision-making with specific regard to their potential environmental impacts.

2 Concerns regarding GM crops

Most concerns about GM crops can be placed into four broad categories: food safety and animal/human health concerns, environmental concerns, agricultural concerns and socioeconomic issues. Although the primary focus of this paper is on the potential environmental effects of GM crops, the term "environment" has a very broad definition in common usage and therefore a wider array of issues surrounding GM crops are also discussed.

Environmental concerns that have been expressed with regard to GM crops include: negative impact(s) on "non-target organisms", gene flow, invasiveness, new pests and diseases, and unexpected variability (Kohi, 2006; Thies & Devare, 2007). For example, potential effects on non-target species may occur if GM crops produce novel defensive compounds (e.g. *Bt* toxin to prevent extended insect attack).

One of the agricultural concerns that have been expressed with regard to pest-resistant GM crops is the development of resistance by the target pest to the protective transgenic compound in the crops (Thies & Devare, 2007). In this case, the primary concern is the loss of usefulness of the control strategy, as has been frequently observed with conventional breeding for resistance or application of chemical pesticides (Conner *et al.*, 2003). Strategies to delay the development of such resistance include the selection of transformation events expressing very high toxin levels, stacking different insect-resistance transgenes together in the same GM variety, and strategically planting nearby non-resistant crops or plants as refugia to allow any resistant individuals that might develop to mate with non-resistant individuals in order to reduce the frequency of resistance genes in the insect population (Bates *et al.*, 2005).

While the aforementioned agricultural and environmental safety-related concerns are often presented as generic concerns when discussing biotechnology, socioeconomic issues also pose challenges to decision-making bodies. The issues raised include: monopoly control by transnational companies; profit margins being squeezed between seed cost and declining world prices; possible loss of existing robust crop varieties and technologies and challenging market dynamics, especially with the European Union (EU). Other issues include benefit-sharing, the transferability of biosafety assessments across the region and beyond, and the co-existence of organic and GM crops (Sengooba *et al.*, 2009).

In addition to potential negative effects of GM crops on the environment, there are also potential positive effects. For example, the use of insect-resistant transgenic crops can lead to lower applications of conventional pesticides, and hence minimise environmental pollution. Potential effects of GM crops therefore run right through the continuum from negative to positive, as illustrated by the following examples pertaining to insect-resistant and herbicide-tolerant crops. Obonyo (2009) found variable effects of *Bt* maize plants on a number of non-target organisms associated with maize fields. The farm-scale field trials in the UK also clearly documented the fact that the impact of GM crop cultivation on biodiversity can be either positive or negative and always depended upon the agriculture system as a whole, and not on the GM crop (Firbank *et al.*, 2003).

2.1 Insect-Resistant (IR) GM Crops

Numerous reports have documented reduced pesticide use resulting from the cultivation of *Bt* crops engineered for resistance to specific insect pests (Morse *et al.*, 2005; Brookes & Barfoot, 2006; Raney, 2006; Vitale *et al.*, 2008). Introduced genes in *Bt* crops encode crystalline (Cry) toxins, each of which acts very specifically on a narrow range of insect or nematode species. *B. thuringiensis*, either in the form of spores, bacterial suspension or partly purified toxin preparation, is commonly used by organic farmers as a biopesticide. However, the more spatially controlled toxin application via GM crops has raised concerns about possible effects on non-target organisms. A well-cited case by opponents of the technology is that of the laboratory studies on the Monarch butterfly (Losey *et al.*, 1999), where the consumption of excess (and therefore unrealistic) doses of *Bt* expressing maize pollen by larvae was shown to have a deleterious effect. Follow-up studies in the breeding grounds of Monarch butterflies, however, demonstrated that pollen distribution patterns and subsequent deposits on milkweed plants (the main food source of larvae) within and outside the corn fields are at levels that are highly unlikely to affect caterpillars which feed on them (Pleasants *et al.*, 2001; Sears *et al.*, 2001; Stanley-Horn *et al.*, 2001). Beneficial effects from the cultivation of *Bt* crops include the reduction of insecticide use (this also implies further savings on manpower, fuel consumption and less soil damage caused by heavy machinery), more effective pest control, and consequently higher yields (Ismael *et al.*, 2002). Indirect benefits include reduced contamination of the soil and waters by crop-protection chemicals and in some situations reduced mycotoxin contamination in the crop (Huesing & English, 2004).

2.2 Herbicide-Tolerant (HT) GM Crops

Herbicide-tolerant GM crops are those which have been transformed by genetic engineering such that they are unharmed when sprayed with a broad-spectrum herbicide while crop-infesting weeds are destroyed. However, the transfer of herbicide resistance genes to previously susceptible wild species may allow the recipients to proliferate in the presence of the herbicide (Dale, 1992). In addition, if two HT transgenes become present in the same host variety or varieties, the resulting plants are likely to be tolerant to both herbicides. This could have an impact if the host plants become volunteers in the next growing season. Therefore there is a need to assess the consequences of any potential transfer, and to consider suitable crop management strategies to minimise likely negative impacts.

The selection and spread of weeds resistant to a particular broad-spectrum herbicide is the most frequently highlighted risk of HT crops (Sehnal & Drobnik, 2009). HT weeds could evolve either through (a) gene transfer to any weeds that successfully hybridise with the GM crop (for example, rice can cross-pollinate with wild relatives that already frequently appear as significant crop infestations), or (b) spontaneous mutation, followed by selection under herbicide pressure. This potential adverse effect aside, it is worthy of mention that the cultivation of HT crops has led to the use of less toxic herbicides and reduced fuel-use, and has facilitated the adoption of reduced-tillage or no-till production methods, hence helping to preserve soil quality and reducing soil erosion (Brookes & Barfoot, 2006).

3 What does the scientific literature say?

3.1 Effects of Insect-Resistant *Bt* Crops on Non-Target Organisms

This section reviews some of the studies that have been carried out on impacts of *Bt* crops on non-target organisms, with significant focus on natural enemies (predators and parasitoids) of agricultural pests.

A number of meta-analyses of data, collated from a wide range of non-target studies conducted on *Bt* crops, mainly from peer-reviewed journals but also from non-peer-reviewed reports, and from industry studies conducted to gain regulatory authorisation, were recently published (e.g. Duan *et al.*, 2008; Marvier *et al.*, 2007; Wolfenbarger *et al.*, 2008). These have largely shown the expected lack of effect of *Bt* proteins on non-target invertebrates, regardless of whether organisms were categorised taxonomically (order to species) or by ecological functional guilds. However, with the exception of Duan and colleagues (laboratory honeybee studies), the analyses focused on field studies. In an extension to these analyses, Naranjo (2009) added data from 14 more studies (on *Bt eggplant* and *Bt* rice) to the cotton, maize and potato analyses from the original study by Wolfenbarger and colleagues (2008). The results from this later enlarged meta-analysis did not indicate any qualitative alteration to the patterns for ecological functional guilds previously observed.

Collectively, the non-target studies performed to date demonstrate that *Bt* crops do not have any unexpected toxic effects on natural enemy species of agricultural pests, as would be predicted from knowledge of the mode of action and specificity of *Bt* proteins. *Bt* crops therefore effectively preserve local populations of various economically important biological control organisms that can be adversely impacted by broad-spectrum chemical insecticides. The only indirect effects on non-target organisms that have been observed with *Bt* crops are local reductions in the numbers of certain specialist parasitoids whose hosts are the primary targets of *Bt* crops. Such trophic effects will be associated with any effective pest control technology, whether it be transgenic, chemical or cultural, as well as with natural fluctuations in host populations (Head, 2005).

3.1.1 Effects of Insect-Resistant *Bt* Crops on Insect Predators

Natural enemies of crop pests, and particularly generalist arthropod predators, have been the focus of many scientific studies due to their role in the biological control of various agricultural pests. Based on what is known about the limited spectrum of activity of the *Bt* proteins (Cry proteins) expressed in current *Bt* crops, no direct toxic effects from *Bt* crops would be expected for any of these species. As predicted, Tier 1 ("worst case scenario") laboratory studies required by the regulatory process for *Bt* crops have not demonstrated any direct toxic effects of Cry1, Cry2 or Cry3 proteins against insect predators for concentrations at or much greater than maximum possible exposure levels under natural conditions (for example, see reviews in Betz *et al.*, 2000). Obviously these tests are not designed to mimic natural exposure, nor do they test all possible species that could be exposed, but they do represent stringent tests of possible hazard characterisation using carefully chosen surrogate species.

Researchers interested in the fate of particular predatory species have carried out additional laboratory and semi-field tests of potential non-target impacts (e.g. Pilcher *et al.*, 1997; Bai *et al.*, 2005; Ahmad *et al.*, 2006; Ludy & Lang, 2006). These tests have used a variety of designs, with differing degrees of realism in terms of the route and level of *Bt* exposure. Given that many predators feed on pollen at some point in their life-cycle, many of these studies have involved feeding predatory insect species pollen from *Bt* crops and comparable control lines. None of these studies have found any adverse impacts of *Bt* pollen on the survival or development of various insect predators.

Even though the above studies involved direct exposure, under field conditions exposure can also occur through secondary pathways, with predators feeding upon herbivores that have fed on a *Bt* crop. Secondary exposure of this sort should have relatively little impact on arthropod predators for the same reasons outlined above for direct exposure. However, one set of studies has been presented as a possible example of adverse impacts through secondary exposure. Hilbeck and colleagues (1998a, 1998b) performed a number of tri-trophic laboratory studies with the predatory lacewing *Chrysoperla carnea*, feeding these larvae on prey lepidopteran larvae that had previously fed on *Bt* corn. They found higher mortality and slower development of lacewings exposed to *Bt*-intoxicated insects than for lacewings fed on comparable controls. Subsequent studies by other researchers indicate that these results actually reflected feeding on nutritionally poorer prey rather than any toxic effect of the *Bt* protein (Dutton *et al.*, 2002; Romeis *et al.*, 2004). Such a situation should have little relevance in the field due to the presence of other prey sources that are not affected by *Bt* crops. Furthermore, tri-trophic studies by Al-Deeb and colleagues (2001) with *Orius insidiosus* saw no effect when feeding on *Bt*-intoxicated prey. In this case, the results were confirmed with direct feeding studies on *Bt* corn silks and field observations.

Numerous field studies (e.g. Riddick *et al.*, 1998; Sisterson *et al.*, 2007; Wolfenbarger *et al.*, 2008) have focused on generalist predators, particularly *Coleomegilla maculata*, *C. carnea*, *O. insidiosus*, and guilds of carabids because of their abundance in crop fields and their perceived importance. No adverse effects have been observed for any of these species or in the broader, community-level studies of *Bt* corn (e.g. Pilcher *et al.*, 1997; Lozzia, 1999; Candolfi *et al.*, 2004; Pilcher *et al.*, 2005) and *Bt* cotton (Xia *et al.*, 1999; Hagerty *et al.*, 2005). The absence of even indirect trophic effects of *Bt* corn and *Bt* cotton in these studies is not surprising because most of the predatory species feed on a wide array of prey species, the vast majority of which are not directly impacted by *Bt* corn, e.g. sucking insects such as aphids and whiteflies. In contrast, insecticidal sprays used in the cultivation of conventional corn have clear adverse impacts, at least transiently, on almost all common predators, and particularly those species foraging above ground (Candolfi *et al.*, 2004). Similarly, the insecticidal sprays used in conventional cotton also had clear adverse impacts on almost all of the important arthropod predators studied (Xia *et al.*, 1999; Hagerty *et al.*, 2005; Wu & Guo, 2005).

3.1.2 Effects of Insect-Resistant *Bt* Crops on Parasitoids

Given what is known about the spectrum of activity of the *Bt* proteins expressed in currently commercially available *Bt* crops (Clark *et al.*, 2005), no direct toxic effects on any parasitoid species are expected. Furthermore, because the larvae of these groups feed solely on other arthropods, larval parasitoids will not face any direct exposure (Head, 2005). Adult exposure due to their occasional feeding on pollen or nectar will also be very limited. As with arthropod predatory species, Tier 1 laboratory studies have not found any direct toxic effects on parasitoids of Cry1, Cry2 or Cry3 proteins, at concentrations equivalent to or much greater than the maximum possible exposure level under natural conditions (see reviews in Betz *et al.*, 2000). However, secondary exposure to *Bt* proteins may occur if the parasitoids feed on herbivore larvae that have fed upon *Bt* plant material. In addition, indirect effects may occur at the population level if the host species of the parasitoid(s) are a target of the *Bt* crop and are depressed in numbers. Secondary exposure studies indicate that parasitoids developing on hosts exposed to *Bt* protein may be adversely impacted. When reared on *Bt*-susceptible insects previously fed on *Bt* corn, the larval development and mortality of the parasitoid *Parallorhogas pyralophagus were* adversely affected, but the fitness of emerging adults was not impacted (Bernal *et al.*, 2002). Obonyo (2009) found varying effects of *Bt*-intoxicated stem borer hosts on the development and fitness parameters of their tested parasitoids *Cotesia sesamiae*, *C. flavipes* and *Xanthopimpla stemmator*.

