Biosafety in Africa:
Experiences and best practices

Edited by David P. Keetch, Diran Makinde, Cholani K. Weebadde
and Karim M. Maredia
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Acknowledgements
This publication is made possible through the resource network established under the NEPAD-MSU Partnership for the African Biosafety Network of Expertise (ABNE) project funded by the Bill and Melinda Gates Foundation. We are grateful to Ms. Joy Neumann Landis from Michigan State University (MSU) for her support in editing, formatting and final publication of this book. We are also grateful to Dr. Dilrukshi Hashini Galhena from MSU for her technical support in preparing the book cover.
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<th>Meaning</th>
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<tr>
<td>AATF</td>
<td>African Agriculture Technology Foundation</td>
</tr>
<tr>
<td>ABBC</td>
<td>Agricultural Biotechnology &amp; Biosafety Committee</td>
</tr>
<tr>
<td>ABNE</td>
<td>African Biosafety Network of Expertise</td>
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<tr>
<td>ABS</td>
<td>Access and Benefit Sharing</td>
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<tr>
<td>ABSD</td>
<td>Agricultural Biotechnology for Sustainable Development</td>
</tr>
<tr>
<td>AC</td>
<td>Advisory Committee</td>
</tr>
<tr>
<td>AMCOST</td>
<td>African Ministerial Council on Science and Technology</td>
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<td>AMCN</td>
<td>African Ministerial Conference on the Environment</td>
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<td>AML</td>
<td>African Model Law</td>
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<tr>
<td>ANB</td>
<td>Agency National Biosecureite</td>
</tr>
<tr>
<td>AU</td>
<td>African Union</td>
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<tr>
<td>BCH</td>
<td>Biosafety Clearing House</td>
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<tr>
<td>BMGF</td>
<td>Bill &amp; Melinda Gates Foundation</td>
</tr>
<tr>
<td>BRIC</td>
<td>Biotechnology Regional Innovation Centres</td>
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<tr>
<td>CBD</td>
<td>Convention on Biological Diversity</td>
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<tr>
<td>CBSD</td>
<td>Cassava Brown Streak Disease</td>
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<tr>
<td>CEN-SAD</td>
<td>Community of Sahel-Saharan States</td>
</tr>
<tr>
<td>CFT</td>
<td>Confined Field Trial</td>
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<tr>
<td>CGIAR</td>
<td>Consultative Group on International Agricultural Research</td>
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<tr>
<td>CILSS</td>
<td>Interstate Committee for Reducing Desertification in the Sahel</td>
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<tr>
<td>CISANET</td>
<td>Civil Society Agriculture Network</td>
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<td>CEPA</td>
<td>Centre for Environmental Policy Advocacy</td>
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<td>CLI</td>
<td>Crop Life International</td>
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<td>CMD</td>
<td>Cassava Mosaic Virus</td>
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<td>CNA</td>
<td>Competent National Authority</td>
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<tr>
<td>COMESA</td>
<td>Common Market for Eastern and Southern Africa</td>
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<td>COPAGEN</td>
<td>Coalition pour la Protection du Patrimoine génétique africain</td>
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<td>CPB</td>
<td>Cartagena Protocol on Biosafety</td>
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<tr>
<td>CSIR</td>
<td>Council for Scientific and Industrial Research</td>
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<tr>
<td>DAES</td>
<td>Department of Fisheries, Department of Agricultural Extension Services</td>
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<td>DARS</td>
<td>Department of Agricultural Research Services</td>
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<td>DAHLD</td>
<td>Department of Nutrition, Department of Animal Health &amp; Livestock Development</td>
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<td>DCD</td>
<td>Department of Crop Development</td>
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<td>DNA</td>
<td>Deoxyribonucleic acid</td>
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<td>DREA</td>
<td>Department of Rural Economy and Agriculture</td>
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<td>DST</td>
<td>Department of Science &amp; Technology</td>
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<td>EAC</td>
<td>East African Community</td>
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<td>EC</td>
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<td>ECOEWS</td>
<td>Economic Community of West African States</td>
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<td>EFSA</td>
<td>European Food Safety Authority</td>
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<td>FARA</td>
<td>Forum for Agricultural Research in Africa</td>
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<td>FAO</td>
<td>Food and Agriculture Organization</td>
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<td>FMENV</td>
<td>Federal Ministry of Environment</td>
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<td>FRD</td>
<td>Foundation for Research Development, now the National Research Foundation, NRF</td>
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<td>GE</td>
<td>Genetically engineered</td>
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<td>GEF</td>
<td>Global Environment Facility</td>
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<td>GIZ</td>
<td>Deutsche Gesellschaft für Internationale Zusammenarbeit</td>
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<td>HRST</td>
<td>Human Resources Science &amp; Technology</td>
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<td>HT</td>
<td>Herbicide tolerant</td>
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<tr>
<td>IBC</td>
<td>Institutional Biosafety Committee</td>
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<td>ICGB</td>
<td>International Centre for Genetic Engineering and Biotechnology</td>
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<td>IDA</td>
<td>International Development Agency</td>
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<td>IFPRI</td>
<td>International Food Policy Research Institute (IFPRI)</td>
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<td>INERA</td>
<td>l'institut de l'environnement et de recherches agricoles,</td>
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<td>IPPC</td>
<td>International Plant Protection Convention</td>
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<td>Acronym</td>
<td>Full Form</td>
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<td>IR</td>
<td>Insect resistant</td>
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<td>ISAAA</td>
<td>International Service for The Acquisition of Agric-biotech Applications</td>
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<td>ISF</td>
<td>International Seed Federation</td>
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<tr>
<td>LMO</td>
<td>Living Modified Organism</td>
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<td>LUANAR</td>
<td>Lilongwe University of Agriculture and Natural Resources</td>
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<td>MDG</td>
<td>Millennium Development Goals</td>
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<td>MIBC</td>
<td>Ministerial Institutional Biosafety Committees</td>
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<td>MoAFS</td>
<td>Ministry of Agriculture &amp; Food Security</td>
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<td>MSU</td>
<td>Michigan State University</td>
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<tr>
<td>MZUNI</td>
<td>University of Mzuzu</td>
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<tr>
<td>NABDA</td>
<td>National Biotechnology Development Agency</td>
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<td>NBA</td>
<td>National Biosafety Authority</td>
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<td>NBC</td>
<td>National Biosafety Committee</td>
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<td>NBF</td>
<td>National Biosafety Framework</td>
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<td>NBO</td>
<td>National Biosafety Observatory</td>
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<td>NBRC</td>
<td>National Biosafety Regulatory Committee</td>
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<td>NCST</td>
<td>National Commission for Science &amp; Technology</td>
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<tr>
<td>NEMA</td>
<td>National Environment Management Act</td>
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<td>NEMBA</td>
<td>National Environment Biodiversity Act</td>
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<td>NEPAD</td>
<td>New Partnership for Africa’s Development</td>
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<td>NEPAD/NPCA</td>
<td>New Partnerships for Africa’s Development Planning and Coordinating Agency</td>
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<tr>
<td>NEWEST</td>
<td>Nitrogen-use Efficient, Water-use Efficient and Salt Tolerant</td>
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<tr>
<td>NSBC</td>
<td>National Scientific Biosafety Committee</td>
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<tr>
<td>NTO</td>
<td>Non target organism</td>
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<tr>
<td>OIE</td>
<td>World Organization for Animal Health</td>
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<tr>
<td>PBS</td>
<td>Program for Biosafety Systems</td>
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<tr>
<td>PP</td>
<td>Precautionary Principle</td>
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<tr>
<td>PPRSD</td>
<td>Plant Protection and Regulatory Services Directorate</td>
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<tr>
<td>PQs</td>
<td>Plant Quarantine Officers</td>
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<tr>
<td>PRA</td>
<td>Pest Risk Analysis</td>
</tr>
<tr>
<td>RIBios</td>
<td>Réseau Interdisciplinaire de Biosécurité</td>
</tr>
<tr>
<td>PUB</td>
<td>Public Understanding of Biotechnology (PUB)</td>
</tr>
<tr>
<td>RAEN Africa</td>
<td>Regional Agricultural and Environment Initiatives Network-Africa</td>
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<tr>
<td>REC</td>
<td>Regional Economic Community</td>
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<tr>
<td>RNA</td>
<td>Ribonucleic acid</td>
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<tr>
<td>ToT</td>
<td>Training of Trainer</td>
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<td>SAC</td>
<td>Scientific Advisory Committee</td>
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<td>SADC</td>
<td>Southern African Development Community</td>
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<td>SAGENE</td>
<td>South African Committee for Genetic Experimentation</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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<tr>
<td>TAC</td>
<td>Technical Advisory Committee</td>
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<td>TBT</td>
<td>Technical Barriers to Trade</td>
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<td>TRIPS</td>
<td>Trade Related Aspects of Intellectual Property Rights</td>
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<td>UNIMA</td>
<td>University of Malawi</td>
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<tr>
<td>UNPCB</td>
<td>Burkina Cotton Growers’ Union</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
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<tr>
<td>VIRCA</td>
<td>Virus Resistant Cassava for Africa</td>
</tr>
<tr>
<td>VR</td>
<td>Virus resistant</td>
</tr>
<tr>
<td>WAEMU</td>
<td>West African Economic and Monetary Union</td>
</tr>
<tr>
<td>WEMA</td>
<td>Water Efficient Maize for Africa</td>
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<tr>
<td>WTO</td>
<td>World Trade Organisation</td>
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Foreword

