Biosafety Regulations, Implementation and Consumer Acceptance

Every year during the Plenary Meeting of the ICAC, the Technical Information Section organizes a Technical Seminar on a selected topic. The Seminar, also called the Meeting of the Committee on Cotton Production Research of the ICAC, is usually held on Thursdays, and 6-8 speakers are invited to make presentations on important aspects of each topic. The 2009 Technical Seminar was held on the topic 'Biosafety Regulations, Implementation and Consumer Acceptance.' Six papers were presented from five countries, including a special paper from the 'ICAC Cotton Researcher of the Year 2009,' Dr. Keshav R. Kranthi, Central Institute for Cotton Research, Nagpur, India. The paper by the first 'ICAC Cotton Researcher of the Year 2009' has been published in full and the other five papers appear in the present article in the form of summaries.

Regulatory Requirements and Technology Diffusion: The Case of Biotech Cotton

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The currently available commercial transgenic cottons were obtained by using recombinant DNA and transformation technology to introduce a foreign gene into the target genome.

A promoter drives expression in the plant, and the gene is introduced into the cells of a desirable cotton variety using one of following techniques.

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

Table 1 shows the biotech cotton events that had been commercialized by 2009. The table indicates the year when biotech cotton was first approved for commercial release by a country.

The most significant events were: Bollgard cotton, MON 531/757/1076, carrying a Cry1Ac gene driven by the 35S Cauliflower mosaic virus (CaMV) promoter with the neomycin phosphotransferase (*npt*II) and the aminoglycoside adenyltransferase (*aad*) genes as selectable markers.

Table 1. Approval of Biotech Cotton for Environmental Release 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)

Biosafety Considerations

Once produced, all biotech cottons undergo risk assessment studies based on three components before they can be released into the environment:

- Environmental risk assessment (including effects on non-target organisms, potential for weediness and concerns over gene flow and consequences thereof);
- Food and feed safety (in terms of toxicity, nutritional equivalence, allergencity and digestibility);
- Socio-economic considerations.

In developing countries, if the biotech cotton has not been developed locally, the initial entry point into the system will be to apply for confined field trials. Once the results of the confined field trials are deemed satisfactory, the country might then opt for commercial release. In that case, a field trial is set up for seed multiplication so that the material can be bulked and used for the subsequent food and feed safety tests that the country wishes to conduct; otherwise, the risk assessment at this stage may also comprise an evaluation of the documents submitted by the applicant. The final decision however, may be based on socio-economic considerations and that may have nothing to do with the performance or safety of the technology.

National Biosafety Framework System

Regulation of biotechnology is a requirement under the Cartagena Protocol on Biosafety. The protocol is a legally binding instrument under the Convention on Biological Diversity. The primary objective of the Convention on Biological Diversity is to develop a global framework for the conservation and sustainable use of biological diversity. Most African countries are signatories to the Cartagena Protocol on Biosafety. To-date, 9 African countries have fully developed national biosafety frameworks, 13 have

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, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mauritania, Sao Tome & Principe, Sierra Leone & Somalia

interim biosafety frameworks, 15 are in the process and 16 have none. (See table 2).

There is a need to develop national biosafety frameworks that are better focused and more streamlined in order to harmonize the different national frameworks and facilitate trade and the trans-boundary movement of biotech crops.

The South African Regulatory System

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South Africa implemented the Genetically Modified Organisms (GMO) Act of 1997 (Act 15 of 1997), also called the GMO Act, in December 1999, and since then all activities involving biotech crops are conducted in compliance with permits issued under this Act. Due to the growing importance of biosafety and related issues, the South African Government elevated the GMO unit, which until then had been operating under the Directorate Genetic Resources, to a full-fledged directorate. The Bio-safety Directorate has two regulatory bodies i.e. the Advisory Committee and the Executive Council, in addition to a Registrar and inspectors. The Registrar, who is appointed by the Minister of Agriculture, Forestry and Fisheries is responsible for the administration of all activities within the scope of the GMO Act.

Biotech applications are subjected to a multidisciplinary process of scientific evaluation by the expert panel of scientists that make up the Advisory Committee that acts as a national advisory body on all matters relating to biotechnology issues. The Advisory Committee consists of ten scientists appointed by the Minister of Agriculture, Forestry and Fisheries. Extended pools of experts from various disciplines support the Advisory Committee. The Advisory Committee, together with subcommittee members, is responsible for the evaluation of risk assessments of all applications as related to food, feed and environmental impact. Its findings are then submitted to the Executive Council in the form of a recommendation.