A major determinant of the relative impact that *Bt* crops have on non-target species derives from the fundamental difference in their toxin delivery mechanism (*in planta*) as compared to conventional insecticides (*ex planta*). Non-target species must consume *Bt* plant material in order to be directly exposed, and therefore, as non-herbivores, many parasitoids will never be exposed. Because of their specificity, parasitoids of *Bt* target pest larvae would be expected to be rarer in fields of *Bt* crops than in comparable fields of non-sprayed conventional crops. As expected, the few specialist parasitoids that parasitise

Ostrinia nubilalis and certain other stalk-boring Lepidoptera in corn have been found to be rarer in *Bt* corn than in conventional corn, e.g. *Macrocentrus cingulum* (Candolfi *et al.*, 2004). Similarly, the few specialist parasitoids that parasitise foliage-feeding Lepidoptera, such as *Helicoverpa armigera,* have been found to be rarer in *Bt* cotton than in non-Bt cotton (e.g. Xia *et al.,* 1999). Of course, it is important to consider these results in the context of alternative practices. As mentioned earlier, the insecticidal sprays used in conventional corn (Candolfi *et al.*, 2004) and cotton (Xia *et al.*, 1999; Hagerty *et al.*, 2005; Wu & Guo, 2005) have clear adverse impacts, at least transiently, on these same parasitoid species. Furthermore, any effective pest control practice that decreases the abundance of the host species will have comparable effects.

3.2 Potential Environmental Effects of HT Crops

One of the most widely reported examples of studies on the potential environmental impacts of HT crops were the farm-scale evaluations carried out in the UK. These were a series of multi-year comparisons of agricultural biodiversity in conventional and transgenic HT maize, oilseed rape (spring- and autumn-sown) and sugar beet fields, which were undertaken as a response to public concerns of the effects of cultivation of transgenic HT crops on farmland wildlife (Firbank *et al.*, 2003).The farm-scale evaluations tested the null hypothesis that "transgenic HT crops had no effect on farmland biodiversity compared with a conventional cropping system" (Squire *et al.*, 2003). The results of the studies can be summarised as follows: in oilseed rape and sugar beet there were fewer weeds that set seed in the transgenic HT crop than in the conventional crop, whereas in maize there were more weeds in the transgenic HT crop; invertebrate numbers tended to be positively correlated with the abundance of weeds, although some taxa showed the opposite relationship; and in general, there were more decomposers in the fields of transgenic HT crops (Ammann, 2005). See Raybould (2007) for a critical analysis of the farm-scale evaluation studies.

Sweet and colleagues (2004) observed no direct impact of the transgenes in HT winter oilseed rape and sugar, nor the transgenic crops themselves on crop production and botanical diversity. Differences observed between treatments were attributable to the herbicide programmes. The GM HT crops, however, required fewer herbicide applications than conventional crops. Antonio and Duke (2006), in a review on the environmental impacts of glyphosate-tolerant (GT) crops, noted that no risks had been found with respect to food or feed safety nor nutritional value in products from currently available GT crops. They noted that GT crops have promoted the adoption of reduced or no-tillage agriculture in the US and Argentina, providing a substantial environmental benefit. The review also showed that weed species in GT crop fields have shifted to those that can more successfully withstand glyphosate and to those that avoid the time of its application. It also indicated that three weed species have evolved resistance to glyphosate in GT crops and that GT crops have a greater potential to become problems as volunteer crops than do conventional non-HT crops. They also reported that GT transgenes had unexpectedly been found in fields of conventional oilseed rape, indicating that the largest risk of GT crops may arise from transgene flow (introgression) from GT crops to their related wild species They concluded, however, that all of the minimal environmental risks that have been discussed in relation to GT crops are reversible and are in most cases not exclusive to transgenic crops, except for those associated with flow of transgenes to other plants (the same species or other species).

A review by Kleter and colleagues (2008) of data collected from studies on a number of GT crops in Europe indicated that, depending on the parameters used for the prediction or measurement of the environmental impacts of GT crops, generally similar or less negative impacts were observed compared with conventional crops. They concluded that favourable environmental effects of the glyphosate-containing herbicide regimes on GT crops appear feasible, provided appropriate measures for maintaining biodiversity and prevention of volunteers and gene flow are applied. Graef (2009), in a review of the potential agro-environmental effects of cultivating GM oilseed rape, also noted the importance of monitoring for persistence and/or spread of feral HT oilseed rape and volunteers, the transfer of herbicide tolerance to wild relatives and a decline in agrobiodiversity, the development of herbicide tolerance in weeds, as well as any adverse effects on field organisms and/or soil bio-geochemical cycles. Powell and colleagues (2009) conducted a series of microcosm and field experiments in Ontario, Canada, that estimated the effects of transgenic GT crops and their management on the abundances of detritivorous soil biota and crop litter decomposition. Although the conventional and GT varieties studied differed in composition, they observed few effects of the modification for glyphosate-tolerance on maize and soya bean litter decomposition. Overall, the herbicide system associated with the GT crops reduced soya bean and corn litter decomposition, but responses were inconsistent across Ontario, with many trials demonstrating no effect. Herbicide-tolerant crops can therefore enhance agricultural productivity and, with appropriate measures in place, any potential risks can be kept in check.

4 Principles of biosafety and risk assessment

Biosafety worldwide is heavily influenced by the Cartagena Protocol on Biosafety (henceforth referred to as the Protocol), an international agreement to which many African countries are signatories (CBD, 2000). According to the Protocol, biosafety refers to "the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology". The Protocol recognises that, in as much as modern biotechnology has a great potential for the promotion of human well-being, appropriate procedures have to be put in place to enhance the safety of biotechnology. For example, Article 16, Paragraph 1, states that "The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms". In addition, Article 2, Paragraph 2 of the Protocol states that "The Parties shall ensure the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health".

Therefore in order to evaluate GM crops for safety, an acknowledgment of their potential benefits must be made in addition to an evaluation of the potential damage to the environment and human and animal health. Any biosafety evaluation of GM crops and their products must be based on an understanding of the technologies used in their development, a comparison of GM crops with the non-modified recipients or parental organisms, and the difference of GM crop production practices with those of current agricultural practices and their potential impacts. Evaluation of the benefits and risks of GM crops is necessary in order to set the level of acceptable risk as a basis for decision-making concerning the acceptance or refusal of the technology in any given situation (Sehnal & Drobnik, 2009). Economics may also be taken into account, in particular in any evaluations of the long-term use.

A review by Hill and Sendashonga (2003) identified a number of key lessons (drawn from the experiences with chemical risk assessment) which have possibly served as useful principles to guide the risk assessment of GMOs. These include:

a) considering multiple lines of evidence

b) assessing risks in a comparative context

c) flexibility regarding the level of detail for risk assessments

d) having iterative and adaptive risk assessments which could be re-evaluated whenever there have been changes that affect risk assessments

e) being able to assess cumulative effects as part of the risk assessments.

5 Risk assessment in practice

Risk may be defined as the probability of damage resulting from exposure to a hazard. As no activity is without risk, the risk scale does not start with zero, and only relative risk can be assessed by comparison with alternative human activities. Risk assessment has been defined in a number of ways. For example, the European Commission (EC, 2000) defines risk assessment as "a process of evaluation including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect(s)/event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s)". According to WHO (1995), risk assessment is the "scientific evaluation of known or potential adverse health effects resulting from human exposure to food-borne hazards." A risk assessment generally identifies the likelihood of exposure to a hazard and the magnitude of the consequences of the exposure on human health (Fischer *et al.*, 2005), and the environment. It is often decomposed into four elements: hazard identification, hazard characterisation, exposure assessment and risk characterisation (EC, 2000; Codex Alimentarius, 2007).

Publications and guidance documents on environmental risk assessment (USA EPA, 1998; EC, 2003; Suter, 2006) have outlined coherent and logical steps to progressively and iteratively proceed to a point where a risk is characterised and the evidence supporting the conclusion is clearly communicated. This process has been successfully used for chemical stressors and has been described in detail by the American Environmental Protection Agency (USA EPA, 1998). The process follows the steps of: problem formulation as the beginning; assessment of the exposure, including levels and likelihood of exposure; hazard identification and assessment that examine the potential hazard(s) using effects testing and the magnitude of the potential outcome; and risk characterisation that integrates the hazard, the magnitude of the consequences, and the likelihood of occurrence. Regulatory decisions regarding the acceptability of introducing a potentially harmful agent into the environment are based on the characterised risk (Nickson, 2008). Experimental testing is performed by following established procedures, e.g. feeding tests, allergy induction assays, *in vitro* digestibility tests, etc. (WTO, 2009). Since these tests are expensive, any regulatory decision to require testing should be taken in a responsible manner.

In addition to the intended target effects, these studies may reveal differences between a GM and the comparator, but differences from standard crop cultivation practices that include protective measures against insect pests, weeds, etc. should also be tested. It is necessary also to consider extra comparators that help to place differences between the GM and its counterpart in context (Perry *et al.*, 2009). For example, comparisons should also be made with plots subjected to the standard agricultural practices and, if possible, cultivars with similar properties as the GM cultivars but obtained by other breeding methods (Sehnal & Drobnik, 2009). Furthermore, HT GM plants *per se* are unlikely to affect biodiversity, but the use of herbicides associated with their cultivation may have a deleterious impact. HT varieties developed by other breeding techniques, together with their required herbicide regime, should therefore be included in the studies to act as comparators.

Ideally, a risk assessment should be accompanied by a benefit assessment performed under the same conditions and using an identical methodology. The benefit:risk ratio is not only extremely useful in the identification of an acceptable level of risk, but also in decision-making. The potential risks and benefits from the introduction of a new GM crop can be assessed only by a comparison with currently grown varieties, either conventional non-GM or pre-existing GM, cultivated with the use of standard procedures, including the application of any necessary insecticides, herbicides, etc. (Sehnal & Drobnik, 2009). Agriculture has inevitably converted natural, diversified ecosystems to monoculture-based agro-ecosystems that are sometimes exploited to the point of irreversible damage. The evaluation of the potential environmental impacts of new technologies is dictated by the need to mitigate such damage for the sake of agriculture sustainability. GM crops should be scrutinised as is any other technology, and based upon possible significant effects on food safety and the agro-ecosystem. Even though new cultivars introduce a novel genetic set-up to the ecosystem, care should be taken to discriminate between the direct impact of the new plant varieties themselves with those derived from their associated agronomic practices, i.e. the methods of field management, applications of any chemicals, crop-selection and rotation, etc. The impact of new technologies can be either positive or negative, or even a mixture of the two (Prakash, 2001); there is no reason to classify some technologies *a priori* as negative and "risky".

It is important to note, however, that the collection of large amounts of data may not be necessary for effective risk assessment decision-making. Craig and colleagues (2008) reported that "In the decade since the first authorisations for commercial release of GM crops, there has been an enormous increase in the amount of data generated by scientific studies that relates to risk assessment. If this trend continues, we run the risk of competent authorities being submerged by excessively large amounts of data that may be of questionable pertinence to verifiable safety questions." In fact, an effective risk assessment should seek to minimise the amount of data required to reach a sound judgement because collection of superfluous data often confuses decision-making and diverts effort from more worthwhile activities (Raybould, 2006). Indeed, if the collection of additional data delays the introduction of a beneficial product, overall environmental risk may be increased rather than reduced (Cross, 1996). Emphasis must therefore be placed only on data that will facilitate the making of a sound judgement (Craig & Tepfer, 2007).

6 Conclusion

The regulation of agricultural biotechnology has both immediate and long-lasting socio-economic consequences and can affect the sustainability of agro-ecosystems. Policy-makers are responsible for formulating regulations, while scientists are charged to provide and evaluate information necessary for prudent decisions. It would be extremely useful for open debates if the public were familiar with the nature of various breeding methods, as well as those of GM technologies. Knowledgeable citizens would then be able to positively contribute to the discussions concerning possible safety measures and GM crop deployment. Scientifically unjustified bans on the deployment of GM crops may slow down agricultural output, and could further compound the dire food security situation in Africa. The socioeconomic factors affecting GM crop deployment also include pressure from various interest groups. All these issues are very volatile and hard to control. It is important that GM crops be assessed on a case-by-case basis. The evaluation of the possible risks arising from the deployment of a particular GM crop in the receiving environment should include the results of prior research, and may or may not require the generation of new information.

