Policy brief | September 2013

Adoption Processes and Regulatory Challenges for Genetically Modified Crops in Developing Countries: Lessons for Africa

African Biosafety Network of Expertise

NEPAD Planning and Coordinating Agency

NEPAD
TRANSFORMING AFRICA

The regulation of genetically modified (GM) crops is a topical issue in agriculture and environment. Only five out of the 11 countries which grew more than one million hectares of GM crops in 2012 have a history of orderly adoption of these crops as per the regulatory requirements of the respective individual countries. In the remaining six countries (all developing), GM crops were either smuggled in, released prior to regulatory approval or unapproved GM seeds were sold along with the approved ones in breach of regulatory expectations. Lack of sound biosafety regulatory systems encouraged unregulated and illegal access to GM crop seeds. It is ironic that encumbered biosafety regulatory systems motivate an unregulated and illegal access to the same technology that they are designed to limit access to. Factoring the cost to farmers of overly restrictive biosafety risk analysis and regulatory decision making is suggested. African countries should develop more efficient and responsive biosafety regulatory systems to promote compliance.

The intent of this policy brief is to present the adoption history and regulatory challenges that developing countries have experienced such that aspiring countries might find helpful guidance to make informed decisions on their GM crop biosafety regulatory approach. The brief argues that overly restrictive regulations failed to result in the desired policy outcome when economic stakes were too appealing for farmers to forgo adoption. The brief concludes with regulatory policy implication for African countries.

The Global Perspective

Advances in molecular biology in the second half of the 20th century have brought new tools and techniques for the integration of important agronomic traits into crop varieties beyond what has been possible in nature. Crops developed through the new methods are called genetically modified (GM) or genetically engineered crops. GM crops are the fastest adopted crop technology in history. These crops were grown on 170 million hectares in 2012.

The advent of GM crops was marked by a parallel evolution of the regulation of GM activities, spanning from laboratory to end-use. The conclusion of the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity was a major turning point in the regulation of GM organisms particularly those destined for intentional environmental release.

The CPB is significant for the agriculture sector as it recognizes both the benefits and the potential risks arising from GM technology. Hence, it stresses the need to do scientifically sound risk assessment and management practices to minimize adverse effects.

The CPB has guided the development of biosafety laws, regulations and guidelines in many developing countries that are party to the Protocol. The Protocol is based on the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development. However, different countries have interpreted and implemented this approach differently. Some countries have taken precaution to be decision making based on scientific assessment and have consequently put in place regulatory measures that include science based risk assessment. This has opened doors for testing and commercialization of GM crops. Other countries have issued prohibitive legislations that deny farmers a powerful tool to tackle some crop production constraints.

Despite a disparity in regulatory environments, in 2012, 28 countries grew transgenic crops. Eleven of these countries cultivated more than a million hectares each. These major GM crop growing countries have travelled different paths in terms of frameworks for regulation of the crops. Some countries have built new regulatory structures, others have modified existing ones, while still others have operated within pre-existing regulatory frameworks.

In Africa, farmers in South Africa, Burkina Faso, Sudan and Egypt have adopted GM crops. A number of other African countries are experimenting with them. Despite this demonstration of interest, the establishment of functional biosafety regulations is moving very slowly and arriving at concrete commercialization decisions remains on the whole difficult. As a result of these challenges, the New Partnership for Africa's Development (NEPAD)-African Biosafety Network of Expertise has been assisting African Union member countries to build functional biosafety systems that are flexible and responsive to the needs of African farmers while ensuring safety of this novel technology to the environment and human and animal health.

Regulatory regimes and adoption processes in individual countries

Regulation and diffusion of GM crops operates in a macrocosm of actors that includes national regulatory bodies, multinational biotech companies and a diverse set of other actors put together under national agricultural innovation system. Where a biosafety regulatory system is functional, the interaction among these actors is optimal and decisions are predictable. When this occurs, the result is often timely and regulated access to technology ensured by efficient and flexible regulatory approaches and implementation capacity.

However, experience has shown that the adoption of GM crops has been rife with instances of regulatory inconsistencies. In some countries, technology adoption preceded regulatory regimes. In others, although a potentially workable regulation was in place, the system was held hostage in consideration of the demands of anti-GM environmentalists and their allies. Still in others, indecision was the norm or the regulatory requirement was grossly cumbersome.

Overly restrictive regulations either denied access to technology or were ignored by farmers who found illegal but too convenient access to GM crop seeds through their cross-border networks. In some countries, private seed companies and public research centres were involved in breeding GM traits into locally adapted varieties, which resulted in the illegal cultivation of large acreage of GM crops. Indeed, of the top 11 mega-biotech countries, six have a history of unapproved GM crop seed access especially at the early stages of technology introduction as recounted below.

