Executive Summary
of the
Report of the Second Expert Panel on Biotechnology of Cotton

1. Introduction

Since the first report on cotton biotechnology in 2000, the adoption of biotech cotton has been rapid. According to the ICAC, 21% of the world cotton area in nine countries was planted to biotech cotton varieties in 2003/04 representing over 30% of world production. The technology itself is also evolving with many new developments and possibilities for the future.

This second report aims to provide a balanced treatment of the issues associated with biotech cotton by updating the first report and specifically addressing biosafety issues surrounding biotech cotton, and the potential benefits and challenges for biotech cotton adoption in the developing world. For the purposes of this report the Expert Panel decided to use the generic term “biotech cotton” to describe varieties previously described as GM, GMO, or genetically engineered (GE), because the majority of the Panel[1] believes that the application of modern biotechnology tools is resulting in an expanding number of products best described by the term “biotech cotton”.

2. Global Status of Biotech Cotton and Future Prospects

Key Finding 1. Adoption of biotech cotton varieties has been rapid with the total global area of biotech cotton reaching 7.3 million hectares in 2003, grown in nine countries and representing 21% of cotton planted globally. More than 85% of the 7 million farmers utilizing biotech crops in 2003 were resource-poor farmers planting Bt cotton, mainly in China (Mainland), India and the Makhathini Flats region of South Africa.

Since its introduction in 1996, cotton has been one of the lead crops to be genetically engineered and biotech cotton has been one of the most rapidly adopted technologies ever. The current varieties of commercial importance address crop management or agronomic traits that assist with pest management (Bt) or herbicide tolerance (HT). Nine countries representing 59% of world cotton area allow biotech cotton to be grown: Argentina, Australia, China (Mainland), Colombia, India, Indonesia, Mexico, South Africa, and United States.

Varieties with multiple traits (Bt and herbicide tolerance) are now available. The first varieties with two independently acting Bt genes (pyramided or stacked genes) were introduced in the US and Australia in 2003. These two-gene Bt varieties provide better efficacy and much greater resilience against the risk of resistance evolution.

Independent assessments indicate that millions of farmers in China, South Africa and India have derived substantial economic, environmental, health and social benefits from biotech cotton. That such benefits can be realized elsewhere seems highly likely, but the decision to grow biotech cotton requires an initial careful analysis of the local need for biotech solutions, followed by deployment strategies that ensure farmers have the information and educational support to maximize their benefits from the technology.

Key Finding 2. While insect resistance and herbicide tolerance are the only traits currently available in biotech cottons, a broad range of other traits are under development using modern biotechnology. These may impact agronomic performance, stress tolerance, fiber quality and yield potential directly. Few of these traits are close to commercialization.

Apart from insect resistance and herbicide tolerance, biotechnology is being applied to issues of disease and nematode resistance or tolerance to various environmental stresses (heat, cold, and drought), all of which could improve realized yield. Biotechnology is providing a means for modifying the lipid profile of cottonseed oil to improve it nutritionally (e.g., high-oleic) and provide the functional properties for various food and industrial applications and to remove gossypol from cottonseed to enhance the feed value of meal.

Finally biotechnology is being used to modify cotton fiber quality by targeting specific traits such as fiber length, micronaire, color, and strength. While numerous possibilities can be imagined, and despite some advances in this area, the biology of cotton fibers imposes a strict reality. Because the cotton fiber is a single cell, it has been difficult to obtain accumulation of high levels of functional substances in the fiber. Also, cotton’s crystalline cellulose structure most likely affects many quality parameters that give cotton its desirable traits as a textile fiber, so disruption of the structure could be harmful to its principle use.

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[1] Dr. Roupakias expressed a contrary view that the appropriate terminology should be “Molecularly Genetically Engineered (MGE) cultivars”.

3. Advances in Cotton Biotechnology

Key Finding 3. Technical requirements for cotton transformation and regeneration, although well defined, remain difficult and require skill in the art. Only incremental improvements in procedures have been developed since cotton was first regenerated. Other key limitations include identification of useful, well defined genes and possible constraints to commercialization imposed by intellectual property protection.