New science and technology continue to play a critical role for enhancing agricultural productivity and economic growth in Africa and all over the world. The New Partnership for Africa’s Development (NEPAD) is an initiative of African Union (AU) aimed at stimulating Africa’s development. NEPAD Planning and Coordinating Agency (NPCA) programs offer holistic and integrated approaches for sustainable socio-economic development of the continent with a focus on agriculture and food security, climate change and natural resource management, regional integration and infrastructure, human development, as well as cross cutting aspects such as gender and capacity development.

NEPAD Agency has therefore been at the forefront of championing Africa’s agricultural agenda for economic empowerment of AU member states. This is particularly important for Africa’s development because agriculture continues to be a linchpin of economic growth and transformation in many African countries. Close to 65 per cent of Africa’s population relies on agriculture for their livelihood, of which about 90 per cent are small scale farmers (IFPRI¹). Thus, agricultural growth has been and will remain key to improving livelihoods. There is therefore an urgent need for deliberate efforts at stimulating growth in the agricultural sector in Africa. NEPAD Agency recognizes the pivotal role of new tools of biotechnology for stimulating sustained growth and development of the agricultural sector.

Cognizant of its important role, NPCA, as the technical body of the African Union Commission has prioritized Agriculture and Food Security as one of its six thematic areas for intervention. This is being done through a Comprehensive African Agricultural Development Programme (CAADP) established by the AU assembly in 2003. Through this program, NEPAD Agency hopes to achieve the vision of African leaders to raise agricultural productivity in Africa to at least six percent annually to contribute to poverty alleviation and elimination of hunger in Africa. To achieve this, CAADP requires countries to commit at least 10 percent of their national budgets to agriculture. Since 2003, over thirty countries have signed up to the CAADP Compact and eight have surpassed the 10 percent target (NEPAD Agency). CAADP brings together key players in agriculture – such as African leaders, policy makers, scientists, partners and farmers – to unleash agricultural growth and sustainable development on the continent.

NEW TOOL IN THE TOOLBOX - TRANSFORMING AFRICAN AGRICULTURE THROUGH BIOTECHNOLOGY

Agricultural productivity in Africa is constrained by a multiplicity of challenges requiring multi-prong innovative solutions. To help spearhead agricultural growth and enhance competitiveness, NEPAD facilitates demand-based adoption of safe and useful technologies including modern biotechnology. Indeed, African leaders saw great wisdom in harnessing the enormous potential of biotechnology to transform the agricultural landscape in Africa. In this regard and having at hindsight the controversial nature of this technology, a high level African Panel on Biotechnology (APB) was established through AU and NEPAD, to advise the AU, its Member States and its various organs, on current and emerging issues associated with the development and application of modern biotechnology in agriculture and other priority areas such as human and animal health, industry, forestry and the environment.

The panel report, called Freedom to innovate², entreated African leaders to take advantage of biotechnology and outlined key recommendations and strategies to facilitate the process. This report was considered and endorsed by an Extraordinary Conference of the African Ministerial Council on Science and Technology

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¹ http://www.ifpri.org/publication/agriculture-s-critical-role-africa-s-development
AMCOST) leading to the Cairo declaration \(^3\) in which African leaders made a commitment to “Establish mechanisms to accelerate and monitor the implementation of the Africa’s Science and Technology Consolidated Plan of Action” \(^3\). There is therefore political support at the highest level of governance for the harnessing of science and technology, in this case the enormous potential of traditional and modern biotechnology, in the agricultural transformation agenda being spearheaded by NEPAD.

**OVERCOMING THE REGULATORY HURDLES: NEPAD’S ‘CO-EVOLUTIONARY APPROACH’**

Often, the challenge in accessing new science and technology in Africa is not so much the capacity to utilize the technology, but the lack of capacity to regulate the technology. Modern biotechnology is bound by several international instruments that require technical competence, infrastructure and institutional capacities to use, manage and regulate. Thus, one of the key recommendations of the APB was a co-evolutionary approach in which the technology is developed along with its regulation. To quote recommendation 13;

“Biotechnology regulations should be based on a case-by-case approach, according to internationally-agreed rules and guidelines. They should adopt the ‘co-evolutionary’ approach in which the function of regulation is to promote innovation, while at the same time safeguard human health and the environment” \(^2\).

Weak capacity to regulate biotechnology crops and products is a barrier for African member states to harness its full potential, and there are clear examples to attest to this fact. In this context, through funding from the Bill and Melinda Gates Foundation, the NEPAD Agency in partnership with Michigan State University established the African Biosafety Network of Expertise (ABNE) to support African countries in building functional biosafety systems that will ensure the safe development and deployment of improved biotech crops.

**EMPOWERING AFRICAN REGULATORS: BUILDING FUNCTIONAL BIOSAFETY REGULATORY SYSTEMS IN AFRICA**

In its brief existence over the last five years, ABNE has gained credibility and experience in working with national governments towards building functional biosafety regulatory systems in Africa. The ABNE service network provides up-to-date training, information, technical assistance and networking opportunities in biosafety to regulators and their support systems.

This book is an outcome of lessons learned by ABNE through on the ground engagement with a number of African countries with varying levels of capacity in biosafety policy and practice. This book has been prepared to highlight progresses made, challenges faced and lessons learnt on issues of biosafety regulation and capacity building towards establishing functional biosafety systems in Africa.

I am delighted to recommend this book to stakeholders, especially regulators and policy makers in Africa, as ABNE has maintained fact-based neutrality and avoided taking positions that are the mandates of the national competent authorities and official advisory committees. It is my sincere hope that this book will help to further strengthen NPCA’s efforts in encouraging information sharing and creating awareness among various stakeholders on issues of agricultural biotechnology and biosafety. I encourage readers to provide their feedback to the authors and the ABNE in order to help them improve upon their service provision to national and regional biosafety programmes in Africa.