China. The first biosafety regulation in China was issued by the Ministry of Science and Technology (MoST) in 1993. Thereafter, the Ministry of Agriculture (MoA) issued implementation measures in 1996 under the MoST's regulation of 1993. In 2001, the Chinese State Council issued a decree to regulate agricultural GM organisms replacing the 1996 regulation of the MoA. Subsequently, the MoA issued several regulations in 2002 in order to implement the 2001 decree by the State Council.

The MoA is responsible for the review and approval of GM crops, on recommendation from the National Biosafety Committee (NBC). For imports, China requires a certification that the

GM product is approved in the exporting country. Although familiar technologies like Bt cotton are deregulated at the MoA level, decisions involving staple crops like rice are left to the highest policy makers.

China established its NBC in 1997. In this same year, four Bt cotton varieties developed by Chinese public institutions and one Bt cotton variety from Monsanto were approved for cultivation. Following this, a sharp rise in demand for the Bt cotton seed resulted in the proliferation of Bt cotton varieties, which were disseminated without the necessary regulatory oversight. At one point, the number of illegal varieties exceeded the number of legal Bt-cotton varieties. In fact, nearly all newly approved varieties were already being planted in farmers' fields, indicating that the regulatory system lagged behind the desire and willingness of these farmers to use this technology. Also an underground Bt-cotton market promoted the diffusion of high as well as low yielding Bt-cotton varieties. Interestingly, Bt cotton varieties approved by the NBC benefited farmers more than the unapproved varieties did, as the former gave better yield while reducing pesticide use.

Pakistan**.** The Government of Pakistan constituted its National Biosafety Expert Committee in 1998 to develop a regulatory framework for the biosafety evaluation and release of GM crops. However, it was only in 2005 that the Pakistan Biosafety Rules and the National Biosafety Guidelines were approved. In the interim period and afterwards until 2010, Bt cotton continued to spread from field to field illegally. In 2012, Pakistan grew 2.8 million hectares of Bt cotton.

Illegal Bt cotton seed reached farmers' fields in 2002 through 'informal' channels. These varieties did not perform well because they were not adapted to Pakistani growing conditions. Later on, both the public research institutions and private seed companies introduced Bt genes into local varieties and marketed them without regulatory approval. Pakistan officially approved the adoption of Bt cotton only in 2010. However, such a delay in approval encouraged an unregulated adoption of Bt cotton in the country. In addition to biosafety concerns, lack of regulatory oversight means that seed quality was compromised and support for farmers on ways of managing the technology was at best inadequate.

India**.** The Genetic Engineering Approval Committee is tasked with the assessment of GM crops for commercialization. But final approval rests with the Ministry of Environment and Forestry (MoEF). In 2012, India grew 10.8 million hectares of Bt-cotton. India provides a prime example of the benefits of Bt-cotton to smallholder farmers, where a 24% increase in cotton yield and a 50% gain in cotton profit were reported for Bt-cotton adopting smallholder farmers. Despite such a success, the adoption of Bt-cotton in India was not without challenges.

In 2001,a local seed company in partnership with Monsanto applied for release of Bt cotton varieties. But commercial approval was delayed at least in part because of cumbersome regulatory requirements. However, in the same year another local seed company was found to have illegally distributed Bt cotton seed which was planted on about11000 hectares. The incident did, however, demonstrate that the Bt technology was effective and the Indian Government approved Bt cotton cultivation in 2002. Even after this, many unapproved (genuine and spurious) varieties labeled as Bt cotton were common. In fact, by 2004, it was argued that more than half of the area under Bt cotton was planted with unapproved seeds.

Brazil. By 2012, Brazil grew about 36.6 million hectares of genetically modified crops most of which was herbicide tolerant soybean. Brazil established the National Technical Biosafety Commission (CTNBio) in 1996. Although the CTNBio authorized GM soybean release in 1998, commercialization was delayed because of lawsuits that followed. However, farmers had long planted Monsanto seeds smuggled in from Argentina. Brazil was caught between the anti-GMO activists and politicians on one side and the powerful agri-business lobby on the other. This made arriving at decisions hugely difficult for Brazilian authorities.

However, Brazil officially approved the growing of herbicide tolerant soybean in 2003, initially for a one year period. GM crops are growing in the country legally ever since. Brazil enacted its biosafety law in 2005.