It has been argued that GM crops should not be used, even when there may be a very low probability of the occurrence of an unpredictable adverse effect on the environment or on human health (Nuffield Council on Bioethics, 2003). This case is frequently cited in terms of the precautionary approach in the Protocol which emanated from Principle 15 of the Rio Declaration which states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Some people have contended that irrespective of possible benefits, the precautionary approach argues for a delay in the use of the technology until a complete assurance of absence of risk is available (Nuffield Council on Bioethics, 2003). Interestingly, however, the text of the Protocol can also be interpreted as permitting the introduction of GM crops with their associated risks if they are likely to be less than the risks inherent in current practices, even if the full extent of the reduction is not known. The former argument could lead to an inappropriate embargo on the introduction of all new technology. Since an absolute absence of risk arising from the use of any new technology can never be guaranteed, the only sensible interpretation of the precautionary principle should be comparative, i.e. to select the course of action (or inaction) with the least overall risk (Nuffield Council on Bioethics, 2003).

Scientific research has to clarify the possible environmental effects of GM crops, and place them in the context of real-life scenarios. This should take into account: the gene (or combination of genes) being inserted; the nature of the target crop; local agricultural practices, agro-ecological conditions, trade policies, etc. So far, it is not possible to make generalisations on the effects of GM technologies. Any judgement of the impact of GM crops should be made on a case-by-case basis using a rational, evidence-based approach (FAO, 2003). It is essential to pose the question: "How does the use of a GM crop compare to the alternatives?" In making decisions, all possible paths of action must be compared, including inaction.

Even though there is little evidence of specific harmful effects from the millions of acres of transgenic crops grown worldwide, the potential risks associated with the technology are very pronounced in the perceptions of policy-makers and the general public in Africa. Given this level of concern, there is a great need for accurate, credible information. There has been much effort to communicate issues pertinent to GM crops. While notable progress is being made, inadequate knowledge and misinformation about GM technology still prevails in the region. Efforts to address concerns include: developing national communication strategies, open discussions, training and supporting efficient communicators, developing and using effective messages and Information, Education, Communication (IEC) materials, and using study tours to allow key stakeholders to directly observe GM crops in the field. Ensuring the presence of appropriate biosafety regulatory systems, policies, legal instruments and decision-making processes is critical for the safe deployment of GM crops (Sengooba *et al.*, 2009), as well as for meeting international obligations. Public policy with regard to the deployment of GM crops must be guided by the most accurate and objective scientific advice available.

With a large number of GM crops currently under development in Africa it is evident that regulatory authorities in the continent will continue receiving applications for GM trials and/or environmental releases. In order to be able to effectively evaluate these applications, it is imperative that they have access to relevant information and appropriate training. For this to be possible, efforts have to be made to provide as much information as possible regarding GMOs, and training on how to evaluate them.

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5

Systems Biology Approach to the Evaluation of GM Plants – a Case Study

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SYSTEMS BIOLOGY APPROACH TO THE EVALUATION OF GM PLANTS – A CASE STUDY DR EUGENIA BARROS

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Abstract

A common element in the assessment of food safety of transgenic crops is centred on a comparative analytical evaluation with the conventionally bred crop plant assuming that these products have a history of safe use. This complies with the Organisation for Economic Co-operation and Development (OECD) principle of substantial equivalence. Non-targeted analytical approaches of gene, transcript, protein and metabolite levels are, however, the methods of choice to investigate the physiology of genetically modified (GM) plants as comprehensively as possible, thus increasing the chances of detecting unintended effects. In South Africa, the use of non-targeted analytical approaches to validate the concept of substantial equivalence in GMO plants is being investigated. While the results of the first study have been submitted for a scientific publication, this report summarises some of the outcomes of a specific data set. This case study evaluated the effect of genetic modification and environmental variation of one *Bt* maize cultivar grown in one location over three years (seasons) with its non-GM maize counterpart. Four non-targeted methods were used. The study showed that the variation observed in the two maize lines was mainly due to environmental factors.

1 Introduction

In the early stages of production and commercialisation of foods derived from GM plants, international consensus was reached regarding the principles of food-safety evaluation. The concept of substantial equivalence became the starting point of the safety evaluation framework based on the idea that existing foods can serve as a basis to compare the properties of GM foods with the appropriate counterpart (Kuiper *et al.*, 2001). However, the controversy regarding GM plants and their potential impact on human health and the environment have led to the development of additional methods for risk assessment. Risk assessment focuses on potential adverse effects which could result from unintended effects of genetic modifications. Unintended effects can also occur in conventional breeding. The best way to detect unintended effects is through non-targeted analysis by using profiling techniques. These techniques allow screening of potential changes in the physiology of the modified host plant at different cellular integration levels that include the genome level, during gene expression and protein translation and at the metabolic pathway level (Rischer & Oksman-Caldentey, 2006). Other factors, such as genetic characteristics (cultivar, isogenic lines), agronomic factors (soil, fertilisers) and environmental influences (location, weather, stress), also need to be considered during GM *versus* non-GM evaluations because they could contribute to some alteration that is not necessarily due to the genetic modification. There is therefore a need to use some of these profiling techniques to evaluate a GM plant *versus* a non-GM plant under different conditions to be able to determine their application in future risk assessment evaluations as more complex genetic traits are introduced into plants.

2 Targeted *versus* non-targeted approach to detect unintended effects

The evaluation of GM plants using targeted analysis looks at the compositional variation in the GM plant compared to the non-GM counterpart using a selection of analytes of interest. These key compounds have been determined by international standards to form the basis of substantial equivalence. The substantial equivalence approach was adopted by regulatory bodies to ensure that GM plants and foods are as safe and nutritious as their conventional counterparts (Kuiper and Kleter, 2003). The analytes or key compounds that are included in the baseline analysis of targeted studies include proteins, carbohydrates, fats, vitamins and other nutritional/anti-nutritional compounds that may affect the nutritional value and safety of the crop (Kuiper *et al.*, 2001). The selection of compounds may be limited to a restricted number representing essential biochemical/physiological pathways in the plant. The targeted approach has many limitations with respect to unknown anti-nutrients and natural toxins. Furthermore, any unforeseen, unintended effects of the genetic modification may escape detection using the targeted approach. Thus analyses using non-targeted profiling technologies have been developed that allow the screening of potential changes in the physiology of the plant at different cellular integration levels that include gene expression, protein translation and at the metabolic pathway level. These system biology technologies are also known as "omics" technologies, which refer to the comprehensive analysis of biological systems. In this case study four profiling technologies were used to evaluate one GM maize (*Bt*) and its non-GM counterpart. The effect of genetic modification and the environmental variation were included in the study by growing the two maize cultivars in one location over three growing seasons.

3 Data analysis

Profiling techniques generate a large amount of data even when a limited number of samples are used. To obtain a meaningful analysis of the profiles from the GM maize and its non-GM counterpart, the first stage of data analysis took into account all the compounds at once to give an overall view of the data. The multivariate analysis used in this study to identify the main sources of variation in the data set was the Principal Component Analysis (PCA). This technique reduces multidimensional data sets to smaller numbers of new variables called components that still retain most of the variation in the data. Once the major sources of variation are identified the next step is to examine each component individually using Analysis of Variance (ANOVA), taking into account all the relevant features of the experimental design (Davies, 2009). Compounds are then listed in order of significant level.

3.1 Transcriptomics

The microarray technology is the most common approach for gene expression profiling. cDNA microarrays have been used to investigate changes in gene expression during maize kernel development. One drawback of cDNA microarrays is the false discovery rate that results from cross-hybridisation among family members of the plant being studied. By contrast, oligo arrays can achieve hybridisation patterns of transcript levels relatively accurately and there are a few that are commercially available. The microarray used in this study was obtained from the Maize Oligonucleotide Array Project (US). In total 3 541 spots were included in the data analysis and PCA results showed a separation of the samples according to season and genotype. When the drivers of variation were investigated using ANOVA, the largest variation was due to year, whereas a much lower variation was due to genotype. This suggests that the variation found between GM and non-GM maize at the gene expression level was not significant.

3.2 Proteomics

The main approach currently used in protein profiling studies is two-dimensional (2-D) gel electrophoresis. This technology allows the comparative analyses of protein patterns, changes in protein concentrations or post-translational modifications triggered by environmental factors or genetic modification. There are, at present, two major short-comings with this technology: the first is that only highly expressed proteins can be detected in a complex protein mixture and the second is that there is not sufficient protein sequence data for identification purposes. The protein profiles generated by 2-D electrophoresis of the two maize cultivars showed that 714 proteins were included in data analysis, and PCA results showed that the samples could be separated according to season and genotype. The ANOVA tests showed that the effect of year was stronger than the effect of genotype. There was a very slight separation between genotypes which suggests that no significant variation was observed between GM and non-GM maize at the protein level.

3.3 Metabolomics

The analysis of plant metabolites is generally complicated due to their highly complex nature and vast chemical diversity. There is a range of technologies that can be used to identify individual compounds that could represent alterations in the content of cellular compounds such as sugars, fats, acids and other metabolites. These include Nuclear Magnetic Resonance (NMR), Gas Chromatography–Mass Spectrometry (GC-MS), Liquid Chromatography–Mass Spectrometry and Fourier-transform (near) infrared spectroscopy. Both ^{1}H-NMR and GC-MS were the metabolite profiling techniques used in this case study.

^{1}H-NMR fingerprinting plays a central role in dissecting the relationship between sequence and biological function. Although there is incomplete coverage of the plant metabolome, ^{1}H-NMR was sensitive enough to produce metabolic profiles of the two maize cultivars (15 500 complex data points were examined). Thirty-six compounds were identified for data analysis and the results showed a separation among the three seasons but no visible separation between the genotypes (GM and non-GM).

GC-MS metabolite profiling provides valuable information on the structural identity of compounds, but limitations of this technology include its restriction to low molecular weight constituents and the range of detectable analytes that is dependent on the choice of solvents used in metabolite extraction. Using GC-MS, 120 compounds were included in the data analysis and a separation was observed for seasons and for genotypes. The effect of season was greater than that of genotype.

4 CONCLUSION

The application of systems biology as a multidisciplinary approach to validate the concept of substantial equivalence as part of the safety assessment of GM plants can provide relevant information regarding changes in gene expression and associated protein and metabolite derivatives as a result of genetic modification. The non-selective comparison of

GM maize with its non-GM counterpart offers unlimited possibilities for the identification of unintended effects. In this "case study" non-targeted molecular profiling technologies were used to provide insight into the extent of variation in the maize transcriptome, proteome and metabolome by analysing two maize genotypes grown in the same location in three different years. The results showed that the variation observed was mainly caused by growing season and the associated environmental factors and was not due to genotype. Although the environment was the dominant source of variation, no common drivers of variation could be identified in this dataset. The differences that were observed between the *Bt* maize and the non-GM counterpart using the four technologies were not statistically significant. Since only two maize lines were used the possibility of identifying differences due to natural variation was not part of the scope of this study.

This study also highlighted the possibilities, as well as the challenges, of profiling analysis for food-safety evaluation. A big challenge of the "omics" technologies is the vast amount of data that they generate, making it extremely complex to evaluate individual GM lines and making a meaningful interpretation difficult. Other challenges include the many gaps related to the number of genes for which a function has been identified and the limited coverage of the proteome and metabolome. These technologies still need to be validated before they can be used for routine safety assessment. They are not intended to replace existing analyses but to confirm and supplement current targeted analytical approaches.

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6

Commercialisation of a GM Potato (A Case Study – Lessons Learned)

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COMMERCIALISATION OF A GM POTATO (A CASE STUDY – LESSONS LEARNED)

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1 Why we did the project

The potato tuber moth (PTM), *Phthorimaea operculella* (Zeller), is a serious insect pest of potatoes in South Africa (Visser *et al.,* 2003; Visser, 2007) and has become an increasingly important pest on tobacco and tomato as well (Van Vuuren *et al.*, 1998; Gilboa & Podoler, 1994). Damage has also been reported on eggplant and other solanaceous crops and weeds (Rahalkar *et al.*, 1985). It is an introduced pest, originating from South America (Visser, 2005), and is therefore not a native component of the South African ecosystem. The larvae attack potato plants and tubers under the soil and in stores, and are responsible for losses of up to R40 million per annum to the South African potato industry (Visser & Schoeman, 2004). Commercial producers rely on insecticide application for PTM, generally applied at weekly intervals. Applications start when the first moths appear and the insecticide is applied eight to twelve times per season. Control is not always satisfactory and damage levels vary between seasons and years, depending largely on the survival of over-wintering moths and their re-infestation of newly planted fields (Visser, 2004). No insecticide is registered against the PTM in South Africa under storage conditions. This includes *Bt* sprays, none of which are registered for use against PTM either on foliage or tubers (Nel *et al.*, 2002). The only control strategy that gives consistently good control against the PTM is the use of genetically modified (GM) insect-resistant potatoes containing the Cry1Ia1 gene (Visser, 2004). Because PTM in South Africa occurs outside of its natural distribution range (Visser, 2005), has demonstrated potential to feed on and therefore threaten other species (potatoes, other solanaceous crops, and other wild solanaceous species), and causes economic harm (Visser & Schoeman, 2004), this pest fits the definition of an invasive species. Therefore attempts to control this pest are consistent not only with good agricultural practice, but also with the objectives of the Biodiversity Act.