Key Finding 4. Intellectual property rights are essential for the protection of innovation in biotechnology. While patents do not constrain research, they may seriously constrain the commercialization of biotech products, particularly by the public sector. Private-public partnerships will often provide a realistic option.

A number of patents provide intellectual property rights (IPR) over various aspects of cotton transformation and regeneration, as well as the specific genes to be transferred. In contrast to some opinion which believes IPR stifles public research efforts, we suggest that published patents represent a wealth of new information and potential new leads that may in fact stimulate new research efforts and innovation and allow development of productive collaborations.

Patenting does, however, seriously modify opportunities for commercialization of biotech products. Even in cases where a technology is novel and patented, it may be dependent on earlier developments with broad regional patent coverage and so cannot be freely used even by the inventor.

While research with biotech cotton is being pursued vigorously in many public sector institutions, with the exception of China (Mainland) these efforts have not yet resulted in commercial releases. IPR, together with other financial and marketing possibilities, may complicate the commercialization of outcomes from public research programs. In this case private-public development agreements become realistic options, provided the legitimate aspirations of countries to access biotechnology are not stifled by excessive commercial aspirations of companies.

4. Risk Assessment and Management Requirements

Key Finding 5. Rigorous, transparent, science-based and workable biosafety protocols are essential for risk assessment of biotech crops. Such procedures are well defined in some regions, less so in others. Nonetheless, there seems little doubt that the products of modern biotechnology are the most rigorously evaluated of any products ever introduced.

As with any new technology biotech cotton brings both potential benefits and risks. We can never know everything about a technology, nor definitively predict long-term consequences. Defining an appropriate science-based, risk assessment framework that addresses realistic and assessable risks to human health and the environment and balancing these against potential benefits is a key requirement for the adoption of biotech cotton.

Many of the concerns raised about biotechnology relate to ethical issues, which question the right of man to tamper with the genetic makeup of other organisms, the right of companies to patent genes or various forms of life, or the potential dominance of multinational companies over small, developing economies. We argue that these issues are not resolvable through recourse to science. Hence, as a technical panel we do not address them further, except to aver the legitimate right of countries to formulate their own processes and decisions about adoption, or otherwise, of new technologies and to provide ready access to potential benefits for resource poor populations without ideological or economic interference from outside.

A number of publications by scientific academies provide guidance on assessing the risks of biotech crops, and much research defines the issues that should be considered and incorporated into the regulatory process. A number of countries have well developed biosafety risk assessment frameworks and with the advent of international treaties such as the Cartageña Protocol on Biosafety 2004, a growing number of countries have committed to institute-appropriate regulatory frameworks. There seems little doubt that the products of modern biotechnology are the most rigorously evaluated of any products ever introduced.

Key Finding 6. Rigorous assessments have identified no human health risks from biotech cotton varieties or the products generated from them. Human health assessment of biotech cottons is clearly an area where harmonization of regulatory requirements is feasible worldwide.

Key Finding 7. Environmental risk assessment requires a ***case by case assessment*** within the geographic region being considered for deployment of biotech cotton.

In contrast to human health assessment where we argue that widespread harmonization of regulatory requirements is possible, environmental risk assessment requires a ***case by case assessment*** within the geographic region being considered for deployment of biotech cotton. We note however, that in cases where neighbouring countries jointly consider a biotech introduction, environmental risk assessment could reasonably be done for a broad bioregion where similar environmental conditions and issues apply.

Possible ecological risks requiring pre-adoption assessment are:

1. Potential for gene flow and consequences on biodiversity and weediness
2. Impacts on non-target species
3. Resistance risk and its management

Key Finding 8. The potential for gene flow through pollen movement is an insignificant risk in the case of related species that are genetically incompatible with cultivated cotton (non-*Gossypium* Malvaceae and diploid *Gossypium* species). Where cultivated biotech varieties could co-occur with sexually compatible species (conventional varieties, wild or feral tetraploid species), the potential for pollen transfer is rare event, and specific measures could be implemented to further minimize the possibility of gene flow. Cultivated (and wild) cotton genotypes lack weedy characteristics.

