GMOs Approved for Commercial use

Type of approval: **General release – conditional**
Use of the event: Importation/exportation; commercial planting; food and/or feed

Company	Crop	Trait	Year approved
Monsanto	Cotton	Insect^{R} Herb^{T}	2005, 2007
		Herb^{T}	2000, 2007
		Insect^{R}	1997, 2003
	Maize	Insect^{R} Herb^{T}	2007
		Herbicide tolerant	2002
		Insect resistant	1997
	Soybean	Herbicide tolerant	2001
Syngenta	Maize	Insect resistant	2003

Regulatory Requirements and Technology Diffusion: The Case of Biotech Cotton

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The International Cotton Advisory Committee (ICAC) reported that during 2008/09, 48% of the world cotton area was planted to biotech cotton varieties while 54% of all cotton produced globally was from biotech varieties, and that 52% of all cotton traded internationally was biotech cotton. Biotech cotton consisted of the two major traits, insect resistance (IR) herbicide tolerance (HT) used singly, or in combination. The countries that grew this cotton represented both developed and developing economies, including two from Africa, South Africa and Burkina Faso. Growing biotech cotton requires biosafety regulatory oversight, and in Africa, there are only 9 countries with functioning regulatory frameworks, of which only 6 have conducted confined field trials. This paper presents the regulatory requirements and technology diffusion of biotech cotton in a few African countries.

Development of Transgenic Cotton

Transgenic cotton, biotech cotton, is developed by introducing a foreign gene using recombinant DNA and transformation technologies. Expression in the plant is driven by a promoter, and the gene is introduced into the cells of a desirable cotton variety using one of following techniques:

- *Agrobacterium*-mediated
  - Particle bombardment using the gene gun
  - Pollen tube pathway

The transformed cells carrying a gene of interest are selected using a selectable marker gene, usually coded for an antibiotic or for herbicide resistance. The cells are then regenerated back into a whole plant. Coker 312 is the most common variety that is used for transformation of cotton, as it regenerates with relative ease. Following regeneration, plants with the best agronomic performance and consistent levels of expression of a gene of interest are selected and selfing was done to produce homozygous plants. The progeny is crossed with a preferred variety and back crossed, over several generations, to recover the preferred variety with the gene of interest.

Genes of Interest with Insecticidal Activity

There are four groups of insecticidal genes namely the (a) *Bacillus thuringiensis* (Bt) *crystalline* δ-endotoxins, (b) Bt vegetative insecticidal proteins (Vips), (c) protease inhibitors, and (d) lectins. The Bt crystalline δ-endotoxins are derived from crystalline proteins found in the soil bacterium *Bacillus thuringiensis*. These toxins are activated by proteases in the insect midgut. Following this activation they bind specifically to receptors in the midgut, create pores that eventually lead to lysis and death. The VIPs are also derived from *B. thuringiensis* and bind to separate but specific receptors in the midgut. The protease inhibitors are from plants. They work by inactivating protease enzymes in the gut, thus preventing protein digestion. Lectins are proteins that bind carbohydrate, and in this case bind to carbohydrate moieties on the receptors in the midgut and interfere with gut function and iron metabolism.

The most common lectin with insecticidal activity is the snow drop lectin and has been used in India, although the cotton has not been commercialized (Showalter, 2009).

However, other biotech cotton events that have been commercialized are shown in Table 1. The table indicates the year of first approval for commercial release of biotech cotton by country.

Table 1. First Year of Approval for Environmental Release of Biotech Cotton by Country

Country	Year & Event
Argentina	1998 (MON 531/757/1076)
Australia	1996 (MON 531/757/1076)
Brazil	2005 (MON 531/757/1076)
Burkina Faso	2008 (15985)
China	1997 (various)
Colombia	2003 (MON 531/757/1076)
India	2002 (MON 531/757/1076)
Japan	1997 (MON 1445/1698; MON 531/757/1076)
Mexico	1997 (MON 531/757/1076)
South Africa	1997 (MON 531/757/1076)
USA	1994 (BXN)

Source: James, 2006.

The predominant events were those of Bollgard cotton, MON 531/757/1076, carrying a cry 1Ac gene driven by the 35S Cauliflower mosaic virus (CaMV) promoter, the neomycin phosphotransferase (nptII) and the aminoglycoside adenyltransferase (aad) genes as selectable markers [Perlak et al., (1990), Agbios GM database, (2005) and Kurtz et al., (2007)].

Technology Diffusion

Globally, the area planted to genetically modified (GM) crops in 2008 reached a new milestone of 25 countries. Of these, three were from Africa, two appearing for the first time in 2008 with 2 different crops, biotech cotton and biotech maize. South Africa has ranked 8th in total acreage for a number of years. The increase in adoption is also reflected in an increase in the global value of the market for biotech crops from US$6.9 billion in 2007 to US$7.5 billion in 2008.