Dr. Ibrahim Assane Mayaki, CEO, NEPAD Planning and Coordinating Agency (NPCA)

Preface

Biosafety involves the reduction and elimination of potential risks resulting from the use of biotechnology and its products. Biosafety has also been defined as the avoidance of risk to human health and safety, and to the protection of the environment, as a result of the use of genetically engineered organisms. A large amount of scientific knowledge and information, therefore, has a direct relevance to biosafety and this can create difficulties for the regulator in the accurate assessment of data in order to come to a rational and objective conclusion and make science-based informed decisions.

During the last quarter of the 20th Century, increased awareness and concern over the accelerating ecological degradation of the global environment culminated in the Convention on Biological Diversity (CBD). The objectives of this Convention were “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources”. At that time, the CBD negotiators recognised that biotechnology could contribute to achieving these objectives, if it was developed and used within the necessary safety framework. As a result, procedures were developed to regulate the safe transfer, handling and use of any living modified organism (LMO) resulting from biotechnology that could have an adverse effect on the conservation and sustainable use of biological diversity. These procedures formed the basis of the Cartagena Protocol on Biosafety (CPB). The CPB came into effect in 2003 and since then Parties to the CPB have been busy formulating their national biosafety legislation. This has resulted in a great demand for biosafety-related information, training programmes, and capacity-building projects.

This period of heightened activity in environmental protection was further complicated by the rapid increase in cultivation of genetically engineered (GE) crops. In 2013, the global area planted to GE crops exceeded 175 million ha. From 1996 to 2013 the global area under biotech crops increased from 1.7 million ha to 175 million ha making biotech crops the fastest adopted crop technology in the history of modern agriculture (www.isaaa.org). The number of countries electing to grow biotech crops has been increasing consistently from 6 in 1996 to 27 in 2013. Of the 27 countries growing GE crops in 2013, 19 were developing countries. Another factor complicating the situation has been the public debate on GE Organisms (GEOs - also referred to as Genetically Modified Organisms or GMOs) which relates to the availability of objective, scientific information. Much of the available scientific information regarding GEOs is considered to be confidential by technology developers. In contrast, those in opposition to GMOs have taken to using highly visible and dramatic press announcements that are subjective and inaccurate.

Biosafety regulators and policy makers need to adopt an objective and impartial position in order to compile, coordinate and distribute unbiased and reliable information on biosafety issues. The purpose of this book is to present biosafety regulators and other interested stakeholders with a rational account of the experiences and best practices of selected African countries that have already adopted the cultivation of GE crops or are in the process of adopting them. The experiences of major GE producing countries in Asia such as India and the Philippines are also included for additional information.

The editors hope that the information contained in this book will help those countries wishing to adopt GE crops to formulate an effective and efficient biosafety regulatory framework which will be conducive to the development and implementation of the technology while at the same time providing the necessary safeguards to human and animal health and the environment. The editors would like to thank all those who contributed their time and effort to providing the information contained in the various chapters. We hope that the reader will find this information useful.

Dr. David P. Keetch (Goldamer Consulting cc), Prof. Diran Makinde (NEPAD/African Biosafety Network of Expertise (ABNE), Prof. Karim M. Maredia (Michigan State University), Dr. Cholani K. Weebadde (Michigan State University)
PART 1

BACKGROUND AND INTRODUCTION
Chapter 1. **Biosafety issues in food and agricultural systems in Africa**

INTRODUCTION

The term biosafety has been defined as ‘the avoidance of risk to human health and safety, and to the conservation of the environment, as a result of the use for research and commerce of infectious or genetically modified organisms’ (FAO 2001). Genetically engineered organisms (GEOs/GMOs) are created by transferring genetic material from one organism to another through a process called genetic engineering (GE)\(^4\). The protein encoded by the introduced gene will confer a particular trait or characteristic to the recipient organism. Across the millennia, selective breeding and other such techniques have been used by humans to transfer genetic material within species complexes. New technologies such as GE permit more controlled gene transfers, and also allow for transfers among completely unrelated species (Philips 2008).

The transferred genes or gene sequences are referred to as transgenes, and biotech plants are therefore also known as transgenic plants (the terms GE and transgenic are therefore used interchangeably in this chapter). GE has been used in agriculture to develop crops with increased crop yields; reduced needs for pesticides; enhanced nutrient composition and food quality; enhanced resistance to pests and diseases, and reduced costs for food or drug production, etc. (Takeda & Matsuoka 2008). While the commercial production of biotech crops with various agronomic beneficial traits has opened a new dimension for meeting food security challenges, it has also aroused tremendous debate and concern worldwide (Pretty 2001).

Over the last few years, there has been an increase in research and development in Africa aimed at developing transgenic crops to address constraints to agricultural productivity on the continent. These include projects aimed at developing, amongst many others:

- Insect-resistant (IR) maize in Kenya;
- IR cotton in Ghana, Kenya, Nigeria, South Africa and Uganda;
- Virus-resistant (VR) cassava in Kenya and Uganda;
- Fungus-resistant banana in Uganda;
- VR banana in Egypt;
- Drought-tolerant maize in Kenya, Mozambique, South Africa, Tanzania and Uganda, and;
- Nutritionally-enhanced sorghum in Burkina Faso, Kenya and South Africa (Karembu et al. 2009).

There are also countries that have approved the commercial release of biotech crops, for example IR maize in South Africa and Egypt, and IR cotton in Burkina Faso and South Africa. However, despite the fact that a growing body of evidence continues to document increased crop yields, increased farm income, health and environmental benefits associated with the cultivation of biotech crops (Adenle 2011), there has still been significant debate regarding possible risks to human and animal health, and to the environment, along with associated issues that could arise out of the adoption of such crops. An understanding of biosafety and its related issues is therefore important in helping to make correct decisions when facing and dealing with GE and biotechnology and their products (Lu 2008). This introductory chapter outlines some of the broad biosafety issues pertaining to these technologies that may be pertinent to food and agricultural systems in Africa.

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\(^4\) In this book the term GE (genetic engineering) is used instead of GM (genetic modification), GEO (genetically engineered organism) instead of GMO (genetically modified organism) and biotech crop or plant instead of GM crop or plant.
BIOSAFETY ISSUES/CONCERNS REGARDING GE CROPS

Most concerns about biotech crops can be placed into four broad categories - environmental, food safety, legal/policy, and socio-economic - although there are cross-cutting issues which may span more than one of these categories.

Environmental concerns

Environmental concerns relate to the potential impacts on the ecosystem from the adoption of GEOs. These could include the development of resistance/tolerance by target organisms; consequences of gene flow; negative impacts on non-target organisms (NTOs), etc. (Thies and Devare 2007).

Development of resistance/tolerance by target organisms

One of the concerns, with regard to IR transgenic crops, is the likelihood of the development of resistance/tolerance by insect pests to the transgenic compound in the host crops (Thies and Devare 2007), which may result in loss of usefulness of the control strategy. Pests are considered to have developed resistance if they become able to survive on a transgenic insecticidal plant from egg to adult and produce viable offspring (Andow 2008). A number of strategies to delay resistance development have been proposed, including:

- The use of GE varieties expressing very high toxin levels such that any individuals that may develop a degree of tolerance are still killed by the toxin upon consumption;
- Stacking different insect-resistance transgenes together in the same GE variety such that individuals that may not be susceptible to one toxin are killed by a companion toxin with a different mode of action; and
- Strategically planting non-resistant crops or plants nearby as ‘refugia’ to allow any resistant pest individuals that might develop to mate with non-resistant individuals in order to reduce the frequency of resistance genes in the pest population (Bates et al. 2005).