Cotton is a self-pollinating plant, with heavy sticky pollen that is not wind dispersed. Natural outcrossing can only be mediated by certain insects. For gene flow to occur via normal sexual transmission, certain conditions must exist: the two parents must be geographically associated, their flowering periods must coincide, a suitable pollen vector must be present and active since cotton pollen is not wind dispersed, and the resulting progeny must be fertile and ecologically fit for the local environment. All the essential conditions are rarely present at the same time, so gene flow from cultivated cotton, whether biotech or not, to uncultivated genotypes is a rare event.

Key Finding 9. The well-established specificity of Bt proteins greatly reduces risks of direct effects on non-target species. Likewise there is no evidence for indirect effects on beneficial species through consumption of Bt intoxicated prey. Potential changes in the pest status of pests which are not susceptible to Bt proteins (e.g. sucking pests) must be considered for the sustainable management of Bt cottons.

Potential impacts of biotech cotton on non-target species may involve direct or indirect effects and a range of assessment protocols have been proposed. Defining appropriate methods to assess ecological risk needs to take account of the limited resources available in many developing countries and, hence, set a priority on defining a required minimum set of locally derived data.

In the case of direct effects of Bt proteins on non-target species, the well established specificity of these proteins greatly reduces risks of direct effects on non-lepidopteran species. The much publicized suggestion that pollen from Bt (Cry 1Ab) maize could pose a risk to monarch butterflies in the USA has been rigorously refuted with a series of field studies demonstrating that Bt maize poses no unreasonable adverse impact on the monarch butterfly population. This case, and others, very clearly demonstrate the need for careful and comprehensive experimentation to define risks, rather than extrapolation from inappropriate laboratory hazard assessments.

Indirect effects on non-target species may be mediated through changes in abundance and diversity of prey. Within-field impacts on non-targets, even if they do occur, are unlikely to be significant compared to the undoubted impacts from broad-spectrum pesticides.

Key Finding 10. The evolution of resistance in the target insect pest or weed complex is the major challenge to the sustainable use of biotech cottons. For both herbicide tolerant cottons and Bt cotton some level of pre-emptive resistance management will be required, although the details will vary with local situation. Resistance management strategies will require a sound ecological understanding of the farming system and pest complex to allow development of a pragmatic, yet scientifically valid strategy which can be implemented locally.

Strategies for the pre-emptive management of Bt cotton have been exhaustively explored with population genetic models and innovative methods to modify the selection environment imposed by Bt cotton on the pest. Resistance is not an inevitable consequence of the use of Bt cottons, but susceptibility to Bt proteins should be viewed as a valuable natural resource to be managed as carefully as the soil and water upon which cotton production depends directly. Defining the risk of resistance requires a sound understanding of the biology and ecology of the system, while defining the components of a resistance management strategy requires an ordered process that engages all stakeholders to identify a workable response.

Explicit resistance strategies have been implemented in some countries, notably in Australia and the USA. However, it is critically important that individual countries research and adopt a management strategy appropriate for their environment and cropping system and not simply adopt strategies applied in the USA or Australia. The specific ecological features and assumptions which dictate the need for those strategies may not apply in all countries, particularly where small-holder production systems result in a diverse mosaic of cropping and alternative hosts for the target pests. Again a “case by case” assessment of management needs is critical.

Strategies need to take into account the capacity of local farmers to implement requirements that are often restrictive for small-holders in developing countries. For that reason governments, research agencies and technology providers should consider regional approaches to management which reduce the burden on individual growers.

Key Finding 11. Biotech cotton varieties should not be perceived as "magic bullets" for pest control in cotton, but be recognized as a valuable component of integrated pest management (IPM) systems which can reduce the impact of key pests and address significant environmental concerns.