Another reason for the project is to demonstrate the feasibility of efforts led by the public sector and developing country institutions to make biotechnology products available in Africa. The PTM-resistant potato could be one of the first public sector-developed products to be approved and deployed in a developing country. Largely due to the high cost of developing a transgenic crop, only the large multinational companies have had the financial resources to pursue the commercial development of GM crops. Many laboratories at universities and other research organisations have produced GMOs. However, to put the GMO through all the regulatory hoops and produce a regulatory dossier with all the evidence to demonstrate that the GMO is not harmful is a costly affair. Therefore many of these products will never be commercially released. Proper commercial development of this product will benefit all potato farmers in South Africa. The technology is in the tuber, and the benefit is not scale-dependent.

A further aim is to demonstrate the value of developing country involvement in generating safety assessment data, namely the scientific contribution and at a reduced cost. This would result in the building of capacity of public sector institutions in commercialising GM crops.

2 What was done?

The following product commercialisation approach was followed.

2.1 Technology and Product Development

First field tests had to be conducted under normal agricultural conditions to demonstrate the proof of concept. Multi-location field trials in the major growing regions were conducted over a number of growing seasons to select the ideal clone and for the bulking-up of material.

2.2 Regulatory File Development

Food-safety analysis was performed and environmental studies done.

Intellectual property ownership of product components had to be assessed and "freedom-to-operate" and licensing of the potato had to be done. In the case of this potato some of these licensing issues still have to finalised.

2.3 Marketing and Distribution

A delivery strategy had to be developed that would fit into the existing potato industry in South Africa. Discussions were held with seed producers who had historically supplied small-scale farmers (emerging farmers) with seed potatoes. They were quite keen to distribute the GM potatoes. Initially, due to the small amounts of seed, farmer participatory trials with small-scale producers were planned.

Extension will have to be done to assist farmers to use the technology safely and according to permit regulations. Standard farming extension will also have to be included in this package.

A stewardship and liability strategy was developed.

2.4 Outreach and Communication

Public communication of the benefits and impacts of the potato was started. However, due to budget constraints this part of the project was scaled down. It was also decided that it would perhaps be more beneficial if the potatoes were in the pipeline before more substantial communication efforts were undertaken. Creating expectations of a product that may never be commercialised can also have a negative impact on the consumer. On the whole the retail industry was not opposed to the new potato, but there were fears that organisations would mobilise customers to boycott the product or their stores, thus affecting profits.

2.5 Documentation of Socioeconomic Assessments

The Spunta G2 potatoes offer farmers an alternative to the use of pesticides for controlling potato tuber moth in the field and in storage. The Spunta G2 potatoes can be safely stored without any chemical treatment for tuber moth, even under heavy moth infestations. Socioeconomic studies have shown that smallholder farmers lose a considerable amount of their stored potatoes to the potato tuber moth and that chemical treatments are used in attempts to prevent these loses. Furthermore, some of these chemicals are not approved for use on potatoes. A study was undertaken with commercial farmers as well as five small-scale farmer communities. A few commercial farmers were against the technology as they believed it would interfere with their exports. Some welcomed the potato and others did not see that it would be beneficial to them. The small-scale farmers' major concerns revolved around more basic issues, such as land availability and other input constraints.

3 Summary of data needed for the regulatory dossier

3.1 Agronomic Performance

We had to demonstrate that the GM Spunta G2 potato performed as well as the standard Spunta under various farming conditions. The potato was tested in six potato-growing regions for a number of seasons. Resistance to tuber moth under diffused light store conditions was also examined and found to be excellent. The GM potato performed as well as the standard potato and gave 100% protection against PTM.

3.2 Molecular Data

We demonstrated that we had a single copy gene insert in Spunta G2 without any vector backbone or other additional DNA fragments. The inserted gene, as well as about 1 Kb on either side of the inserted gene, was sequenced to demonstrate that the gene itself was intact and that no new reading frames were generated. The levels of expression of the *Bt* protein were also determined in the leaves and tubers.

3.3 Food and Feed Safety

Both the transformed and non-transformed Spunta potatoes were analysed for nutrient composition and it was found that they were identical. Solanine levels in the tubers were also determined to see if there were any increases in levels. Toxicity tests were performed by feeding mice a large single dose of the *Bt* protein, but no ill effects were seen. A whole food-feeding study with rats was conducted over 90 days and a number of parameters were measured (e.g. growth, organ weight, blood chemistry) and no differences could be determined in the various test groups.

3.4 Environmental Safety

A study in three of the trial locations was conducted over a number of years on the arthropod populations that inhabit the potato plots. Arthropods found above the canopy, within the canopy and on the ground were collected and assessed. Tens of thousands of arthropods were collected during the study and no negative impacts were found. The predation on PTM larvae and eggs was also studied, and no negative results were found.

Studies were also conducted on the soil microflora to determine whether the *Bt* protein produced in the plant affects these populations. Once again, no negative impact could be determined.

3.5 Socioeconomic Impact Data

Two surveys were conducted to attempt to shed light on the socioeconomic impact of the *Bt* potato. It is important to note that although this information is requested by the Executive Council, there are no guidelines on what kind of information is needed. We were subsequently informed that even a "desktop" study may have been sufficient. These studies are very expensive and the Executive Council should provide proper guidelines of what they require.

The two studies that were conducted were for smallholder and commercial producers were: "Smallholder potato production activities in South Africa: a socioeconomic and technical assessment of five cases in three provinces" and "Potential economic benefits of a genetically modified (GM) tuber moth resistant-potato variety in South Africa: an ex-ante socioeconomic evaluation for commercial producers".

Smallholder farmers indicated a range of problems, many of which might be simply and cost-effectively reduced by means of adapting existing technology to local conditions and practices. Engaging in a process of participatory and adaptive research with farmers will enable them to help optimise their potato production within their specific environment. This can be achieved by encouraging farmers, research institutions and community workers (NGOs and PDA) to work together in close collaboration. Adapting current technologies to local conditions tends to be more cost-effective than developing new technologies which, due to their generic nature, are not adapted to local conditions and might not be adopted as a result. Optimising production and storage practices within a low-input situation could help to address many pest and disease problems experienced by subsistence farmers, as many of the problems faced are management problems, exacerbated by lack of access to sufficient resources.

It appears that commercial farmers in general would agree to introduce GM potatoes into their production planning on condition that the new technology significantly increases their profits. The GM potato with PTM-resistant genes might not have the expected rapid adoption rate among farmers, since most farmers have PTM infestation under control at a reasonable cost.

3.6 Post-Approval Stewardship Plan

An 80-page post-approval stewardship plan was developed that could be implemented if approval were granted.

4 Where are we now?

The Regulatory Dossier was compiled and submitted with an application for general release to the office of the Registrar of the GMO Act in 2008. The Executive Council assessed the application and decided not to grant a general release permit in July 2009. The Executive Council cited 11 points for this rejection. The Agricultural Research Council (ARC), with support from their partners, decided to appeal this decision on the grounds that the reasons provided did not warrant a rejection. This process is still in progress at the time of writing, but it is hoped that the appeal process will have been completed by mid-2010. The project has therefore been on hold since 2008. If the appeal is successful, planting material for the farmer participatory trials will only be available at the end of 2011. The project is at a point where it is unable to continue unless we manage to get permission to do "farmer participatory trials".

5 What have we learned?

South Africa has the expertise to assess GM products. However, there are still gaps in this expertise. Many of the tests that were to be performed in South Africa, e.g. testing for the solanine content in potato tubers, soil microbiological work, protein production and antibody production, could not be done here. Either it had not been done before and/or no-one could be found who was willing to develop the methodology or perform the tests. At times the fees that laboratories wanted to charge to develop tests were far higher than those charged in the US. One possible reason for the lack of testing facilities is that there is no demand for these tests and therefore the expertise has not been developed. However, the fieldwork, animal-feeding studies, molecular analysis and food nutritional analysis, for example, could be done at a reasonable cost. Although there is in general a large scientific pool of expertise in South Africa that would be able to be involved in GMO evaluation, research institutions and groups are not necessarily set up to perform these tests.

Stakeholder buy-in from the early stages is essential for success. Stakeholders should be part of the team from start to finish. However, stakeholders can have a change of heart during the project, which can have a severe negative impact on the project. Every attempt should be made to keep communication lines open and to keep all the stakeholders on board. Stakeholders who have inside information about the project can become major liabilities if they decide to withdraw from the project.

Adequate funding is essential. The process of developing and bringing a GM crop to the market can be expensive and can take a very long time. Therefore funders must make long-term commitments as the project can stagnate for years while regulatory authorities make decisions that impact on the project. Unexpected or unplanned expenses may arise during the project which can have severe implications if no additional funding can be sourced.

Intellectual property issues should be addressed before the project begins or as soon as possible after the project has started. Years of work can be wasted if the IP-holders decide not to allow their property to be used for commercial purposes.

Post-release stewardship is a very difficult but important aspect of such a project. Research organisations typically do not have the resources and mechanisms to implement stewardship programmes. Therefore it is essential to have industry or trade partners with the resources and skills to implement the stewardship campaign. These partners should be part of the team from the early stages of the project.

6 Final comments

Before embarking on the long journey of developing and commercialising a GM product, one must ask the following questions:

- Is it only an academic exercise?
- Is it worth the time and effort?

- Is there real benefit to anyone?
- Is it a case of "we have an answer, let us find a problem"?
- Is the government serious about using GM technology and will they create an enabling environment?
- Can public organisations really compete with large multinationals?

I suspect that few research organisations are totally truthful about the answers they will give to the above questions. Financial pressures and the push for publications may encourage research groups to develop GM crops that will have "great benefit" for certain communities, but will ultimately end up as academic exercises.

It is important that all serious role-players should evaluate what they want to achieve, assessing the chances of success and, if successful, how will the product be rolled out for the beneficiaries. Only the larger multi-institutional and multidisciplinary groups stand any chance of success. Expertise and resources must be pooled and directed to a few "good" projects. The South African authorities appear to be becoming more conservative and less keen on granting permits. If this is the case, it may make it more difficult for other African countries to embrace this potentially beneficial technology.

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7

The Use of Nuclear Techniques to Produce Improved Varieties of Food Crops in Africa

Dr Yousuf Maudarbocus

THE USE OF NUCLEAR TECHNIQUES TO PRODUCE IMPROVED VARIETIES OF FOOD CROPS IN AFRICA

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1 Techniques available to produce GMOs

1.1 Recombinant DNA Technology

A genetically modified organism (GMO) is an organism whose genetic material has been altered. Recombinant DNA technology makes use of DNA molecules from different sources which are transferred into the genome of an organism giving it modified or new genes. In general, GMOs are produced to endow them with new useful traits.

However, when no gene, or genes, can be found in the available gene pool to introduce the desired trait into a particular plant, plant breeders have no obvious alternative but to attempt mutation induction.

Mutation can be induced artificially in two principal ways:

1) by the use of chemical agents

2) by radiation techniques.

As these methods work in entirely different ways, they are really complementary.

1.2 Chemical Methods

Chemicals, such as sodium azide and ethyl methyl sulphonate, are used to induce mutations in plants. However, some plant genes are more easily mutated by radiation.

1.3 Nuclear Techniques

Artificial induction of mutation by ionising radiation dates back to the late 1920s. Initial attempts used X-rays, subsequently replaced by gamma and neutron radiation. Currently, gamma radiation is most widely used.

The irradiation of seeds speeds up the natural process of evolution of the plant's DNA. Thus new varieties of crops can be produced with characteristics tailored to a particular need.

The seeds are normally subjected to a range of radiation doses to produce genetic variation. The plant with the desired trait is selected following field trials. The development of plant cell and tissue culture over the past decades has made it possible to transfer part of the breeding work from the field to the laboratory.

2 The importance of breeding new plant varieties

Food security is one of the most challenging problems facing poor countries. The production of improved varieties of food crops can contribute significantly towards alleviating malnutrition in these countries.