The Executive Council is the ultimate decision-making body and currently consists of officials from six government departments/ministries (Agriculture, Forestry & Fisheries, Health, Environmental Affairs, Labor, Trade and Industry and Science and Technology) and the chairperson of the Advisory Committee. With the implementation of the GMO Amendment Act 2006, the Council will additionally include in the near future, members from the Department of Water Affairs and the Department of Arts and Culture. The Council is tasked with advising the Minister of Agriculture, Forestry and Fisheries on all aspects concerning the development, production, use, application and release of biotech products, and to ensure that all activities with regard to biotech products (importation, exportation, transit, development, production, release, distribution, contained use, storage and application) are performed in accordance with the provisions of the Act. Approved biotech activities are regulated by way of permits issued by the Registrar and the accompanying permit conditions are monitored for compliance by inspectors of the Department of Agriculture, Forestry and Fisheries.

The existence and enforcement of the GMO Act in South Africa provides the country with a decision-making tool that enables its authorities to conduct a science-based, case-by-case assessment of the potential risks that may arise from any activity involving a particular genetically modified organism. Despite the ten years elapsed since their adoption in South Africa, biotech crops have almost exclusively incorporated traits for insect resistance and or herbicide tolerance. As biotechnology advances beyond the realm of agronomic traits, the regulatory system will be challenged to respond to the emerging biotechnology applications. The directorate must therefore continue to pursue efforts to strengthen its regulatory framework, exploit capacity building initiatives and participate in regional and international biosafety engagements.

Biotech Cotton in International Trade

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There have been numerous assessments of the economic, social and environmental merits of biotech crops, and they all share common conclusions as below.

- Biotech crops have led to a material reduction in the use of insecticides.
- Biotechnology had a positive impact on community perceptions about our industry's efforts to promote sustainability in crop protection practices.
- Biotech crops have reduced the occupational health and

safety risks associated with the storage, handling and application of pesticides.

- Biotech cotton gives enhanced yields and improves the production reliability of cotton.

The net economic, social and environmental benefit has been unambiguously positive. However, access to biotechnology applications is governed by strict licensing conditions that essentially seek to protect the technology developer's intellectual property rights, eliminate the potential for a secondary market in the product through the retention of seed for future planting and defend the technology from systematic failure. The primary products of currently approved biotech cotton traits are seed, fiber, cottonseed oil and cottonseed meal.

Seed - The pricing strategy for planting seed seems to be based on the principal of "charge as much as the market will bear."

The studies done on its impact on gross margins reveal that, while the value of the technology is relatively consistent, there is wide disparity in pricing. Australia, for example, pays six times the license fees paid by India and the United States but enjoys 84 percent of the benefit that India does and receives double the economic benefit of the USA.

Cotton lint - There has been no observed difference between the fiber characteristics of biotech cotton and those of conventional varieties, and its spinning-ability does not appear to have been affected. On the contrary, there is evidence to suggest that the introduction of herbicide resistance has had a direct and positive impact on the leaf and vegetable matter content of cotton. Other than the restriction related to certification for organic production, there is neither a regulatory nor market differentiation between biotech and conventional cotton and there is no material demand preference for one version over the other.

Cottonseed oil - Global production of cottonseed oil for the 2007 season was estimated at 5.2 million metric tons with approximately 3.6 million tons coming from biotech cotton varieties. The oil is sold in either its raw form or in end use product form without restrictions across the world. Cottonseed oil finds its way into the food chain through its use in table spreads (margarines), salad dressings and as cooking oil. Scientists describe cottonseed oil as being "naturally hydrogenated" because the saturated fatty acids it contains are the natural oleic, palmitic and stearic acids. These fatty acids make it a stable frying oil that needs no additional processing and does not form trans fatty acids There is currently no market segmentation for cottonseed oil derived from biotech seed.

Cottonseed meal - Cottonseed meal accounts for approximately 40 percent by weight of fuzzy cottonseed, depending on the particular extraction process used. It is a high protein stock feed. For the 2007 year, over 10 million tons of cottonseed meal was produced globally with almost ¾ of it from biotech seed. When biotech cotton was introduced, in both the United States and Australia, there was some market interest in segregating biotech cottonseed meal from conventional cottonseed meal. However, within 2 years, market demand became generic.

Market Response to Biotech Cotton Seed

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Argentina established the regulatory framework for commercialization of biotech crops in 1991. The National Advisory Committee on Agricultural Biotechnology (CONABIO) was established under the Secretary of Agriculture, Livestock, Fisheries and Food (SAGPyA) with representatives from various institutions from the public and private sectors for regulatory activities. In Argentina, it takes 5-6 years for a new material to move from the first evaluation phase up to commercial release. Currently, there are seven biotech cotton varieties registered in the records of the National Seed Institute. A stacked gene variety comprising the Bollgard and Roundup Ready genes was recently approved, but its entry in the records of the National Seed Institute is still pending.

According to the National Seed Institute in 2007/08, the total area planted to biotech cotton was 27%, but that figure increased to over 70% in 2008/09. The use of the cottonseed obtained is as follows: 63% goes to crushing for oil extraction, 28% is fed to livestock as raw seed, 5% is exported and about 5% is used to plant cotton. Regarding seed exports, most is exported to Chile, followed by Spain (21%) and Uruguay (9%). Recent data shows that exports of cottonseed oil (semi-refined) are destined for Algeria (43%), Korea (31%), China (18%) and Chile (8%). Cotton seed cake is primarily exported to Chile, the Netherlands and Brazil. In Argentina, cottonseed is usually blended with cereals as a source of proteins.