There are concerns that in traditional low input agricultural systems in Africa, whereby farmers save seed, resistance could develop relatively quickly. This is because the plants obtained from the saved seeds of IR transgenic crops may have lower toxin concentrations as compared to the parental generations, and hence permit insects with resistance genes to survive while those lacking the genes are eliminated, gradually resulting in an increase in the number of resistant individuals in the population, thereby hastening the development of resistance. In addition, seed-saving could result in heterogeneous mixtures of GE and non-GE plants in subsequent crops (Fitt et al. 2004), thus exposing the target organisms once more to sub-lethal toxin concentrations and hastening the development of resistance. In principle, however, the high crop diversity which characterises traditional low input agricultural systems in Africa (Boon 2004) should provide suitable refugia for insect-resistant biotech crops. In such systems, it is possible to have a number of non-transgenic crop species in close proximity to GE counterparts. Structured refugia (where areas under GE and non-GE crops are clearly pre-determined, as opposed to random patches of GE versus non-GE plants) are however recommended but their use could necessitate a change in agricultural practices. In addition, given the small farm sizes in many parts of Africa, there may be issues regarding the availability of spare land for refugia. Seed mixes (where GE and non-GE seed are pre-mixed prior to planting) have been proposed as one possible way to ensure farmers have sufficient area under refugia, but it is likely that this strategy may actually hasten the rate of resistance development, as discussed above.

Consequences of gene flow

Gene flow refers to the introgression of genes or genetic materials from one plant population into another. There are concerns that the integration of transgenes from a biotech crop into its non-GE counterpart (crop-
to-crop) and/or wild or weedy relatives (crop-to-wild relative) could trigger a range of possible environmental consequences (e.g. the creation of new weeds, and changing the fitness-related characteristics and loss of genetic diversity in the wild relatives of crop landraces caused by crop-crop and crop-to-wild relative transgene flow) (Lu 2008).

Genes introgressing into wild relative populations from crops may accentuate the characteristics of weediness in the wild relatives, leading to greater persistence and invasiveness of the wild relatives. Persistence refers to the tendency of a population to remain in a particular setting, over time after it is introduced. Invasiveness, on the other hand, refers to the ability of a population to spread beyond its introduction site and become established in new locations, where it may out-compete existing populations (Lu 2008). There are concerns, therefore, that if wild or weedy species receive genes which increase their fitness in a given environment then they may become more effective and aggressive weeds. With the advent of herbicide tolerant (HT) crops (those transformed by GE such that they are unharmed when sprayed with a broad-spectrum herbicide whilst crop-infesting weeds are destroyed), there is concern that problematic weeds tolerant to multiple herbicides may develop. In addition, those crop plants that emerge in a field in the following growing season as a result of seed spillage (i.e. volunteers) may develop into aggressive weeds after incorporating such transgenes (Ellstrand 2001). Volunteers may be a special problem in the agricultural crop rotations integral to farming systems in Africa (e.g. in South African cultivation, it is common to have maize-cotton-cowpea rotations).

The introgression of genes from one species into the gene pool of another unrelated species may alter the fitness of wild plants and consequently the dynamics of wild populations in two ways:

1) Cause local extinction of the wild population (in the case of reducing the fitness of wild plants) or;
2) Make the wild population more invasive and competitive (in the case of increasing the fitness of wild plants) (Snow et al. 2005).

The potential of transgenes to increase the invasiveness of a wild species is therefore reliant upon:

1) The presence of sexually-compatible wild relatives; and
2) The resultant impact of the introduced gene.

Prediction of the potential environmental consequences of transgene expression in wild relatives under different circumstances can be done through a systematic risk assessment. From the foregoing it is evident that the potential consequences of gene flow should be the focus of risk assessments, rather than gene flow per se. To minimise the possibility of transgene flow, a number of confinement strategies have been developed or proposed, applying physical or biological approaches. Information concerning the location and inter-fertility of compatible relatives, including those of most African crops, is generally available in the scientific literature; whilst information on invasiveness can be obtained from similar sources as well as indigenous knowledge. The most careful evaluation will be needed for those crops that are already invasive or that have invasive sexually-compatible wild relatives (Hancock 2003).

**Negative impacts on non-target organisms**

A non-target organism (NTO) is a plant or animal other than the one against which a specific GEO has been developed to have protection against. For example, a crop may be engineered for resistance to a specific insect pest (the target) and any other insects would then be considered non-target organisms. NTOs can be classified into the following categories:

- Pollinators and natural enemies of the pest, along with the wider category of beneficial species;
- Soil organisms;
- Non-target herbivores;
• Endangered and other species of conservation concern, and;
• Species which contribute to local biodiversity (Craig et al. 2008).

The potential impacts of GEOs on NTOs could be:
1) Direct toxicity through ingestion of a toxin produced by the biotech plant, or
2) Indirect via multi-trophic food chains, involving, for example, organisms not directly consuming the biotech plant but predating on prey that consume the transgenic plants (Gatehouse et al. 2011).

Possible effects of a biotech crop on NTOs should only be an issue if:
1) The crop has been engineered with a toxin that makes it insect-resistant and there are other organisms present that might be sensitive to the toxin; and
2) The toxin-sensitive organisms can encounter the toxin. NTOs are not expected to be affected by a biotech crop engineered with a trait such as tolerance to herbicide, virus or drought.

Food/Feed safety concerns

Other than the improvements which are intentionally introduced by the genetic modification, concomitant unintended differences may also occur. The latter have been defined as those differences which go beyond the primary expected effect(s) of introducing the target gene(s) (EFSA 2011). Potential adverse effects of GE food/feed which have raised concerns may include: toxicity of GE food/feed; allergenicity to GE food/feed; changes in nutritional value of GE food/feed; and emergence of resistant strains of bacteria (Key et al. 2008).

Toxicity

There is a remote possibility that GE could unintentionally introduce a toxic substance, for example a newly-expressed protein, or elevate the expression of an endogenous toxic substance(s) (Key et al. 2008). Conventional non-GE foods already contain a large number of toxic and potentially toxic products, and so the key question is whether a specific GEO could result in a new hazard. The potential toxicity of the protein expressed in a GE food is an essential component of the requisite safety assessment carried out during product development (Malarkey 2003). The safety assessment requires that the amino acid sequence of a novel protein is demonstrated to be sufficiently dissimilar to known protein toxicants, and that the new protein is rapidly digested under simulated mammalian gastric conditions. Animal bioassays may also be conducted on individual proteins to reveal any potential toxicity.

Allergenicity

Allergic reactions are hypersensitivity responses of the immune system that may occur in sensitive individuals after exposure to certain substances, usually proteins (Bush and Hefle 1996). Concern pertaining to allergenicity relates to:
1) The possibility that genes from known allergens may be inserted into crops not typically associated with allergenicity; and
2) The possibility of creating new, unknown allergens by either inserting novel genes into crops or changing the expression of endogenous proteins (Key et al. 2008).

A number of different organisations have produced guidelines and decision trees to experimentally evaluate allergenic potential (Metcalfe 2003).

Iteration of nutritional value

An unintended effect during the development of a biotech plant may be the lowering of its nutritional quality as compared to its traditional counterpart. This could occur by making nutrients unavailable or
indigestible to humans through the interference of key metabolic pathways and consequently affecting the production of nutritional components, hence compromising the nutritional quality of the product.