In seeking to establish policy on the introduction of biotech cotton varieties, all governments should take account of the potential for integrated pest management (IPM) and integrated weed management (IWM) systems to reduce insecticide and herbicide reliance and assess the need for biotech cotton as a component of such systems, not as an alternative. While Bt cottons clearly provide an opportunity to address significant environmental concerns about cotton production, their real value is as a foundation to build IPM systems which incorporate a broad range of biological and cultural tactics.

5. Environmental, Economic and Social Impacts of Biotech Cottons

Key Finding 12. A review of published literature from all countries growing biotech cottons indicate significant economic, environmental and social benefits, particularly for resource-poor farmers in developing countries. Farmer benefits accrue through reductions in pesticide use, equal or higher yields, no impact on fibre quality and increased income, while clear environmental benefits are delivered through reduced pesticide input.

Published literature from all countries growing biotech cottons indicate significant economic, environmental and social benefits. Biotech cottons, compared to their conventional counterparts, consistently have lower pesticide use and higher average profit in both large-scale and small-holder systems. Yields are usually higher and fiber quality is not affected. Indirect significant benefits of the technology include improved populations of beneficial insects and wildlife in cotton fields, reduced pesticides runoff, and improved farm worker and neighbor safety as well as soil-related environmental improvements through changed tillage practices with HT varieties. Perhaps most importantly the growing body of socio-economic analyses supports the view that Bt cotton at least can bring increased income levels to resource-poor farmers with significant flow-on gains for communities.

Perhaps the most striking documented impacts to flow from biotech cotton is the human health benefits now widely identified in China and South Africa. These benefits flow directly from the reduced pesticide use required in Bt cotton varieties. Similar and perhaps larger benefits could be expected in other developing countries where resource-poor small-holders are required to apply pesticides by hand using minimal or no protection and poor equipment. Moreover the improvements in cash flow and reductions in time demand for manual spraying of crops opens up considerable opportunities for flow-on community benefits.

However, concerns remain about the influence of multinational companies with regard to the deployment of biotech crops in developing countries. As we stress in our conclusions, all countries should to be free to make their own decisions about adoption of biotech cotton or other products of modern biotechnology unconstrained by philosophical, ideological or economic pressures from outside.

It is imperative that small-holders are provided with options to adopt Bt or HT traits alone or in combination as the needs of their local situation demand, and with the educational support required to maximize value and environmental benefits.

6. Sustained Access to New Technology in Developing Countries

Key Finding 13. Sustained access to biotech cotton varieties requires a combination of political will and commitment to provide the components of: a rigorous, transparent and effective regulatory process; a professional seed supply industry; farmer education and support structures; IPR and a conducive business environment.

The most significant requirement for biotech crops is that they must satisfy a clear agronomic, environmental or social need and can bring demonstrable benefit to local farmers. So the trait(s) must be tailored to local needs, not imposed from other systems.

Key Finding 14. Potential benefits from biotech traits can only be realized when they are expressed in well adapted and thoroughly tested varieties suitable for a given region. Full recognition and value should be placed on locally developed and adapted germplasm during any implementation of biotech cottons. The ongoing importance of conventional breeding efforts through public or private institutions should not be lost in an era of biotechnological advances.

We provide some recommendations for the adoption of technology by developing countries:

1. All countries should to be free to make their own decisions about adoption of biotech cotton or other products of modern biotechnology unconstrained by philosophical, ideological or economic pressures from outside
2. Develop a centralized regulatory process that is clear, rigorous, expeditious, harmonized and science based, that requires testing to demonstrate benefits and follow-up procedures to ensure sustainability
3. Ensure that legislation is in place to protect both the germplasm and the technology
4. Develop technical teams that can educate farmers and support the use of new technology.
5. Encourage the adoption of the best technology in varieties with demonstrated local performance.
6. Include biotech cotton as one component of an integrated farming system supporting adoption of IPM (Integrated Pest management) or IWM (Integrated Weed management), not as a replacement or alternative technology.