The National Institute for Agricultural Technology (INTA) has undertaken research on milk and meat from livestock fed on raw cottonseed.

Specific studies designed to compare the performance of cows fed on biotech and non-biotech materials to detect differences in milk production and the chemical composition of the milk revealed no significant differences in the variables analyzed. These results indicate that when the diets of dairy cows are supplemented with seeds from biotech cotton varieties containing Bt and RR genes, their performance, in terms of consumption, production and chemical composition of milk, is similar to that of cows fed seed supplements from non-biotech varieties.

Cottonseed marketing practices in the domestic market do not differentiate between biotech and non-biotech origins and refer exclusively to the differential contributions by destination: industry or fodder.

Improving Confidence in Biotech Cotton

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After its commercial release in South Africa in 1996, biotech cotton quickly spread among small and large cotton growers. Although cotton area in South Africa has been decreasing, yields have gone up, and over 90% of the area planted to cotton is still under biotech varieties. Studies have shown that large cotton farmers adopt biotech cotton mainly because of savings in spray labor (63%) and higher yields (32%). All other factors form only 5% of the reasons for adopting biotech cotton by large growers in South Africa. Small growers in South Africa benefit from higher yields and income, savings on insecticide costs and safety in terms of reduced handling of chemicals. The two implications of biotech cotton faced by small growers in South Africa are the same as in other countries, i.e., higher seed cost and emergence of secondary pests.

Some of the reasons for slow adoption of biotech cotton in the world are continued concerns about possible food and environmental safety, weak regulatory capacity in potential countries, complexity of trade in biotech crops, high regulatory barriers leading to restriction or slow access to beneficial technologies and high barriers that may restrict competition in seed market and reduce options for farmers. Confidence in biotech cotton can be improved through following means.

- Ensure effective, stringent and transparent enforcement of biosafety regulation
- Showcase the benefits of biotech cotton
- Address arising concerns
- Highlight socio-economic benefits, and
- Regular consultations with farmers are critical for harnessing their support and addressing their needs.

Biotech crops can contribute to improved food security and poverty alleviation in Africa. Commercialization of biotech cotton in South Africa and Burkina Faso, and confined field testing in Kenya, Malawi, Uganda and other developing countries shows that farmers in Africa are able to access the benefits of biotech crops. However, they need good governance, financial support, skills training, market access, the support of competent extension service and an adequate rural infrastructure.

~~Producing Triploid Hybrid Plants Through Induced Mutation to Broaden Genetic Base in Cotton~~

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~~Abstract~~

~~Gibberellic acid was used as a growth regulator to obtain interspecific hybrids between tetraploid and dioploid species of cotton. Two commercial *G. hirsutum* varieties (Sahel and Siokra) were used as female parents; pollen grains from Hashem Abad and Kashmer (*G. arboreum*) were used to fertilize emasculated flowers. Pollinated flowers were treated with different concentrations of gibberellic acid to overcome the flower abscission barrier. The Chi-square tests showed that different gibberellic acid concentrations produced significant differences (α=0.05) in cross combinations for boll development. Highly significant differences in hybrid boll setting were observed between control plants and hormone growth regulator plants. The maximum boll development (92%) was observed in Siokra x Hashem Abad when the pollinated flower was treated with 100 ppm gibberellic acid at 70-80 days after pollination; in contrast, only 2-3% of pollinated flowers led to boll formation when gibberellic acid was not applied. The number of seeds set per boll varied from non-mature seeds to an average of 2.8 seeds per boll. Additionally, the seeds were not as well developed as those of the self-pollinated female parents. The hybrid plants were found to have either more vigorous growth than both parents, or to be at an intermediate level between the two parents for some traits.~~

~~Introduction~~

~~Cotton belongs to the genus *Gossypium* and has genetic resources both in domesticated and wild forms (Bhale, 1999). The species cultivated in Asia, *G. arboreum L.* and *G. herbaceum* L., are diploids with 2n=26 chromosomes, while *G. hirsutum* and *G. barbadense,* species cultivated in the New Word, are allotetraploids with 2n=52 chromosomes (Ravikesavan *et al*., 2002). The world's commercial cotton production is dominated by tetraploids, thus, there is a constant need to broaden its available genetic base (Stewart and Hsu, 1978). Resistance to certain pathogens and insects, male sterility and certain morphological plant traits possessed by Old World cotton (diploids) are potentially useful for incorporation into tetraploid cottons for higher production (Stewart and Hsu, 1977).~~

~~Cotton breeders have been trying to obtain hybrids between diploid and tetraploid species for a long time, (Gill and Bajaj, 1987), but it has been difficult, and some times impossible, to obtain many hybrids under in situ conditions because of several incompatibility factors. Meanwhile the diploid species~~