Important desirable properties which can be achieved through plant breeding include:

(a) **Increased disease resistance:** This is very important, as many crops are ruined by diseases. The use of chemicals for protection may be limited by cost or concern for the environment.

(b) **Improved lodging resistance:** Lodging is a serious problem, affecting cereal crops such as barley and durum wheat in particular. The desired properties are a reduction in plant height and a stiffer stem with at least an equal or an improved yield.

(c) **Earlier or later maturing time:** The "earliness'' of many important crop plants, such as bread wheat, rice and barley, can be improved by five to ten days, thus making room in the field for other crops. Altering the maturing time may also allow some crops to escape drought, frost or pests.

(d) **Improved seed characteristics:** These concern the improvement of nutritional value (protein or oil content), baking qualities, reduction of cooking time and taste.

(e) **Improved agronomic characteristics:** These are, for example, greater heat tolerance and better adaptability to adverse soil conditions (barren or high-salinity land).

(f) **Increased yields:** These techniques have resulted in an increase in yield of up to 45% for certain crops.

3 Mutation breeding in African countries

3.1 New Wheat Varieties in Kenya

In Kenya and other African countries wheat crops are plagued by a virulent new strain of fungus called "wheat rust''.

Using radiation-based techniques to modify crop characteristics and traits, scientists and crop researchers at the Kenya Agricultural Research Institute (KARI), working closely with the International Atomic Energy Agency (IAEA), developed new wheat seeds over the past decade. The first mutant wheat variety, called Njoro-BW1, was released in 2001. It is tolerant to drought and uses limited rainfall efficiently. Moreover, it exhibits moderate resistance to wheat rust, has high yields and the flour is of good baking quality.

Today, Njoro-BWI is cultivated on more than 10 000 ha in Kenya. It has become so popular among Kenyan wheat farmers that KARI's seed unit can hardly keep up with demand.

Another high-yielding mutant, codenamed DH4, is due to be released soon.

3.2 New Sorghum and Rice Varieties in Mali

Mali's native sorghum has traits that give it some resistance to drought, but it still needs substantial rainfall for a good harvest. As sorghum production has not kept up with population growth, Malian scientists, especially at the Institut Polytechnique Rural, initiated a programme to improve the production of sorghum while conserving their essential traits. With the assistance of the IAEA, traditional varieties of sorghum were irradiated with gamma rays according to prescribed procedures. Initial field tests show increases of more than 10% in productivity.

It is worth noting that other traits of sorghum in Mali have also been altered using different gamma irradiation doses, as shown in Table 7.1.

Table 7.1: Altered traits of sorghum

Dose	Year	Traits
300 Gy	1992	Increased lodging resistance
250 Gy	1998	Earliness
100 Gy	1998	Increased panicle size, increased yield and change in grain colour

Rice has been grown in the flood plains of the Niger River for several centuries. Following irradiation of the local variety, new mutants have been developed with white colour characteristics and higher yields (> 15%). White rice in Africa fetches double the price of red; so for farmers, the colour alone means a substantial increase in income.

3.3 Sesame in Egypt

In Egypt, three mutant varieties of high-yielding, disease and insect-resistant sesame are bringing higher economic returns than standard varieties.

3.4 Cassava in Ghana

Ghana's cassava variety "Tek Bankye'', with improved cooking quality, was released recently. Trials are underway to produce higher-yielding, disease-resistant cassava, with improved starch content.

3.5 Other New Radiation-Induced Varieties

Several other radiation-induced varieties of crops with improved traits, higher yield and better nutrition value, which are adaptable to harsh environments have been released. These include, among many others, finger millet and cotton in Zambia and banana in Sudan.

3.6 Ongoing Activities

Numerous research and development (R&D) activities are being carried out in African countries to develop improved varieties of various crops through the use of nuclear technology. These include the development of:

a) A better lodging and higher-yield variety of tef in Ethiopia.

b) An improved variety of rice at the Sokoine University of Agriculture, Morogoro, Tanzania.

c) A disease-resistant variety of cocoa at the Cocoa Research Institute of Ghana (CRIG), Tafo, Ghana.

The cocoa swollen shoot virus (CSSV) is a major disease which has destroyed more than 40% of the cocoa production in Ghana. In fact, during the last 50 years, about 200 million cocoa trees have been destroyed in Ghana as a result of CSSV.

Buds of cocoa plants are subjected to gamma radiation at the Ghana Atomic Energy Commission (GAEC) with a view to producing new plant strains with disease-resistant properties. Some of these new strains are being field-tested; if successful, the economic benefit to Ghana would be immense.

4 Conclusion

Nuclear techniques can help to address the issues of food security in Africa. These techniques are highly competitive in relation to non-nuclear technologies and can be used to achieve better solutions to new challenges in Africa.

Other regions have already derived huge economic benefits through the use of radiation-induced mutations.

In China, up to 2005, a total of 638 mutant varieties of 42 plant species have been released, covering 9 million ha of planting area. The economic benefit derived from increased cereal production alone is estimated to be about US$420 million a year.

In Pakistan, a mutant producing better quality and higher-yielding crops quadrupled cotton production within ten years of release (1983–1992) and now accounts for 70% of all cotton grown in the Punjab region, resulting in an economic benefit of US$20 million a year.

In Peru's high Andes, stronger and healthier varieties of barley, grown at altitudes of up to 5 000 m, produce about 1 200 kg per hectare, that is, an increase of 50% in relation to previous varieties. This translates to an economic benefit of about US$9 million a year.

There is no doubt that the use of nuclear techniques to produce improved varieties of food crops in Africa could contribute significantly towards alleviating the food crisis and bring about considerable economic benefits.

8

Opinion Paper: Sustainable GMO Technologies for African Agriculture

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OPINION PAPER: SUSTAINABLE GMO TECHNOLOGIES FOR AFRICAN AGRICULTURE

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Abstract

Agricultural sustainability usually refers to agronomic sustainability, including aspects such as agronomical practices, productivity and ecological diversity – all factors that should be considered during the risk assessment of a genetically modified (GM) crop before it is released commercially. Most GM crops that have been commercialised to date were developed primarily for large-scale farming systems and would, arguably, not impart the same scale of benefit to small-scale and subsistence farmers, typical of developing countries. Therefore, to allow developing countries to derive the full potential benefits of biotech crops, we propose that, in addition to the traditional biosafety aspects mentioned above, technology developers should also more carefully consider factors such as the relevance and accessibility of a particular technology to ensure sustainability. Risk assessment and risk management play a critical role in the successful commercialisation of GM crops and should therefore be considered as an integral part of any GM research and development programme. This paper will develop these concepts and present a risk analysis framework which can be used in an R&D programme to identify, assess and mitigate potential biosafety and other deployment risks.

1 Introduction

In a discussion on the sustainability of genetically modified organisms (GMOs), it usually revolves around their sustainable use in agricultural systems, focusing predominantly on food/feed and environmental safety. Sustainability is therefore often equated to the post-release safety of the GMO, an aspect that is regulated in all systems and is therefore carefully considered during the development and risk assessment processes. Potential socioeconomic impacts, by contrast, are currently either not regulated in many countries or are only considered at a very late stage of product development. The facts that most of the current commercial GMO crops were designed around the needs of specific markets that differ considerably from those in the developing world, and that they were not developed based on locally established priorities and competencies, resulted in GMO products that are unable to deliver positive socioeconomic impacts to many farmers in developing countries.

The sustainable adoption and use of GM technology also depend on many socioeconomic and practical constraints, which should be considered proactively in *ex ante* sustainability analyses. By integrating sustainability analyses, including biosafety and socioeconomic assessments, into a GMO research and development pipeline, the development of both safe and economically sustainable products could be ensured. Such an approach should also improve the overall efficiency of the innovation system because it will help to ensure the development of safe, relevant and accessible products that are truly sustainable.

2 Why focus on sustainable GM technologies?

Obvious answers to this question will revolve around the post-release endurance, safety, diversity and productivity aspects of the GM crop and its receiving environment, but it also has an important developmental or strategic aspect. To successfully unlock the potential of GM technology, it is important to realise that the technology in itself is not a product. GM technology should be packaged into a final product that, in addition to the sustainability aspects listed above, is also relevant and accessible to ensure adoption and continued use. Defining sustainability in this holistic way and integrating these considerations from an early stage into a GM research and development programme will not only help with the development of safe, sustainable products, but will also improve the efficiency of the innovation process because flawed products can be discarded at an early stage.

3 Defining the sustainability of GMOs

Sustainability implies safety and the safety of GMOs is defined in terms of their food/feed and environmental safety, issues that should be proactively considered from the very start of a GM research and development project to ensure regulatory compliance. These safety aspects of sustainability are not disputed and are similar for all markets, but GM crop sustainability also includes a socioeconomic aspect that can vary dramatically between different markets. It should therefore come as no surprise that the socioeconomic sustainability and benefit of the currently available GM crops have been questioned in many developing countries. Even in countries where the potential socioeconomic impact of GMOs is considered before general release, this is only done as part of regulatory compliance with the aim of limiting undesired *ex post* impacts and is not intended to be a comprehensive feasibility analysis. To ensure the sustainable adoption and use of GMOs in a particular environment, these aspects should be considered proactively during the development process of the specific product. The integrated, proactive assessment of both the biosafety and socioeconomic aspects, i.e. a continuous sustainability assessment, of a new GMO is therefore critical to ensure the development of sustainable products for African agriculture that will impart a real benefit to the adopters of the technology (Figure 8.1).

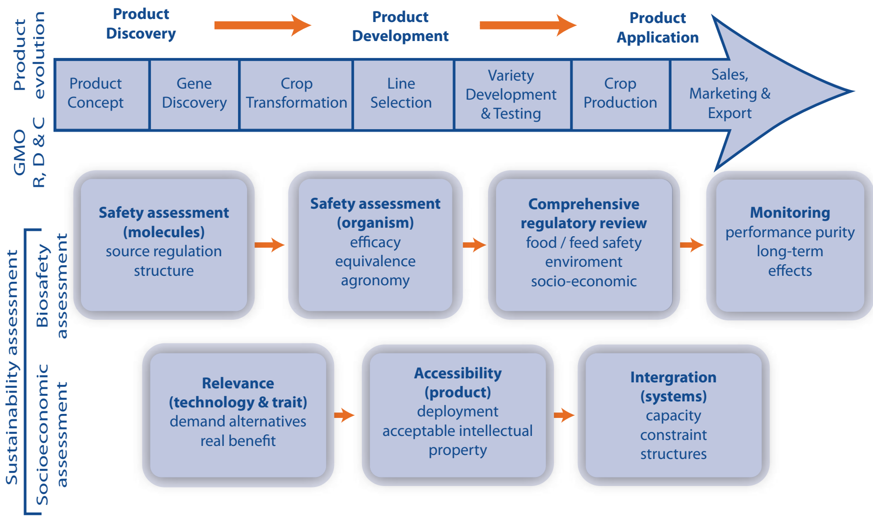

Figure 8.1: Integrating sustainability assessments into a GMO crop R,D&C programme

To be sustainable, GMOs for African agriculture have to be safe, relevant and accessible. The best way to ensure this is to develop these crops locally, based on local knowledge, priorities, capacities and constraints.

4 Sustainability assessment of GMOs

Sustainability was previously defined on the basis of its three contributing aspects, i.e. food/feed safety, environmental safety and socioeconomic feasibility. However, when using it as an integrated tool for decision-making in a GMO R,D&C programme, it is more relevant to define it chronologically. I will therefore briefly discuss the seven sequential sustainability assessment clusters as indicated in Figure 8.1 and illustrate the principle of integrated sustainability assessment by way of a few examples in each cluster.

(a) ***Biosafety assessment – at molecular level:*** Even before the first construct is developed for a transformation programme, the possible implications of the individual genetic

components and interventions should be considered. This early-stage, strategic assessment could help to ensure that the final product will be safe and viable. Possible impacts of the molecular biology interventions/protocols and tools that are used during the transformation programme include the following:

- The choice of a particular transformation system can impact on transgene copy number and the presence of partial vector sequences.
- Using tissue-specific promoter sequences could reduce the possible environmental impact of the transgene.
- Certain selectable markers such as antibiotic resistance genes might be prohibited in certain regulatory territories.
- Under the current South African legislation the use of a human gene will have specific labelling implications while analogues from different sources will not.

(b) ***Biosafety assessment – at organism level:*** Both the selection of a particular organism/crop and the GM trait(s) of the resulting organism should be considered at an early stage. Possible risks associated with different organisms will obviously vary – targeting a particular crop disease via the causative agent, its possible vectors or the crop itself will, for example, have very different possible impacts.