Bolivia. The government of Bolivia is said to have a strong anti-GM crop stand. The regulatory approval process for Monsanto's herbicide tolerant soybean began in 1998.And Bolivia approved it for commercial growing in 2005. However, farmers had already introduced glyphosate tolerant soybean seeds from Brazil and/or Argentina through family networks towards the end of the 1990s.

***Paraguay*. ** Up until the 2004/2005 season, Paraguay did not allow the use of GM seeds. However, herbicide tolerant soybeans were illegally cultivated starting from 1997. The seeds were probably introduced from Argentina and Brazil. In 2004, having run out of options, Paraguay allowed the cultivation of GM soybean, by which time about 80% of soybean planted was GM. In 2012, Paraguay grew about 3.4 million hectares of GM crops. Paraguay appears to have not yet passed a biosafety law.

Lessons from History

GM crop agriculture has rapidly become part of the cropping systems of the world. In countries that grow commodity crops such as soybean, cotton, corn and canola, the introduction of GM crops has reduced crop losses due to weeds and insect pests, lowered pesticide use and increased grower incomes. In addition, use of reduced tillage and improved weed control in glyphosate-tolerant crops has enhanced soil conservation, reduced costs and eased crop management, in the end promoting more sustainable agriculture.

In Latin American countries, the introduction of glyphosate tolerant soybean has expanded the area under cultivation, attracted large investment, increased aggregate production and stimulated export-oriented economic growth. In India, Pakistan and China, Bt cotton cultivation has benefited small farmers by increasing incomes, enhanced supply of raw materials to local industry and export market, generated employment and overall stimulated the national economy. However, the introduction of these crops in many countries continues to face resistance because of biosafety and socio-economic concerns.

The fact that these crops have been in use over the last 17 years without any incidence of harm demonstrates their safety. Moreover, there is little evidence that GM crops pose serious socio-economic problems that are different from other known agricultural technologies. Rather, major GM crops such as glyphosate tolerant soybean and Bt cotton are agronomic traits that confer advantages for the farmers. In the absence of convincing risks and existence of these apparent advantages, obviously farmers are the bearers of the burden of over regulation. The illegal access to GM crop seed indicates the natural reaction by farmers as a counterbalance to unsound regulatory measures in individual countries.

Our analysis of situations in Latin America included cases where large scale farmers illegally gained access to GM seeds and demonstrated the attributes of the technology in crop success. The respective governments subsequently established regulation and approved the cultivation of GM crops. The experiences of China, Pakistan and India where small farmers are the majority indicate the tenacity for introducing and copying a technology illegally by the national innovation systems including public research centres and private seed companies. The Pakistan, India and China Bt cotton biosafety non-compliance cases also indicate the difficulty of ensuring GM crop biosafety in the absence of functioning regulation.

By and large, our analysis contradicts the presumption that regulatory inflexibility deters illegal access to GM crop technology. Rather, in a climate of regulatory indecision and/or regulatory encumbrances, the unregulated environmental release of GM crops did occur regularly. Hence for crops that farmers find desirable and where farmers are strongly independent or the innovation system allows copying technology, putting a functional biosafety system in place seems not so much an option but rather a necessity to avoid the prospect of unregulated adoption.

This brief history suggests that farmers are the global drivers of the adoption of GM crops especially in the developing world. With cross border linkages and relationships among communities, GM crops have been infiltrated into several countries without regulatory oversight. These incidences argue for the importance of regional reconnaissance of the state of GM crops and the need for building functional biosafety systems in individual countries. Not least important is the need to consider regional approaches to biosafety with the ultimate goal of harmonization of regional biosafety and biotechnology policies.

Implications for Africa

Africa is characterized by a rapidly growing population and a relatively large expanse of potentially arable land. The continent needs to enhance agricultural production through harnessing its land and labour resources to bring about human security and sustainability. As one means for reducing area expansion, raising productivity on the already cultivated land is of prime importance in order to prevent the ill effects of expanding agriculture on nature reserves. To this end, the rapid adoption of conventional and new technologies such as GM crops is a proven tool.

In Africa, while many more GM crop traits of relevance are in the pipeline, the two most widely commercialized traits – herbicide tolerance and insect resistance– have a demonstrated potential to increase crop productivity, reduce environmental impact, attract investment, create employment, and enhance farm incomes and economic growth. However, making use of these opportunities requires the adoption of biosafety regulations that are workable, responsive and flexible. African countries are testing GM crops and several are expected to progress towards commercialization. If history is a guide, this means there will be cross-border leakage of GM crop seeds from one country to the other without regulatory approval. This calls for expedited establishment of legal and institutional biosafety frameworks. From the lessons learned in Asia and Latin America, such frameworks need to consider practicality and functionality of the systems in order to avoid unregulated release into the environment of the GM crops. Given the potential for cross border informal seed movement, the need for harmonization of GMO policies under regional blocks is warranted.