**Antibiotic resistance marker genes**

To facilitate the transformation process, a selectable marker gene conferring, for example, resistance to an antibiotic (e.g., kanamycin, which will kill a normal non-GE plant cell during in vitro culture), is often co-transferred with the gene of interest to allow the discrimination of GE tissue and regeneration of GE plants. There have been concerns that this approach presents a route to increasing the spread of antibiotic resistance to bacterial populations either in the soil or in the human gut after ingestion of GE food (Key et al. 2008). This could then render these antibiotics ineffective and/or make some strains of bacteria untreatable in human therapies. The increase of antibiotic resistance in the human population as a result of GE has yet to be demonstrated empirically. In addition, antibiotic resistance genes were originally isolated from bacteria and are already widespread in the bacterial population. Selection strategies that do not rely on antibiotic resistance have however been developed (Goldstein et al. 2005), and procedures to eliminate the selectable marker from the plant genome once its selection purpose has been fulfilled have also been designed (Hare and Chua 2002). These may be recommended for use in commercial GEOs.

In light of the food/feed safety issues outlined above, it is necessary that GEOs are assessed to determine the biological relevance and potential to cause harm of any intended or unintended differences. This is especially so given that differences between GE and non-GE crops (whether intended or not) may not necessarily be indicative of an adverse effect. Bodies like the Codex Alimentarius Commission, International Life Science Institute, and the Organization of Economic Cooperation Development have developed guidelines to assist the assessment of the safety of GE foods (Malarkey 2003). Generally, the safety assessment of GE plants and derived food and feed follows a comparative approach, i.e. the food and feed are compared with their non-GE counterparts (comparators). The comparators are crops that already have a so-called “history of safe use”. In the comparative safety assessment, the biotech crop and the comparators are assessed in both phenotypic as well as analytical terms, with the aim to identify differences between the two (types of) crops. Subsequent safety assessment steps then focus on any differences that have been identified, to determine whether these detected differences have any (unintended) toxicological and/or nutritional consequences. In practice, if differences have been identified, the subsequent steps of the food and feed safety assessment procedure are decided on a case-by-case basis, depending on the nature of identified difference(s) (Kok et al. 2010).

**Legal/policy issues**

A biosafety regulatory system should ensure the safe use of GEOs, with no significant risks to humans, animals, and the environment, while acknowledging that zero risk technologies are impossible. Assessing the risks of GEOs is regularly done by national regulatory systems strictly following scientific principles, with some authorities also including socio-economic and even political issues in their biosafety regulation. This last approach has been criticised as being outside of the scope of the risk assessment process, and at the same time, opening the GEO authorisation process to interference by special interest groups (Falck-Zepeda and Zambrano 2011).

National biosafety regulatory systems are the desired outcome of national biosafety laws and policies and attempts to harmonise them (or otherwise) with international agreements. Directly involved in the international regulation of GEOs are two international organisations: the Convention on Biological Diversity (CBD) and the World Trade Organization (WTO). The first specific international legal framework for biosafety regulation came from the Cartagena Protocol on Biosafety (CPB or “the Protocol”) adopted in 2000 as a supplement for the CBD. The Protocol has specifications concerning the safe use and transport of GEOs (or LMOs, as the Protocol defines them), with the exception of those GEOs used for pharmaceutical production.
and those products derived from GEOs that are not intended either for food or feed. The main provisions of the Protocol concern:

- The establishment of procedures for: advanced informed agreement (AIA) between trading Parties;
- Risk assessment;
- Handling, transport, packaging and identification of geos;
- A biosafety clearing house;
- Capacity building, especially for Parties from the developing world;
- Public awareness and participation; socio-economic considerations in decision-making; liability and redress; and
- Compliance (Gupta et al. 2008).

Under the WTO, the agreement on the application of sanitary and phytosanitary (SPS) measures, although not specifically focused on biosafety, concerns food safety as well as animal and plant health, while the technical barriers to trade (TBT) agreement concerns product standards more generally. There are also trade-related aspects of intellectual property rights (TRIPS) agreement setting minimum standards for intellectual property. These WTO agreements allow the member states to set the appropriate level of protection on a case-by-case basis, as long as trade discriminations on similar products are avoided. Similar to the Protocol, the WTO agreements can allow for socio-economic measures, but in very narrowly-defined instances (e.g. damage of production or sales, spreading of pests or diseases). The WTO agreements recommend the use of international standards developed by the Codex Alimentarius Commission, the World Organization for Animal Health (OIE) and the International Plant Protection Convention (Jaffe 2006).

Among the 163 signatories of the CPB, approximately 50 are from Africa (Table 1) yet few of these have biosafety laws and regulations in place. As such, the possibility of a conflict between domestic and international regulations is not yet a significant issue in the region. However, capacity building for biosafety regulators remains a key priority for African states (Obonyo et al. 2011). The main needs centre on: an overall lack of local funding, with too many projects depending on external funds; a general lack of awareness of biosafety issues by the public; a dearth in human capacity with experience in the specialist fields supporting GEO decision-making; the application of overly-stringent precautionary regulations in some countries; and the lack of harmonised biosafety regulations at the regional level (Mtui 2012). With respect to the latter, an attempt at harmonising African biosafety regulation occurred in 2007 with the presentation of the African Model Law on Biosafety in Biotechnology, which however takes a more stringent approach to GEO regulation than the Protocol (Gupta et al. 2008).

<table>
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<th>Table 1: African countries status on Cartagena Protocol on Biosafety*</th>
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<td><strong>Country</strong></td>
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<td>Côte d’Ivoire</td>
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<td>Democratic Republic of the Congo</td>
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<td>Djibouti</td>
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<td>Egypt</td>
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<td>Equatorial Guinea</td>
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<td>Guinea-Bissau</td>
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<td>Liberia</td>
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<td>Libya</td>
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<td>Malawi</td>
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<td>Mali</td>
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<td>Mauritania</td>
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<td>Mauritius</td>
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<td>Morocco</td>
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<td>Namibia</td>
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<td>Niger</td>
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<td>Rwanda</td>
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<td>São Tomé and Príncipe</td>
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<td>Senegal</td>
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<td>Seychelles</td>
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<td>Sierra Leone</td>
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<td>Somalia</td>
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<td>South Africa</td>
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<td>Sudan</td>
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Socio economic issues

Due to their centrality in current biosafety-related debates, socio-economic issues, although mentioned in the category above, are treated separately here. The Protocol gives parties discretion to decide whether or not to include socio-economic considerations in their decision-making processes. Currently, discussions revolve around the need to:

- Agree on a working definition;
- Develop specific methods for assessment;
- Determine the timing for such evaluations (ex ante/ex post), and;
- Establish if socio-economic considerations are to be mandatory or voluntary.

The issues included under the umbrella of socio-economics go beyond the strict interpretation of the term, and concern ethical, philosophical, and even religious issues pertaining to GE Os. However, there are a few regulatory systems that included socio-economic considerations in their specifications e.g. South Africa, and the AU Model Law (Falck-Zepeda and Zambrano 2011).

Beyond the regulatory conundrums, the socio-economic concerns brought by biotech crops in agriculture centre on the possibility of making farmers more vulnerable to market forces as a result of: changes in cost of agriculture and in agricultural practices; monopoly control of seed supply by trans-national companies; profit margins for farmers being squeezed between seed cost and declining world prices; possible replacement and thus loss of existing robust crop varieties and technologies; challenging market dynamics (Sengooba et al. 2009); and the fear of losing entire portions of foreign markets (Paarlberg 2006).