- Modifying food crops to sustain industrial applications could also have significant socioeconomic impacts.
- The availability of biological containment measures could play a significant role in risk management strategies.
- The introduction of a GM crop into its geographical centre of origin or where sexually compatible wild relatives are present would imply vertical gene flow, which could limit the type of GM traits that could be transferred to that particular crop.

(c) ***Biosafety assessment – comprehensive regulatory overview***: The regulatory overview or development of the regulatory dossier for a GMO constitutes the comprehensive characterisation of the final transgenic line that has been earmarked for commercialisation, i.e. the GM product. At this stage, all the aspects of biosafety, i.e. food/feed safety and environmental safety, and where appropriate, the potential socioeconomic impacts of the GMO are considered.

- As part of the food/feed safety assessment, possible toxic components, allergens, nutrients and their interactions will be investigated, with the frame of reference for many of these studies being substantial equivalence.
- Possible environmental impacts will be considered with reference to the new GM trait and where relevant, e.g. the transgene's possible impact on the competitiveness of the organism, the potential for gene flow and its likely impact, non-target organisms and resistance development.
- Currently, no clear guidelines exist for evaluating the possible socioeconomic impacts of GMOs, but it is probably fair to say that current evaluations focus on ensuring that the impacted industry and the majority of its stakeholders will not be disadvantaged by the release of the GMO. Possible changes in agricultural practices and potential gains and losses in agricultural inputs, yields and markets are also considered.

(d) ***Biosafety assessment – monitoring:*** In most countries the release of GMOs is conditional on post-release monitoring to gauge possible long-term effects and to ensure the employment of prescribed management practices, e.g. the use of refugia as part of a resistance management programme. One strategic aspect to assess here is the identification of measurable endpoints, e.g. exactly how will non-target impacts be evaluated over time?

(e) ***Socioeconomic assessment – relevance:*** When considering the use of GM technology, its relevance to a particular targeted community should be carefully considered. As stated earlier, the focus should be on the intended product and its potential benefits and not on the technology. The potential benefit for the specific target market/community under their particular circumstances should be clearly described. The benefit should be a priority for the targeted community. Other technologies that could deliver the same benefit and the acceptability of GM technology should also be considered.

(f) ***Socioeconomic assessment - accessibility:*** Many technical and practical aspects surrounding the deployment of a GMO can impact on its accessibility in a developing country.

- The potential costs or legal obligations associated with intellectual property rights could impact on many of the technology packages that have been used during the development of a GMO. Also, technology deployment should never be at the expense of freedom to choose.
- Management practises associated with particular GM traits could make them non-viable on a small scale or in an informal environment, e.g. seed-saving and associated introgression could contribute to resistance development.
- Cultural practices and preferences could impact on the acceptability of a particular trait, e.g. yellow maize as a result of high ß-carotene levels for human consumption, or the presence of an inconspicuous trait in an unacceptable variety.

(g) ***Socioeconomic assessment – integration:*** Integrating GM technology effectively and seamlessly into current local agricultural systems is crucial for the sustainable use of the technology. If the deployment of GM technology remains dependent on sophisticated distribution, implementation and management programmes, the distribution of its benefits will be severely limited in the developing world. Again, the sustainable solution is to focus more widely on issues such as institutional development than just on the technology.

5 Conclusion

A final strategic aspect of sustainability that deserves brief mention is the public acceptance of GM technology. Other applications of GM technology, such as that in the medical industry have not initiated as many negative perceptions, most probably because the potential benefit/risk ratio is perceived to be much more favourable in these applications. The nature of the debate on GM foods will therefore probably change significantly when more products are developed that deliver a tangible benefit to the end consumer. Developing such products specifically for application in the developing world and ensuring that they are supported with credible biosafety and sustainability data and underpinning principles as described above, will help to ensure that the true potential of GM technology can be unlocked for African agriculture.

Acknowledgements

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9

Agricultural Biotechnology: Does it work in Africa?

Mrs Remi Akanbi

AGRICULTURAL BIOTECHNOLOGY: DOES IT WORK IN AFRICA? MRS REMI AKANBI

AfricaBio, South Africa

1 Introduction

Africa is home to over 900 million people representing 14% of the world's population. It is the only continent where food production *per capita* is decreasing and where hunger and malnutrition afflict at least one in three people (James, 2008). Africa is recognised as the continent that represents by far the biggest challenge in terms of adoption and acceptance of new technologies.

Present agricultural practices in Africa are not producing adequate amounts of food for its growing population (Blancfield *et al.*, 2008). For this reason farmers are putting additional pressure on the environment in their quest to feed more and more people.

Success in meeting these challenges will depend on the unearthing of new information and knowledge, and the development and use of new technologies. If these are combined with the broader adaptation of existing technologies, it will allow increased crop production on the continent.

Africa is yet to fulfil its food production potential and it is especially vulnerable in terms of food security (Brink *et al.*, 1998). To meet Africa's food requirements, it is therefore necessary to increase the efficiency of food production. Several key factors including plant biotechnology are required for improved crop production.

New technologies need to be assessed to determine the role they can play in improving crop yield, controlling diseases and pests and improving nutritional content. Africa is very poor and challenges to the development and effective use of biotechnology exist not only in financial constraints but also in policy, national capacities, information access and the regulatory environment.

2 Agricultural biotechnology

Agricultural biotechnology has been around for centuries. Mankind has been manipulating living organisms for thousands of years. Three thousand years ago civilisations were using yeast to make bread, beer and wine and using bacteria to extract minerals from ore; for the past 500 years we have been selectively breeding crops and since 1920 we have been able to increase crop yields six-fold (Evansa & Fischerb, 1999).

Agricultural biotechnology is vital for addressing the chronic food shortages in sub-Saharan Africa. Despite the Green Revolution, crop yields in sub-Saharan Africa have hardly changed over the past 40 years and cereal production *per capita* is steadily declining. It has been estimated that with current yields the projected shortfall of cereals will be 88.7 million tons by 2025 (Thompson, 2002).

3 The role of biotechnology in Africa

Biotechnology offers considerable opportunity for addressing many of Africa's pressing challenges. Ongoing biotechnology research in Africa focuses largely on attempting to solve local problems associated with food production, health and the environment.

Biotechnology can play a role in increased global crop productivity to improve food, feed and fibre security in sustainable crop production systems that also conserve biodiversity. It can contribute to the alleviation of poverty and hunger, augmentation of traditional plant breeding, reduce the environmental footprint of agriculture, mitigate climate change and reduce greenhouse gases and contribute to the cost-effective production of biofuel.

4 The status of biotechnology in Africa

Genetic modification technology is being employed only in a very few African countries, namely South Africa, Zimbabwe, Egypt, Kenya, Burkina Faso, Uganda and Malawi, and to a lesser extent in Mauritius. Of all these countries, only South Africa, Egypt and Burkina Faso have reached the commercialisation stage. The remaining countries have either only recently approved contained trials of crops such as cotton and maize (e.g. Kenya, Uganda, Zimbabwe and Malawi), or do not as yet have any regulatory or scientific capacity to conduct such trials.

Most countries in Africa have ratified the Cartagena Protocol on Biosafety (CPB) and have received United Nations Environment Programme – Global Environment Facility (UNEP-GEF) assistance to formulate their biosafety frameworks. Only a few have functioning biosafety legislation that allows field trials of GM products (South Africa, Zimbabwe, Malawi, Kenya, Uganda, Tanzania, Burkina Faso, Ghana, Nigeria, Egypt, Tunisia, Morocco, Mauritania).

5 Challenges

- A third of the African population suffers from chronic hunger.
- There is a volatile political environment in most African countries.
- Lack of biosafety regulation is the biggest limitation to biotech growth in Africa. Changing regulatory regimes or lack of them have serious implications for the development of biotechnology in Africa. Biosafety regulations and legislation are in place only in a few countries in Africa, and such a limitation is a serious constraint that impairs the use, evaluation and release of GMOs.
- Extension services are virtually non-existent.
- The media and anti-biotechnology groups: three countries in Africa have commercialised biotechnology crops and a few are conducting or are on the verge of conducting confined or field trials. Anti-biotech campaigners will increasingly target these countries.
- Public awareness and acceptance – biotechnology regulation is essential to promote public interest and ensure safety. Consumer acceptance will increase when there is confidence in the checks and balances that biosafety regulations offer.

6 Opportunities

There is political will for biotech in Africa. The lack of priority setting in agricultural research is evident in many African countries, which is reflected in a lack of awareness and commitment by the national governments. Continuous technical and financial support will assist Africa to create an enabling environment for biotechnology to thrive.

Over 90% of sub-Saharan Africa relies on rain-fed agriculture. Severe drought occurs approximately every eight years. Drought-tolerance technology could help farmers to maximise their inputs and management practices and protect their investments in times of water shortages. Without Africa-focused R&D, capacity building and policies that enable the safe and beneficial use of biotechnology, African farmers may be denied access to drought-tolerance technology.

Biotechnology products in the pipeline that will revolutionise agriculture in Africa for the poor are drought-tolerant, nitrogen-efficient and biofortified crops. South Africa has the capacity, expertise, experience, enabling legislations and resources to lead the continent in R&D, innovations and expanding crop acre. South Africa's experience and vast capacity should be shared with the rest of Africa.

The Millennium Development Goals (MDGs), launched in 2000 (MDG Africa Steering Group, 2008), consist of eight key objectives, one of which is the eradication of poverty and hunger in Africa by 2015. The G8 nations have, however, been lagging behind in their commitments to boost aid to Africa. With rising food prices, hunger and poverty the G8 leaders are under immense pressure to do something.

We need to ensure the renewal of the G8's commitments by developing an initiative to tap into the G8's resources and those of other organisations, such as the World Bank and the FAO, which would help Africa to realise some key MDGs.

Networking and training opportunities in Africa should be continued. Linkages between African countries as well as with the developed world should be stimulated through existing networks and joint projects.

7 The South African experience

South Africa became the first country in Africa to adopt GM crops when it approved its first transgenic crops for commercial use in 1997. To date the commercial release of insect-resistant (*Bt*) cotton and maize as well as herbicide-tolerant (RR) soya beans, cotton and maize have been approved in South Africa. In October 2005, stacked-gene cotton (*Bt* & RR) was approved and in March 2007 the stacked-gene maize (*Bt* & RR) was approved. The present national GM crop percentages are: cotton 90%, white maize 56%, yellow maize 72% and soya 80% (James, 2008).

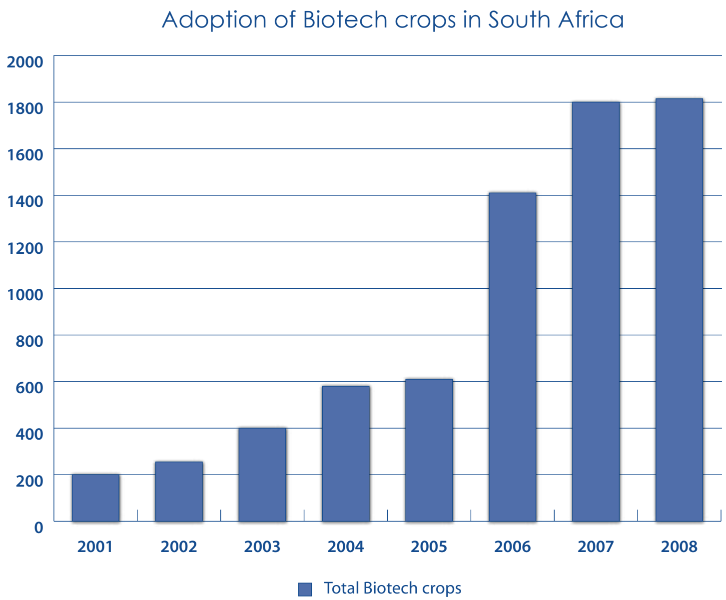

Figure 9.1: Adoption of GM crops in South Africa (James, 2008)

For the first 12 years of commercialisation of biotech crops from 1996 to 2007, South Africa was the only country on the African continent to benefit from commercialising biotech crops. In 2008, Burkina Faso grew 8 500 ha of *Bt* cotton for seed multiplication and initial commercialisation, and Egypt grew 700 ha of *Bt* maize for the first time (James, 2008).