The Center for Chinese Agricultural Policy (CCAP) conducted a study that revealed that in 2008, 7.1 million small farmers benefited from biotech cotton. These benefits were realized as increases in yields of 9.6%, reduction in insecticide use of 60%, and increased incomes of US$220/ha. In addition, in another study conducted by Wu et al. (2008), the results showed a 10-fold suppression of bollworm infestations in alternative hosts, thus indirectly benefiting 10 million other farmers in the process. These beneficial effects are not only limited to China; India also experienced marked benefits. Five million small farmers planted 7.6 million ha of Bt cotton in 2008, compared to 3.8 million small farmers in 2007, indicating an adoption rate of 82%. Yields increased by 31%, insecticide application decreased by 39%, while profitability increased by 88%, equivalent to US$250 per ha. Other welfare benefits such as increased numbers of the farmers' children attending schools, more children being vaccinated, while more women received assistance with home births, were also realized.

South Africa was the first African country to commercialize biotech crops in 1997. However, in 2008 two other African countries, Egypt and Burkina Faso joined the fray (James, 2008). South Africa first commercialized Bt cotton in 1997, and herbicide tolerant varieties in subsequent years. In 2005, approval was granted for stacked traits (IR and HT). The adoption reached 92%. Meanwhile, confined field trials were initiated in Burkina Faso in 2003, and in 2008, Burkina Faso became the second country in Africa to commercialize biotech cotton. It planted 8,500 ha of biotech cotton for seed multiplication and initial commercialization.

Biosafety Considerations

Once produced, and before release into the environment, biotech cotton commonly undergoes a risk assessment based on three components:

- Environmental risk assessment which includes:
  - Effect on non-target organisms
  - Potential for weediness
  - Concerns over gene flow and consequences thereof
- Food and feed safety
  - Toxicity
  - Nutritional equivalence
  - Allergenicity
  - Digestibility and
- Socio-economic considerations

In developing countries, if the biotech cotton has not been developed locally, the initial entry will be to apply for confined field trials. Ideally the risk assessment should focus on the fact that such trials take place under strict confinement, i.e., the necessary procedures are in place to prevent any of the materials entering the environment and food/feed chains. Risk assessment consideration should be limited to the first step; the environmental risk assessment as outlined above. The risk assessment is usually a paper evaluation exercise coupled with multi-locational confined field trials in the country. Once the results from confined field trials are satisfactory, a country might then opt for commercial release. In this case, a field trial is set up for seed multiplication so that the material can be bulked and used for subsequent food and feed safety tests that the country wishes to conduct. Otherwise, the risk assessment at this stage is also an evaluation of documents submitted by the applicant. The final decision, however, may lean on socio-economic considerations and have nothing to do with the performance or safety of the technology.

Main Components of a National Biosafety Framework System

Why do we need regulation of biotech products in the first instance? Regulation of biotechnology is a requirement provided under the Cartagena Protocol on Biosafety (CPB). The protocol is a legally binding instrument under the Convention on Biological Diversity (CBD). Its objective is to develop a global framework for the conservation and the sustainable use of biological diversity. Most African countries are signatories to the Cartagena Protocol on Biosafety. The Protocol recognizes that modern biotechnology has the potential to contribute to achieving the goals of the Convention on Biological Diversity, as long as it is developed and used with adequate safety measures to conserve both the environment and human health.

Table 2. Status of National Biosafety Frameworks (NBFs) in Africa

Fully developed NBFs	Interim NBFs	Work in Progress	No NBFs
Algeria, Burkina Faso, Egypt, Kenya, Mauritius, Malawi, South Africa, Tunisia and Zimbabwe	Ethiopia, Ghana, Madagascar, Mali, Mozambique, Namibia, Nigeria, Rwanda, Senegal, Sudan, Tanzania, Uganda & Zambia	Benin, Botswana, Cameroon, Congo, Democratic Republic of Congo, Djibouti, Eritrea, the Gambia, Lesotho, Liberia, Libya, Niger, Seychelles, Swaziland & Togo	Angola, Burundi, Cape Verde, Chad, Comoros, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mauritania, Sao Tome & Principe, Sierra Leone & Somalia
Status of CONFINED FIELD TRIALS & Commercialization			
Countries conducting Confined Field Trials		**Countries with commercial approvals**	
South Africa & Egypt Burkina Faso & Kenya Uganda & Zimbabwe		South Africa Egypt and Burkina Faso	

Source: Adapted from Makinde *et al*., 2009

The Cartagena Protocol on Biosafety seeks to contribute to the safe transfer, handling, and use of living modified organisms (LMOs) created through modern biotechnology, specifically focusing on transboundary movement. The protocol does not replace national biosafety regulatory frameworks, and calls for the implementation of biosafety policies and procedures at the national level.

As such, countries have been working towards establishing national biosafety frameworks (NBFs) (Murdock et al., 2008). A national biosafety framework is a system that is established at the national level to provide oversight on activities surrounding the safe use of biotechnology. The national biosafety frameworks vary across Africa; some are in the form of biosafety regulations, laws and acts, and other are embedded in other existing laws or biotechnology and or biosafety policies. The main mechanisms under these national biosafety frameworks include institutional arrangements for handling and managing biotechnology, and systems for giving consent to specific activities. These activities include consent for registration of materials for contained use, as well as consent for the conduct of confined field trials and commercial releases. A system for monitoring and conducting inspections is also put in place, as are mechanisms for public awareness, participation and dissemination of information.