Conclusion

The genetic manipulation or modification of plants and animals to obtain improved products has been practiced for thousands of years. However, modern technology allows a greater specificity in employing genes to facilitate crop improvement. In assessing the safety of such products for humans, animal, and the environment, the public debate has evolved beyond technical scientific risk assessments, to encompass issues such as socio-economics. This chapter has outlined some of the key issues that have dominated public discourses on biosafety issues in Africa. However, given that Africa has varied agricultural systems (agro-ecological conditions, farming systems and types of crops) (Detthier and Effenberg 2011; FAO and World Bank 2001) some of the issues highlighted have pertinence in some settings and less relevance in others. It is therefore prudent to consider the issues on a case-by-case basis, rather than to generalise for all contexts.
REFERENCES


Chapter 2. Transgenic Crops in Africa: Current status and future prospects

DAVID KEETCH

INTRODUCTION

Food production and poverty reduction are among the main goals in efforts to promote socio-economic development in Africa. However, the ability to increase food production through expanding the current area under cultivation, increasing the application of agro-chemicals and extending the use of irrigation is limited. The key for Africa’s future is rather to increase the per hectare yield of crops and to achieve this Africa needs to adopt technologies that will raise the production capacity of resource-poor farmers with access to few external inputs.

The use of biotech crops has been identified as one of the technologies that can help Africa increase crop yields and/or reduce production costs and post-harvest loses. However, by 2012 only four African countries had commercialized biotech crops.

A common concern of many national authorities in Africa is that the products of modern biotechnology might affect a nation’s health and biodiversity, and thus raise health and environmental safety issues. However, transgenic crops (also known as genetically modified, genetically engineered or biotech crops) such as maize, soybean, rapeseed and cotton are being approved for commercial use in an increasing number of countries. From 1996 to 2013, there was more than a 100-fold increase in the area grown with transgenic crops worldwide, reaching a total of 175.3 million hectares in 2013. At this time there were 19 countries that grew 50 000 hectares or more of biotech crops. These countries were the USA, Brazil, Argentina, India, Canada, China, Paraguay, South Africa, Pakistan, Uruguay, Bolivia, the Philippines, Australia, Burkina Faso, Myanmar, Spain, Mexico, Columbia and Sudan in decreasing order of area of biotech crops cultivated.

Table 1 shows the 2012 global adoption rates for the four principal biotech crops (James 2012) and economic benefits for 1996-2011 and 2011 (Brookes & Barfoot, 2013).

Table 1: 2012 global adoption rates for biotech soybean, maize, cotton and canola and the economic benefits for 1996-2011 and 2011 only.

<table>
<thead>
<tr>
<th>Crop</th>
<th>Global area planted in 2012</th>
<th>Economic benefits</th>
<th>1996-2011</th>
<th>2011</th>
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<tbody>
<tr>
<td>Soybean</td>
<td>100 million ha</td>
<td>80.7 million ha</td>
<td>81</td>
<td>$32.2 billion</td>
</tr>
<tr>
<td>Maize</td>
<td>159 million ha</td>
<td>55.1 million ha</td>
<td>35</td>
<td>$30 billion</td>
</tr>
<tr>
<td>Cotton</td>
<td>30 million ha</td>
<td>24.3 million ha</td>
<td>81</td>
<td>$32.5 billion</td>
</tr>
<tr>
<td>Canola</td>
<td>31 million ha</td>
<td>9.2 million ha</td>
<td>30</td>
<td>$3.1 billion</td>
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</table>

So far, most commercialisation has focused on these four crops, and the genetic engineering has involved two traits: insect resistance (IR) and herbicide tolerance (HT). Globally, a total of 18 million farmers grew biotech crops in 2013 with 16.5 million or 90% being small resource-poor farmers from developing countries (James, 2013).
The trend for an increase in the global area planted to transgenic crops seems set to continue, given the large range of biotech crops in research and development. In all countries official national approval has to be obtained for the commercial use of a biotech crop – whether for planting and growing or for use in human or animal foods. Such approval is always based on a safety assessment by the national authority, which in turn is based on scientific information regarding the crop, its specific trait and the receiving environment. It is important, therefore, for African governments to implement effective biosafety systems to ensure that good quality safety information is publicly available and, where possible, to adopt international approaches to risk and safety assessment that ensure the efficiency of the risk assessment process. Efficient biosafety systems are also important to protect agricultural and animal biodiversity and minimise unintended effects from influencing agricultural productivity as well as human health.

In developing countries it is common to not only check safety, but to also check the potential socio-economic impact prior to giving approval for release of a biotech crop. Such socio-economic assessments are generally made under the same conditions as the biosafety assessments. The processes for biosafety assessments and biotech crop approvals are developing in tandem and are being implemented in countries around the world. There are also international regulations in place to ensure that biotech crops and their products are transported safely between countries and not released in areas where their health and environmental safety has not been reviewed.

**BIOTECH CROPS IN AFRICA**

By 2012 four African countries had commercialized biotech crops: South Africa, Burkina Faso, Egypt and Sudan (James. 2012). These four countries together planted 3.2 million hectares (ha) of biotech crops. In 2013, however, only South Africa, Burkina Faso and Sudan grew GM crops as the Egyptian Government placed a temporary planting restriction on Ajeeb YG pending further review.

**South Africa**

- In 2013, 2.85 million ha of biotech crops were planted compared to 2.9 million ha in 2012.
- The total maize area in 2013 was 2.73 million ha, a slight reduction from 2012 (2.83 million ha) due to drought.
- The area of biotech maize in 2013 was 2.36 million ha compared to 2.42 million ha in 2012
- Over 18 million ha of GE maize (white and yellow) were planted in the period 2001 to 2013 without a single adverse report or a negative effect on human health, animal health or the environment.
- The total area planted to soybeans increased from 500,000 ha in 2012 to 520,000 ha in 2013. Of this, the adoption rate of HT soybeans was 92% (478,000 ha).
- The total cotton area was 8,000 ha, with the adoption rate of GE cotton reaching 100%, 95% of which was the stacked Bt/HT traits and the remainder the HT trait which was used as a mandatory refuge.

**Maize**

- Of the total maize area of 2.73 million ha, 86.6% or 2.364 million ha were GE.
- Of this 2.364 million ha GE maize, 28.4% or 680,342 ha were the single Bt gene and 18.2% or 409,032 ha HT. The remainder, 53.4% or 1.274 million ha was planted with stacked Bt/HT traits.
- White maize was planted on 1.580 million ha, 83.7% or 1.322 million ha were GE. Maize with a single Bt gene at 412, 707 hectares, HT trait at 165, 347 ha and Bt/HT stacked traits at 744, 725 ha.
- The yellow maize planting of 1.150 million ha comprised 90.5% or 1.041 million ha of GE, with 25.7% or 267, 635 ha for the single Bt trait, 22.4% or 243, 684 ha for HT, and 50.9% or 530, 065 ha for the stacked Bt/herbicide tolerant traits.
• Three trends have emerged from the collected data:
  1. The adoption rate of biotech maize is very similar for both white and yellow maize.
  2. The adoption rate of traits (insect resistance, herbicide tolerance and stacked) is similar for white and yellow maize.
  3. The adoption rate is reaching saturation. This is because not all maize plantings require Bt insect resistance due to cost saving when pesticide can be applied through overhead irrigation, when necessary. Furthermore, some plantings are not subject to severe stalk borer infestation.
• Over 92% of maize samples tested positive for GE traits, pure GE or co-mingled.
• A niche market has developed for non-GE maize.

**Soybean**

• In 2013 soybean was planted on 520,000 ha.
• HT soybean was planted in 478,000 ha or 92% of the total area planted.

**Cotton**

• Almost 8,000 ha was planted to cotton in 2013.
• All of the cotton planted was biotech with 95% stacked (Bt/HT) and 5% RR used in ‘refugia’.
• The stacked BtRR (Bollgard® II RR) was replaced with BtRRFlex. Virtually no conventional cotton was grown.

**Approval of Biotech Crops**

The field trial approvals for 2013 included:
• Biotech maize with drought tolerance;
• Stacked insect resistance/drought tolerance;
• Biotech cotton with insect resistance/drought tolerance;
• Biotech sugarcane with altered sugar; and
• Cassava.