Table 9.1: Total area of GM crops planted in South Africa in 2008 (James, 2008)

Crop	Total area	Area GM	% GM	Remarks
Maize				
White maize	1 600 000 ha	891 000 ha*	56%	* Bt/HT 164 000 ha (83%) HT 148 000 ha (9%) Bt 576 000 ha (8%)
Yellow maize	1 000 000 ha	720 000 ha*	72%	* Bt/HT 138 000 ha (83%) HT 131 000 ha (9%) Bt 455 000 ha (72%)
Soybeans	230 000 ha	184 000 ha*	80%	* HT soybeans
Cotton	13 000 ha	12 000 ha*	92%	* Bt/HT 10 000 ha (83%) HT 1 000 ha (9%) Bt 950 ha (8%)

8 Socioeconomic benefits of GM crops in South Africa

In South Africa a study published in 2005 involving 368 small and resource-poor farmers and 33 commercial farmers, the latter divided into irrigated and dry-land maize production systems. The data indicated that under irrigated conditions, *Bt* maize resulted in an 11% higher yield (from 10.9 MT to 12.1 MT/ha), a cost savings in insecticides of US$18/ha equivalent to a 60% cost reduction, and an increased income of US$117/ha. Under rain-fed conditions, *Bt* maize resulted in an 11% higher yield (from 3.1 to 3.4 MT/ha), a cost saving on insecticides of US$7/ha equivalent to a 60% cost reduction, and an increased income of US$35/ha (Gouse *et al.*, 2005). Farmers are paying premium prices for the use of the technology because of increased productivity and efficiency gains (Brookes & Barfoot, 2008).

South Africa is estimated to have increased farming income from biotech maize, soybean and cotton by US$383 million in the period between 1998 and 2007, with benefits for 2007 alone estimated at US$227 million (Brookes & Barfoot, 2009).

9 Conclusion

With the commercialisation of biotechnology products in other parts of Africa, South Africa is no longer the sole producer of biotechnology products in Africa. However, the country remains the pioneer of the technology and is a role model for the rest of Africa.

South Africa is seen as the hub of agricultural biotechnology for Africa as it is one of the few countries in Africa that has a well-developed regulatory system and the expertise to manage the technology. However, South Africa seems to be moving towards stricter legislation which is not based on scientific fact.

There is therefore a need in South Africa to ensure that decision-makers who develop policies, amend and enforce the existing legislation and regulations are continuously educated and well informed on biosafety and biotechnology.

GM crops can contribute to improved food security and poverty alleviation in Africa. Developing farmers in Africa have shown that they are able to access the benefits of GM crops, but they need good governance, financial support, skills training, market access, the support of competent extension services and an adequate rural infrastructure.

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10

Regulation of GMO Activities in South Africa: Experience from a Technology Developer

Ms Michelle Vosges

REGULATION OF GMO ACTIVITIES IN SOUTH AFRICA: EXPERIENCE FROM A TECHNOLOGY DEVELOPER

MS MICHELLE VOSGES

Monsanto, Johannesburg, South Africa

1 Introduction

As a technology developer, one experiences various challenges as a result of the regulatory frameworks in particular countries. This also applies to the biosafety framework in operation in South Africa. These challenges are discussed below, with some recommendations.

2 Discussion

Challenges are experienced at various levels: design of the legislative framework, operational procedures and authorisations granted. These levels are discussed below.

2.1 Legislative Framework

A functional, practical and operational biosafety framework in a country is essential for a technology developer to invest in that country. More importantly though, protection of the technology and rights of the developer should be provided for in such legislation. The provisions of the legislation must be conducive for an application to be made and activities to be conducted in that country. Assessments should be science-based and reviews conducted in a transparent manner with clear communication on the requirements, review process and reasons for decisions taken.

In many countries a lack of knowledge, third party influences and political pressure can lead to "over-regulation" of the technology. This very often results in the requirements and restrictions imposed on activities being so strict that the developer is unable to meet the requirements and restrictions, which means that the developer does not invest in that particular country, thus preventing access to the technology and the eventual "killing" of the technology in that country.

Biotechnology products have been used safely in many countries for many years. This implies that a country that does not have experience in the regulation of this technology can obtain not only guidance in the safety assessments of biotechnology products, but also information and data from reviews already conducted by other regulatory authorities.

Although it is still a relatively new technology, the developments in this field are tremendous. From planting single events in the beginning, we are now moving towards commercialising products containing four or more traits in a single product. This, however, provides challenges to the regulators as to how they will assess these new stacked products, as the approach followed for assessments for single events would not be practical for stacked products.

2.2 Operational Procedures

2.2.1 Applications

The process of applying for authorisation and the review process must be practical and reasonable. Application forms must be easy to understand with clear directions on which application is applicable to which activity. As the technology develops and experience is gained by regulators, it is obvious that application requirements and forms will change from time to time. It is, however, important that any change be communicated to the developers in a transparent and efficient way to enable a smooth transition from one set of requirements/forms to another.

Several committees and experts are involved during review of an application, requiring the need for several copies of the application to be submitted to the authorities. It is recognised that it may not always be possible and may be a challenge in some developing countries, but the replacement of hard copies with electronic copies could save time and costs for the regulators and developers.

As indicated before, this technology is moving fast and stacked products will be prominent in the future. It is therefore unavoidable that activities containing more than one transgenic product will be present in single activities such as confined field releases. It is therefore important that the regulatory process be structured in such a manner that applications that enable such activities are possible.

2.2.2 Review process

Time is always of the essence for developers, hence the review process must be conducted in such a manner that any additional information/clarity required from the applicant is requested in a coordinated manner. Requesting additional information/data from an applicant at various intervals during the review process not only frustrates the regulatory system, but also delays the time in which an application is processed.

Certain information is definitely required to enable an informed decision on the safety of a product or proposed activity. However, regulators should refrain from requesting information or data from the developer that are not relevant to the safety assessment ("nice-to-know" data). These requirements often result in unnecessary costs and time delays, without adding substance to the decision on safety.

The developer aims to provide enough information and data to enable a scientific safety assessment of a product. In the event that additional information or data is requested, the developer would aim to address the outstanding issues as quickly as possible, as it means that the review process can be continued sooner. However, it is very difficult to respond with the correct information or data if the requests from the regulators are not clear. It is therefore important that the requests be clearly defined. Furthermore, in many instances, concerns could be addressed through direct communication between the individuals/ committees assessing the application and the applicant. Opportunities where there could be some sort of direct communication between the review committees and the applicant could ease the review process and again reduce cost and time, without impacting negatively on the quality of the assessment or integrity of the review bodies.

Although transparency is important, it is well known that there are some institutions that would take certain actions in an attempt to prevent or delay an assessment or activity. It is important that the regulators should therefore manage third parties who participate in the review process through public consultation processes.

2.2.3 Authorisations

Applications are submitted with the intention of conducting the activity in a particular growing season, regardless of the type of activity. The timely issue of permits/authorisations to enable execution in the planned growing season is therefore of crucial importance to developers. Activities with regulated transgenic events are normally subject to specific conditions. These conditions are not only important during the activity *per se*, but are used as a reference by developers when planning future activities. This is especially important during confined field trial activities, when trial sites for activities in the follow-up growing season are selected based on the ability to meet the isolation conditions that were applicable to the same activity in the previous growing season. Although permit conditions are designed on the basis of the specific conditions and product, some conditions would remain constant for similar conditions. Changing conditions, and especially isolation conditions, a few months or weeks prior to a growing season could have serious impacts on the ability of developers to continue with authorised trials, as the trial locations may no longer meet the new isolation conditions.

Conditions should further be practical and in line with current agricultural practices. It serves no purpose to institute conditions that cannot or are very difficult to implement in the field.

As experience is gained by the regulators, permit conditions will be amended. This is very important for adapting to the different requirements applicable during different activities. There should also be a procedure in place whereby developers are able to request amendments and regulators can review proposed amendments and make decisions within a short time period, as there are normally not weeks available in which to deliberate on whether a proposed condition should be approved or not, and the amendment authorisation be granted.

3 Conclusions

Legislative frameworks must be functional, practical and operational, while providing protection of the developer's investment in terms of intellectual property. Application forms should be activity-specific, easily accessible and science-based.

Assessment of applications by regulators should be timely, transparent and focused on information that will assist in determining the safety of the proposed activity and product. Concerns, decisions and reasons for decisions should be communicated in a timely fashion and be clearly stated.

Conditions should be activity-specific, based on agricultural practice and remain consistent to enable implementation, unless supported by scientific evidence that would necessitate any amendment to the conditions.

Applications should be processed within the time periods described in legislative frameworks.

Appendix 1:

BIOGRAPHIES

APPENDIX 1: BIOGRAPHIES

Committee Members

Dr HENNIE GROENEWALD (Chairperson) is the Executive Manager of Biosafety South Africa, a national biosafety platform initiated by the national Department of Science and Technology (DST). Biosafety South Africa supports innovation in biotechnology through the delivery of value-adding services and investment in biosafety research to help ensure the safety and sustainability of biotechnological products. He has a PhD in plant biotechnology and has 20 years of experience in research and development, teaching, project management, entrepreneurship and business development. His research career focused on aspects of plant molecular physiology, biosafety, tissue culture, molecular biology and biochemistry, and he has authored several peer-reviewed papers and patents on these subjects. Prior to joining Biosafety South Africa, he worked at Stellenbosch University and still holds an Extraordinary Senior Lecturer position at that institution. He has previously also worked at the South African Sugarcane Research Institute and has been a visiting researcher at the Texas Agricultural & Medical University, Weslaco, US, the Max Planck Institut für Molekuläre Pflanzenphysiologie, Golm, Germany, and the Commonwealth Scientific and Industrial Research Organisation (CSIRO), Plant Industry, Brisbane, Australia.

Dr ANTONIO LLOBELL is the Chief Executive Officer of PlantBio Trust, which he joined in April 2004. He has played an integral role in building the PlantBio team and growing the portfolio of projects funded by the Trust. He has been instrumental in establishing a wide base of strategic initiatives, both locally and internationally. With more than 12 years of senior management experience in research in the plant and microbial biotechnology field, he was Professor of Plant Biotechnology at the African Centre for Crop Improvement, University of KwaZulu-Natal, Pietermaritzburg, before joining PlantBio. He has also been Professor Titular at the Department of Biochemistry and Molecular Biology and Institute of Plant Biochemistry and Photosynthesis, University of Seville and the Spanish National Research Council, CSIC *(Consejo Superior de Investigaciones Científicas)*. He has a strong entrepreneurial background and was co-founder and scientific consultant in Newbiotechnic S.A. (NBT) in Spain, a biotech company specialising in the development of applications for the agri-food and industrial sectors, and in NBT Diagen, S.A., also in Spain, a biotech company commercialising molecular diagnosis services for the medical sector. He has published more than 60 scientific articles in books and first-rated, peer-reviewed international journals and more than 100 communications to national and international congresses. He has also been referee for a number of international journals and is the inventor of six Spanish patent applications and four international patent applications on antifungal genes and proteins, gene expression systems and biocontrol formulations.

Prof. PATRICK RUBAIHAYO is Professor of Crop Science at Makerere University (Uganda). He has expertise in plant breeding, genetics, plant tissue and cell culture, and genomics. He has worked with a number of crops including grain legumes, bananas, tomatoes, potatoes, maize and sorghum. He moved up through the ranks from Special Lecturer to Associate Professor and was appointed Professor in 1995. Prior to joining Makerere University he was a member of the Ugandan parliament and minister of state for agriculture and forestry where he was in charge of the Coffee Rehabilitation Programme, the Agriculture Rehabilitation Project, and agricultural research among other duties. He coordinated the National Banana-Based Cropping Systems Research Programme, the National Pigeon Pea Improvement Programme and the Tomato Improvement Programme. He is a member of the Ugandan National Academy of Sciences.

Prof. EDWARD RYBICKI is a Professor in Microbiology at the University of Cape Town (UCT). He is also a Founder Member of the Institute of Infectious Disease and Molecular Medicine (IIDMM) based in the Health Sciences Faculty (UCT). His main research interests are in making human and animal vaccine candidates in plants and insect cells, these include vaccines for mucosal human papillomaviruses (HPV) and human immunodeficiency virus type 1 (HIV-1) subtype C. He also works on the characterisation and molecular biology of the parrot beak and feather disease virus and the possibility of making vaccines and therapeutics for this viral disease. He also has an interest in the diversity of southern African

Mastreviruses (family Geminiviridae), the molecular determinants of pathogenicity and host range in these viruses, and especially in maize streak virus, the use of geminiviruses as vectors of foreign genes in plants, and in the engineering of viral resistance, especially in maize. He has authored or co-authored some 90 articles in peer-reviewed journals, and approximately 20 book chapters, as well as a number of popular or opinion articles and report-backs in journals. He has deposited a significant number of virus-related nucleic acid sequences in GenBank. He is a Member of the Academy of Science of South Africa.