Conclusion

The expansion of GM crops in many developing countries, driven by farmers, often circumvented biosafety regulatory requirements. Regulatory intransigence did not preclude farmers' access to GM crop seeds. Flexible and responsive biosafety systems that consider regional dynamics may promote biosafety regulatory compliance and minimize the illegal adoption of GM crops.

References

Cardoso, T.A.O., Albuquerque Navarro M.B.M., Soares B.E.C., Lima e Silva F.H., Rocha S.S., and Oda L.M. 2005. Memories of biosafety in Brazil: Lessons to be learned.*Applied Biosafety, 10:*160-168.

Huang, J., Hu, R., Rozelle, S. and Pray, C. 2005. Development, policy and impacts of genetically modified crops in China: A comprehensive review of China's agricultural biotechnology sector. Paper presented at the workshop held at Villa Bellagio, Bellagio, Italy, June 2005.

Huang, J. and Yang, J. 2011. China's Agricultural Biotechnology Regulations—Export and Import Considerations: Trade and Economic Implications of Low Level Presence and Asynchronous Authorizations of Agricultural Biotechnology Varieties. International Food & Agricultural Trade Policy Council http://www. agritrade.org/Publications/ documents/LLPChina.pdf.

James, C. 2012. Global Status of Commercialized Biotech/GM Crops: 2012. ISAAA Brief No. 44. ISAAA: Ithaca, NY.

Jayaraman, K.S. 2001.Illegal Bt cotton in India haunts regulators. Nature Biotechnology 19: 1090 | doi:10.1038/nbt1201-1090.

Jayaraman, K. S. 2004. Illegal seeds overtake India's cotton fields. Nature Biotechnology 22: 1333-1334.

Jepson, W.E. 2002. Globalization and Brazilian biosafety: the politics of scale over biotechnology governance. Political Geography 21: 905–925.

Kathage, J. and Qaim, M. 2012. Economic impacts and impact dynamics of Bt (*Bacillus thuringiensis*) cotton in India. PNAS USA. www.pnas.org/cgi/doi/ 10.1073/pnas.1203647109.

Lagos, J.E. and Jie, M. 2012. China Agricultural Biotechnology Annual. USDA Foreign Agricultural Service, Global Agricultural Information Network (GAIN). GAIN Report Number CH12046.

Nazli, H., Orden, D., Sarker, R. and Meilke, K..2012. Bt cotton adoption and wellbeing of farmers in Pakistan. Selected paper prepared for presentation at the International Association of Agricultural Economists (IAAE) Triennial Conference, Foz do Iguaçu, Brazil, 18-24 August, 2012.

Smale, M., Zambrano, P., Paz-Ybarnegaray, R., Fernández-Montaño, W. 2012. A Case of Resistance: Herbicide-tolerant Soybeans in Bolivia. *AgBioForum 15: 191-205.*

The Economist. 2003. GM crops in Brazil: An amber light for agri-business. 2 October 2003.

USDA Foreign Agricultural Service. 2010. Paraguay biotechnology annual report. Global Agricultural Information Network Report.

Acknowledgements

My heartfelt thanks go to Prof. Karim Maredia for facilitating a critical review of this brief by notable experts in the field. This brief benefited immensely from the insightful reviews of Dr. Bob Frederick, Prof. Diran Makinde, Dr. Bill Doley, Prof. Rebecca Grumet and Dr. Anastasia Bodnar.

Woldeyesus Sinebo is the Agricultural Biosafety Programme Officer at the NEPAD Agency African Biosafety Network of Expertise. He can be reached at w.sinebo@nepadbiosafety.net.

Suggested Citation: Sinebo, W. 2013. Adoption Processes and Regulatory Challenges for Genetically Modified Crops in Developing Countries. Lessons for Africa. Agricultural Biosafety Policy Brief No. 1. NEPAD Agency African Biosafety Network of Expertise, Ouagadougou, Burkina Faso.

This brief was developed by the African Biosafety Network of Expertise (ABNE) to address biosafety regulatory aspects of genetically modified crops and is primarily for regulators, and policy and decision makers.

AU-NEPAD AFRICAN BIOSAFETY NETWORK OF EXPERTISE (NEPAD-ABNE),
06 BP 9884 OUAGADOUGOU 06 BURKINA FASO,

www.nepadbiosafety.net

Working towards building functional biosafety systems in Africa

September 2013

ABNE September, 2013