**Economic Benefits**

The economic gains from biotech crops for South Africa for the period 1998 to 2013 was US$1.15 billion and US$218.5 million for 2012 alone (Brookes and Barfoot, 2014). Studies have reported farm-level benefits that have translated into increased adoption rates. Yield gains exceeding 40% have been reported to in comparison with conventional cotton in addition to reduced spraying costs by 42%, reduced number of pesticide sprayings from 10 to 4 sprays per season, reduced production costs resulting in higher gross margins ranging from US$ 70–130 /2 ha of cotton (Ismael et al., 2002; Morse et al., 2005; AfricaBio, 2007).

A study by Gouse et al. (2005) on Bt maize involving 368 small-scale and resource-poor farmers compared to 33 commercial farmers was quite revealing. The commercial farmers were grouped into two, those cultivating under irrigation and those under rain-fed production systems. Higher yields were observed for farmers who cultivated under irrigation systems. This group obtained 12.1 MT/ha, an 11% increase over the previous year’s yield. These farmers also obtained cost savings in insecticide use of US$18/ha representing a 60% reduction and an increased income of US$117/ha. Farmers who grew Bt maize under rain-fed conditions obtained 3.4 MT/ha, also an 11% yield gain over the previous year’s yield. Cost savings on insecticide use for this group was US$7/ha representing a 60% reduction and the combined effect was an increase in income of US$35/ha.
The smallholder Bt maize farmers group was compared to others who grew conventional hybrid and open pollinated maize varieties in terms of yield per hectare (Gouse et al., 2005). Bt maize recorded yield gains of 31% and 134% over conventional hybrids and open-pollinated varieties, respectively. Another study that used longitudinal study over 9-year period (2000 to 2008) reported that small-scale Bt maize farmers in South Africa gained an additional US$ 267 million (Gouse et al., 2008).

Burkina Faso

Cotton is the principal cash crop in Burkina Faso generating over US$ 300 million in annual revenues representing about 60% of the country’s export earnings (ICAC, 2006). Despite this achievement, the agricultural sector in the country is beset by a number of challenges including low yields, drought, poor soil, insect pests and lack of infrastructure and inadequate credit. Studies have also reported crop losses in excess of 30% due to insect-pests of cotton (Goze et al., 2003; Vaissayre and Cauquil, 2000).

At the national level, the annual cost for insecticides for the control of cotton bollworms and related insect-pests was around US$ 60 million (Toe, 2003 cited in Karembu 2009). However, insecticides proved ineffective, with losses due to bollworm as high as 40% even with full application of insecticides (Traoré et al., 2006). As a result of this damage, Burkina Faso’s cotton production decreased to 0.68 million bales in 2007/08 from 1.3 million bales in 2006/07.

To address this situation and after 5 years of fields trials, approval was granted for the commercial cultivation of Bt cotton. In 2008, Burkina Faso planted approximately 9,000 hectares of Bt cotton for seed production and initial commercialization, becoming the 10th country globally to grow commercial Bt cotton. Vitale et al. (2008) estimated that cultivation of Bt cotton would result in yield increases of 20% and a decreased need for insecticides that would generate US$ 106 million per year.

Cotton

- In 2012, of a total of 615,795 ha were planted to cotton, 313,781 ha or 51%, were planted to Bt cotton. In 2013 a total of 474,229 ha of Bt cotton were grown.
- There were about 100,000 Bt cotton farmers in 2012, majority of whom were small-holder resource-poor farmers.
- Burkina Faso started to plant Bt cotton in 2008 with approximately 9,000 ha, this area increased to 116,000 ha in 2009, 260,000 ha in 2010, 247,000 in 2011, 313,781 in 2012 and finally 474,229 ha in 2013.
- The adoption rate of Bt cotton in Burkina Faso has increased from 2% of 475,000 cotton ha in 2008 to 51% or 313,781 ha in 2012.

Economic Benefits

In 2009, a survey conducted by Vitale et al. (2010) showed that:

- The yield advantage of Bollgard®II over conventional cotton was 18.9%.
- Yield increase plus labour and insecticide savings (2 rather than 6 sprays) resulted in a gain of US$ 65.57 per ha compared with conventional cotton; this translated to a 206% increase in cotton income.
- The main benefit of Bollgard®II derives from the increase in yield whereas the reduction of production costs associated with four less insecticide sprays is offset by the higher cost of the seed. Extrapolating from the 2011 data the national benefit for biotech cotton in 2012 was about $30 million.
• In 2011 the average yield increase for Bt cotton over conventional cotton was 19.7% and insecticidal sprays were reduced from 6 to 2. Profit increase by 5% to US$95.25/ha. Extrapolating the data from 2011, the national benefit from Bt cotton in 2012 was about US$30 million.

Egypt

• In 2012, Egypt planted 1,000 ha of Bt yellow maize (IR MON 810) known in Egypt as Ajeeb YG® compared to 2,800 ha in 2011. In 2013, Egypt officially did not grow any GM maize due to a temporary restriction imposed by the Egyptian Government.
• Egypt was the first North African state to adopt biotech crops when it planted Bt maize in 2008 on 700 ha.

Maize

• Egypt grew approximately 660,000 hectares of conventional maize in 2010, and imports annually 4.5 million tons of yellow maize valued at US$1.3 billion.
• Of the 660,000 ha of maize, 160,000 ha (25%) are yellow maize and 500,000 ha are white maize.
• The biotech maize hybrid is resistant to three maize insect pest borers (Massoud 2005).
• Field trials that were conducted in Egypt from 2002 to 2007 indicated that the yield of Bt yellow maize could be increased up to 30% over conventional yellow maize hybrids.

Economic Benefits

In 2009, for IR Bt maize there was an increase in yield of US$267 per ha, plus an insecticide saving equivalent to US$89 per ha. This gave a total gain of US$356 per ha, minus the additional cost of seed per ha at US$75 for a net benefit per ha of US$281. Extrapolating from these data, the economic benefits from planting 1,000 ha of Bt maize in 2012 is about US$281,000.

Sudan

In 2012, Sudan became the fourth African country to commercialise a biotech crop – Bt cotton.

Cotton

• A total of 20,000 ha of Bt cotton were planted in the Sudan by about 10,000 smallholder farmers.
• The GM cotton variety planted is named “Seeni 1” and was developed in China.
• The availability of GM cotton seed was a limiting factor in 2012, but in 2013 the area tripled from 20,000 ha to 62,000 ha and is expected to expand even further.

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## STATUS OF BIOTECH CROPS IN AFRICA

The current status of biotech crops in Africa is shown in Table 2 (James, 2012).

### Table 2: The current status of biotech crops in Africa in 2012.

<table>
<thead>
<tr>
<th>Country</th>
<th>Crop</th>
<th>Trait</th>
<th>Stage</th>
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</thead>
<tbody>
<tr>
<td>Burkina Faso</td>
<td>Cotton</td>
<td>Insect resistance</td>
<td>Commercialised</td>
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<td></td>
<td>Cowpea</td>
<td>Insect resistance</td>
<td>Field trials</td>
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<td>Potato</td>
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<td>Viral resistance</td>
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<td>Rice</td>
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<td></td>
<td>Strawberry</td>
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<td>Sugarcane</td>
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<td>Wheat</td>
<td>Drought tolerance</td>
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<td></td>
<td>Salt tolerance</td>
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<td>Cowpea</td>
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<td>Drought tolerance</td>
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<td>Alternative sugar</td>
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**FUTURE PROSPECTS**

The largest group of potential beneficiary countries that have yet to adopt and benefit from biotech cotton are in sub-Saharan Africa where at least 15 countries, each growing more than 100,000 ha of cotton, for a total of almost 4 million ha of cotton could benefit significantly, plus Egypt in North Africa.