Speakers

Mrs REMI AKANBI is at present the Director for Project and Operations at AfricaBio, a biotechnology stakeholder association working in South Africa and the SADC region. Since joining AfricaBio, she has headed and participated in research on consumer perceptions and public awareness of biotechnology in South Africa and other southern African countries under various project activities. She has also been involved in demonstrating the impact of agricultural biotechnology on small-scale farmers in South Africa. She has participated in numerous international conventions and conferences and has also made numerous presentations at workshops, to community groups, consumers and farmers. The focus of her current research is the socioeconomic impact of biotechnology on farming communities in South Africa. She has a Master of Science Degree in microbiology from the University of Pretoria.

Dr EUGENIA BARROS is a Research Fellow at the CSIR in the Bio/Chemtek business unit and is the business area manager of the crop genomics group. She studied genetics, biochemistry and microbiology at the University of the Witwatersrand and obtained a PhD in molecular biology at the University of Cape Town. She has more than ten years' experience in molecular marker technology in cereal crops and eucalyptus. She also works closely with the tree improvement group on biotechnology projects. She has worked in research projects involving gene cloning and gene expression of bacteria for industrial applications and in projects involving the development of molecular markers using various molecular marker technologies for DNA profiling, genetic purity evaluation and marker-assisted selection (MAS) of cereal crops, legumes, trees and fungi. She has also worked on detection methods for genetically modified (GM) plants using protein (ELISA) and DNA methods (normal PCR and real-time PCR). Her research interests are the development of molecular markers linked to genes coding for important traits using cDNA-based marker technologies. It includes the generation of ESTs for both MAS and identification of candidate genes, the generation of diversity arrays, and the integration of bioinformatics with marker-assisted selection. She is involved in DNA fingerprinting of cereal crops, trees, fungi and other plants for identity preservation, parentage analysis, molecular marker development for MAS and for gene identification.

Mr GURLING BOTHMA has recently joined CSIR, and prior to this he was a scientist at the ARC-Roodeplaat Vegetable and Ornamental Plant Institute, South Africa.

Dr AUGUSTINE GUBBA is a Senior Lecturer in Plant Pathology at the University of KwaZulu-Natal (School of Agricultural Sciences and Agribusiness). He holds a BSc. Agric (Hons) degree from the University of Zimbabwe, an MSc in applied plant sciences from Wye College (University of London) and a PhD in plant pathology from Cornell University (USA). His area of expertise is plant virology focusing on the identification and characterisation of viruses, developing sustainable control strategies for plant viral diseases and plant transformation for transgenic virus resistance. He has worked in both agricultural extension and research in Zimbabwe. His research interests are on developing transgenic vegetables with broad resistance to virus infection. He is currently investigating the development of sweet potato plants with multiple resistance to different viruses that infect the crop under field conditions. In 2005, he spent a six-month sabbatical attached to the USDA in Hilo, Hawaii studying the transgenic papaya that has been commercialised. He intends to play an active role in current efforts to use biotechnology to address some of the agricultural challenges facing Africa.

Prof. HANS-WALTER HELDT is Emeritus Professor at the University of Göttingen in the Plant Biochemistry Section of the Albrecht von Haller Institute for Plant Sciences. He studied chemistry at the Universities of Innsbruck (Austria), Marburg (Germany) and Edinburgh (Scotland), and obtained his D.Phil. from the University of Marburg, where he also served as Scientific Assistant at the Institute for Physiological Chemistry. He has worked in the sabbaticals in the Department of Plant Industry, CSIRO, in Canberra, Australia, and was Director of the Albrecht von Haller Institute for Plant Sciences at Göttingen. From 2000 to 2006 he served as representative of the Union of German Academies of Science in the InterAcademy Panel. Prof. Heldt's interests are metabolite transport across cellular and subcellular membranes of plants, photosynthesis metabolism and gene technology. He is the author of the textbook *Plant Biochemistry*, which is in its 4th German edition – there are also US, Japanese, Chinese and Indian editions of the book, with a Russian edition in preparation.

Dr YOUSUF MAUDARBOCUS is a physicist with broad experience in project management and is a lecturer at the University of Mauritius. As Regional Programme Manager for Africa with the Department of Technical Cooperation of the International Atomic Energy Agency (IAEA), Vienna, Austria, he evaluated, designed and formulated technical co-operation projects for African member states. He managed several projects in the fields of human health (radiotherapy, nuclear medicine, radiation protection), food and agriculture (pest eradication, food preservation, crop improvement, animal disease monitoring), water resources management (especially ground water assessment), pollution monitoring (mainly the marine environment) and industrialisation (non-destructive testing and tracer techniques, strengthening of materials through irradiation). He also led multi-disciplinary team missions and conducted programming and project monitoring missions in various African member states. He is an ex-IAEA member and he is currently a member of the Mauritius Academy of Science & Technology. He has a PhD in physics from the University of London.

Prof. CARL MBOFUNG is the Director and Lecturer for the National Advanced School of Agro-Industrial Sciences (ENSAIC) at the University of Ngaoundere in Cameroon. He is also a member of the Cameroon Academy of Science.

Dr DENNIS OBONYO is a Biosafety Specialist in a major biosafety capacity-building project for sub-Saharan Africa, implemented through a partnership between the International Centre for Genetic Engineering and Biotechnology (ICGEB) and the Bill and Melinda Gates Foundation. He is based at the Cape Town component of the ICGEB. Prior to joining the ICGEB he worked as KARI Deputy Co-ordinator of the BiosafeTrain Project (a DANIDA-funded programme involved in building capacity for biosafety and ecological impact assessment of transgenic plants in East Africa [DANIDA; Danish International Development Agency: KARI; Kenya Agricultural Research Institute]) in Nairobi, Kenya. He was also the theme leader of the Environmental Impacts Assessment group (responsible for conducting studies on the potential impacts of *Bt* maize on non-target arthropods in Kenya) of the Insect-Resistant Management for Africa (IRMA) project (a Syngenta Foundation funded joint KARI-CIMMYT programme)(CIMMYT; International Maize and Wheat Improvement Centre). He has a PhD in entomology from the University of Nairobi.

Dr GOSPEL OMANYA is the Seed Systems Manager at the African Agricultural Technology Foundation (AATF). He is an accomplished plant breeder and geneticist with a PhD in plant genetics and breeding from the University of Hohenheim in Germany. He has worked for the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Sahelian Centre in Niamey (Niger) as a Special Project Scientist responsible for pearl millet improvement for West and Central Africa, where he facilitated the development of farmer-managed seed production and distribution systems. At the AATF he oversees the formulation and implementation of technology deployment policies and strategies, including stewardship, products demonstration and delivery to target users in Africa. His biography was also in the *Marquis Who's Who in Science and Engineering* (2008–2009).

Ms MICHELLE VOSGES is currently responsible for matters pertaining to regulatory affairs at Monsanto South Africa. Prior to joining Monsanto she worked at the Biosafety Directorate of the Department of Agriculture. After eight years at the Department and as Registrar for the Genetically Modified Organisms Act, 1997, she joined Syngenta South Africa as Regulatory Affairs Manager for Biotechnology. She has a Masters' degree in plant physiology from the University of Pretoria.

Staff Members

Prof. ROSEANNE DIAB is the full- time Executive Officer of ASSAf and Emeritus Professor in the School of Environmental Sciences, University of KwaZulu-Natal. She is a Member of ASSAf and is recognised for her research contributions in the field of atmospheric sciences, particularly air quality, and more generally environmental management. She is a Fellow of the University of KwaZulu-Natal and of the South African Geographical Society. She has been a Fulbright senior research scholar, is a member of a number of international bodies such as the International Ozone Commission (IOC) and the Commission on Atmospheric Chemistry and Global Pollution (CACGP), and serves on the editorial board of the journal *Atmospheric Environment*.

Dr NTHABISENG TAOLE is a Project Manager at ASSAf. Her primary responsibility is to lead and manage the implementation of the ASSAf's approved projects. She was also a study director for the consensus study entitled *A Strategic Approach to Scholarly Publishing in Books and Book Chapters in South Africa*. She serves on the ASSAf task team on "A Possible Scholarly Publishing Platform". She also serves on the ASSAf peer-review panel on Agriculture and Related Basic Life Sciences. Before joining ASSAf she worked as systems manager at the National University of Lesotho Library and as ICT Advocacy Manager at the Southern African NGO Network (SANGONeT). She holds a PhD in information science from the University of Pretoria.

Ms PHAKAMILE MNGADI is a Project Officer at ASSAf. She is responsible for all administrative aspects of the GMOs Forum project. She is also responsible for the "Consensus Study on Clinical Research in South Africa", the "Consensus Study on Long-term Strategy on the Burden of HIV/AIDS" and a "Forum Study on Improving Maternal, Newborn and Child Health in Africa". Prior to joining ASSAf, she worked for the Medical Research Council as a project leader for a microbiocide clinical trial. She has a Masters degree in biotechnology from the Durban University of Technology.

Appendix 2:

WORKSHOP PROGRAMME

APPENDIX 2: WORKSHOP PROGRAMME

WORKSHOP AGENDA/PROGRAMME

GMOs FOR AFRICAN AGRICULTURE: OPPORTUNITIES AND CHALLENGES

DATE: 17-18 September 2009

VENUE: ASSAf Offices [Persequor Park, Lynnwood, Pretoria SOUTH AFRICA]

DAY 1 (17 September 2009): Chaired by DR HENNIE GROENEWALD	
09:30-10:00 **10:00-10:10**	**TEA/ARRIVALS** **Opening/Welcoming Remarks** **PROF. ROSEANNE DIAB** *[ASSAf Executive Officer]*
10:10-10:20	**Overview/Introductions** **PROF. ROSEANNE DIAB** *[ASSAf Executive Officer]*
10:20-10:45	Introduction and problem statement **DR GOSPEL OMANYA – African Agricultural Technology Foundation (AATF) [Kenya]**
10:45-12:30	**Presentations [20-25 minutes each]** The situation concerning GM crop plants in Germany **PROF. HANS-WALTER HELDT – Union of German Academies of Sciences and Humanities [Germany]** The role of GMOs in Africa: Food and nutrition security **PROF. CARL MBOFUNG – University of Ngaoundere [Cameroon]** Transgenic plants with virus resistance: opportunities and challenges for Africa **DR AUGUSTINE GUBBA – University of KwaZulu-Natal [South Africa]**
12:30-13:00	**DISCUSSION**
13:00-13:45	**LUNCH**

13:45–15:00	**Presentations [20-25 minutes each]** 1. Challenges of GM technologies [with a focus on potential risks, how these risks are addressed through policy, legal and administrative frameworks including risk assessment] **MR ABISAI MAFA – National Biotechnology Authority [Zimbabwe]** 2. Challenges of regulating agricultural biotechnology in Africa **PROF. DIRAN MAKINDE – West African Bioscience Network (WABNet) [Senegal]** 3. Challenges for GM technologies: Evidence-based evaluation of the potential environmental impacts of GM crops **DR DENNIS NDOLO OBONYO – International Centre for Genetic Engineering and Biotechnology (ICGEB) [South Africa (base)]**
15:00-15:30	**DISCUSSION**
15:30-15:50	**TEA BREAK**
15:50-16:30	Group discussion and closure for the day
DAY 2 (18 September 2009): Chaired by PROF. PATRICK RUBAIHAYO	
09:30-09:45	**Re-cap from DAY 1 and Outline for DAY 2**
09:45-10:45	**Presentations [20-25 minutes each]** 1. Systems biology approach to the evaluation of GM plants: a case study **DR EUGENIA BARROS – Council for Scientific and Industrial Research (CSIR) [South Africa]** 2. Commercialisation of a GM potato for South Africa developed by publicly funded research organisations – lessons learned: a case study **MR GURLING BOTHMA – Agricultural Research Council (ARC) [South Africa]**
10:45-11:10	**DISCUSSION**
11:10-11:30	**TEA BREAK**

11:30-13:00	**Presentations [20-25 minutes each]** 3. The use of nuclear techniques to produce improved varieties of food crops in Africa **DR YOUSUF MAUDARBOCUS – Mauritius Academy of Science & Technology [Mauritius]** 4. Challenges in effective implementation of biosafety legislative frameworks in Africa **MS LILLIAN NFOR - International Centre for Genetic Engineering and Biotechnology (ICGEB) [South Africa (base)]** 5. Sustainable GM technologies for African Agriculture **DR JAN-HENDRIK GROENEWALD – Biosafety [South Africa]**
13:00-13:30	**DISCUSSION**
13:30-14:15	**LUNCH**
14:15-15:15	**Presentations [20-25 minutes each]** 6. Agricultural biotechnology: Does it work in Africa? **MRS REMI AKANBI – AfricaBio [South Africa]** 7. Regulation of GMO activities in South Africa: Experience from a technology developer **MS MICHELLE VOSGES – Monsanto [South Africa]**
15:15-15:40	**DISCUSSION**
15:40	Way forward and closure

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