To date, nine African countries have national biosafety frameworks that are fully developed. The largest regional economic block is Southern Africa (South Africa, Malawi, Mauritius and Zimbabwe) with 4 countries, North Africa with three countries (Tunisia, Algeria, and Egypt), East (Kenya) and West Africa (Burkina Faso) with one country each. Some of these countries have legal frameworks specifically covering biosafety (e.g South Africa, Malawi and Zimbabwe) while others use existing laws to regulate biotech products, often complemented by regulations or guidelines (Tanzania and Egypt). There are 13 countries with interim national biosafety frameworks, 15 that are in progress and 16 that have none, as summarized in Table 2 (Makinde et al., 2009). Six countries in Africa have conducted field trials, with South Africa having an excess of 500 confined field trials, and only three countries have commercialized GM crops, and only two for biotech cotton, South Africa and Burkina Faso (James, 2008).

While several biotechnology and biosafety capacity development initiatives are on-going in Africa, the Program for Biosafety Systems (PBS) is noteworthy in that it relies on strengthening science-based decision making in partner countries (Sithole-Niang, 2008). Examples of technology diffusion for biotech cotton can be seen in Program for Biosafety Systems partner countries, such as Kenya, Uganda and Malawi. In these countries, in collaboration with national institutes and experts, Program for Biosafety Systems has supported the development of biosafety laws, regulations and guidelines, and detailed procedures for conducting confined field trials. This work is complemented by technical training to ensure national biosafety frameworks implementation and to enhance regulators' confidence in biosafety decision making.

Program for Biosafety Systems has been assisting partner countries with the initial stages of biotech crop deployment, especially with the conduct of confined field trials. Confined field trial guidelines have been developed and adopted in Kenya, Uganda and Malawi based on the Integrated Confinement System (ICS) portfolio of Program for Biosafety Systems that includes:

- Confined field trials guidelines
- Containment & Confinement manuals
- Regulatory procedures
- Trial manager & Inspectors handbook.

The Integrated Confinement System has been developed in collaboration with in-country partners. Kenya has been conducting confined field trials on Bt cotton since 2004. The enactment of a Biosafety Law in Kenya, may see the country commercialize Bt cotton as early as 2010. While Uganda moves towards adopting a biosafety law, it has given approval for commercial field trials of banana, cotton and cassava already underway in the country. The first commercial field trials of Bt cotton commenced June 29, 2009 at Serere in Uganda. The second site at Kasese was recently planted. Both Kenya and Uganda have other crop/trait combinations in the pipeline, which continue to improve the biotechnology research capacity in these two countries. It is expected that Malawi will also be conducting its first Bt cotton trials at Bunda College of Agriculture this year. In subsequent years it is envisaged more trials will be conducted at 3 other locations in the country.

Program for biosafety systems, in collaboration with the Food Agriculture and Natural Resource Policy Analysis Network (FANRPAN), supported ex ante studies on potential benefits for cotton farmers if Bt cotton were adopted commercially in Malawi. Assuming a current 20% yield loss due to insect infestations, and taking into account chemical costs and labor, adopting Bt cotton would realize US$78 gross benefit/ha which translates into nearly double the income of US$40/ha that is obtained with conventional varieties (Manda et al., 2007; van der Walt, 2009).

Concluding Remarks

Globally, the distribution and adoption of biotech cotton continues to increase annually. Countries like China, India and South Africa continue to reap benefits, and with two new ones, Egypt and Burkina Faso, also getting on board. Another trend is the increase in the number of countries conducting confined field trials in Africa. Furthermore, these trials were conducted around specific products. This trend is likely to result in national biosafety frameworks that are much better focused and more streamlined than those developed in a vacuum. As activity increases across the continent, synergies could be built around harmonization efforts that could facilitate trade and the transboundary movement of biotech organisms.

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~~Biotech Cotton in International Trade.~~

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~~This paper briefly overviews the state of play with respect to the production of cotton that has been genetically modified, and then looks at each of the primary products that emerge from this activity, namely cotton planting seed, cotton lint, cottonseed oil and cottonseed meal. The paper concludes with some remarks about the contribution that GM cotton can make to development and food security in a capital-constrained world.~~

~~Genetically modified cotton was first released in commercial quantities in the late nineteen nineties following an exhaustive and at times exhausting testing and approval regime. The technology achieved instant adoption by growers. It's creation was to control the heliothis which had become so destructive to cotton as it was resistant to conventional chemistry and other crop protection practices. As with any new technology, the introduction of biotech cotton was not without challenges, as we came to understand that it alone was no silver bullet. However, after several iterations and enhancements, today almost 50 % of the worlds cotton production employs this technology.~~

~~Today, the big three of China (with 67 % of its production being GM), the United States (86 % of its production) and India (76 % of production) account for more than 90 % of the world's GM cotton. 95 % of Australia's cotton is GM and 10 % of Brazil's cotton is estimated to be GM. Modern traits include enhanced inbuilt insecticides and herbicide tolerance~~