Future prospects for Africa look encouraging with Cameroon, Egypt, Ghana, Kenya, Nigeria, Malawi and Uganda presently conducting field trials with biotech crops. Trials focusing on Africa’s priority staple crops, such as maize, cassava, cowpea, banana, sorghum and sweet potato, have made good progress while trials are underway in Kenya, South Africa and Uganda on drought tolerant maize through the WEMA (Water Efficient Maize for Africa) project.

Biotech crops have the potential to make a substantial contribution to achieving the 2015 Millennium Development Goals (MDG) of cutting poverty in half, by optimizing crop productivity. This goal can be expedited by public-private sector partnerships, such as the drought tolerant maize for Africa project supported by the Bill and Melinda Gates Foundation.

Globally, there are numerous new products at different stages of research and development. They include:

- Insect resistance – high priority is now being given to the control of sucking insect pests as they have become the top priority now that the previously top priority bollworm pests are effectively controlled by current Bt crops.
- Disease resistance to the pathogens *Fusarium*, *Rhizoctonia*, *Pythium* and cotton leaf curl virus.
- Crops that are more resistant to abiotic stress such as drought tolerant maize and cotton that is more tolerant to salinity, high and low temperatures and water logging.
- Crops with greater efficiency to use soil nutrients.
- Cotton with improved fibre, better oil quality and gossypol-free seed.

Climate change is a major threat to sustainable growth and development in Africa, and the achievement of the MDG. According to the Intergovernmental Panel on Climate Change (IPCC 2012), the impact of climate change is expected to be greater in low latitude sub-tropical and tropical developing nations, where farmers have more limited ability to adapt. Africa is particularly vulnerable to the effects of climate change including reduced agricultural production, worsening food security, the increased incidence of flooding, drought and disease and an increased risk of conflict over scarce land and water resources (OECD 2007).

The importance of climate change and concerns about the environment have implications for the future of biotech crops, which contribute to a reduction of greenhouse gases and help mitigate climate change by:

- Reducing carbon dioxide ($CO_2$) emissions through reduced use of fossil-based fuels, associated with fewer insecticide and herbicide sprays;
- Promoting the use of conservation tillage (need for less or no ploughing facilitated by herbicide tolerant biotech crops) for GE food, feed and fibre crops.
With climate change, droughts, floods, and temperature changes predicted to become more prevalent and more severe in Africa, there will be a need to develop crop varieties and hybrids that are well adapted to more rapid changes in climate. Several biotech tools, including tissue culture, diagnostics, genomics, molecular marker-assisted selection (MAS) and biotech crops can be used collectively to speed up the breeding process.

One factor that is hindering a faster adoption of biotech crops is the current low level of awareness of biotechnology and biosafety in Africa. At present only 12 African countries (Burkina Faso, Ghana, Kenya, Malawi, Mali, Mozambique, Nigeria, South Africa, Tanzania, Togo, Uganda and Zimbabwe) have established regulatory systems, 5 countries are at an interim stage and 32 countries have little or no interest in developing regulatory systems (ABNE, 2012). To counter this situation, vigorous awareness activities are needed. Capacity building for GE and non-GE products must be enhanced. There is also a need for the regional harmonization of biosafety legislation and regulations. It is crucial that Africa accepts biotechnology and develops products that will be appropriate to its needs. Above all, Africa must develop the capacity to be its own spokesperson on the safety and the risks of biotech crops.

CONCLUSION
The capacity of biotech crops to contribute to the sustainability of food production in Africa is significant and it can help the continent overcome the formidable challenges associated with climate change and global warming. Biotech crops can also increase productivity and income, and hence serve as an engine for rural economic growth that can contribute to the alleviation of poverty for Africa’s small scale and resource-poor farmers.

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Chapter 3. Environmental biosafety issues associated with GE crops in Africa

MOUSSA SAVADOGO

INTRODUCTION

Africa is endowed with rich and varied biological resources (UNEP 2010). At the same time the continent is faced with environmental challenges that negatively affect its economic progress. Among the most serious environmental concerns are deforestation, desertification, degradation and fragmentation, air and water pollution and loss of soil fertility (http://wikis.lib.ncsu.edu/). These cause a dramatic decline in local biodiversity and such concerns are aggravated by poverty and the need for survival that inevitably lead to the over-exploitation of local natural resources. It is estimated that if such a trend is maintained the environmental problems could double or triple by 2025 when the total population of the continent reaches over one billion (http://www.articlesbase.com/). It is hoped, however, that with the advent of new agricultural technologies including genetic engineering, farmers will have the opportunity to use more efficient practices that will significantly reduce the pressure on the environment through increased agricultural productivity and a reduction of chemical pesticides use. Indeed on the 17th anniversary of the first commercial cultivation of a genetically engineered crop, it was estimated that this technology had contributed globally to a better environment by saving considerable amounts of pesticide active ingredient, reducing CO₂ emissions and conserving biodiversity on millions of hectares of land (James, 2013).

Paradoxically, in Africa the adoption of the same technology is being slowed down if not rejected for the same reason – the need to protect the environment that the new agricultural technology will help save. However, African countries such as Burkina Faso, which have taken the lead in adopting Bt cotton, have seen their environmental conditions improve through a significant reduction in the use of chemical pesticides (Vitale et al. 2011).

This chapter briefly reviews the environmental issues, especially those associated with the loss of biodiversity in Africa, the perceptions on the impact of GE crops on the environment, the GE crops of interest to Africa that are either commercially cultivated or under development and the critical information necessary to perform an assessment of their potential for gene flow and weediness.

CRITICAL ENVIRONMENTAL ISSUES IN AFRICA

The environment of sub-Saharan Africa is affected by various factors including deforestation, desertification, degradation and fragmentation, all of which are responsible for a dramatic loss of biodiversity. Deforestation refers to the clearing and destruction of forests in order to create land for agriculture, provide wood for domestic needs of energy and/or create space for building settlements (http://wikis.lib.ncsu.edu/index.php/). It is estimated that about one million km² of forest is destroyed every 5 to 10 years and as a result the forest land has declined from 16 million km² a century ago to only half today (Braun and Ammann, 2003). Between 1981 and 1990 around 25% of African forested land was converted into agricultural land (Mabogunje, 1995). However in a number of countries, including Nigeria and Niger, governments have been making efforts to mitigate such extensive loss of forest by planting trees and trying to preserve existing ecosystems (Niamey, 2005).

Desertification refers to the expansion of desert conditions as a result of many factors including drought and the overuse of local ecosystems. Degradation refers to the deterioration in the density or structure of vegetation cover or species composition (Mabogunje, 1995). Selective logging without replanting, removal of
plants and trees that are of importance in the life cycle of other species and soil erosion are the main causes of degradation.

Fragmentation is caused by various forms of human intrusion in forest areas, such as road construction. It causes increased vulnerability of natural ecosystems through changes in micro-climates and subsequent loss of native species and invasion by alien species (Mabogunje, 1995).

Deforestation, degradation fragmentation and desertification all cause a sever degradation in natural habitat which is the primary threat to biodiversity, not only in Africa but also globally. In addition to habitat loss, pollution and invasive species are also considered major threats to wild biodiversity (Millennium Ecosystem Assessment 2005).

To protect the environment, the main question for most African governments is how to reverse the loss of biodiversity caused by the destruction of the natural habitat. In answer to this question, Braun and Ammann (2003) suggested that the single most promising way to avoid habitat destruction was to increase farm yields in a process that has been called the “Second Green Revolution.”

PERCEIVED CONCERNS ASSOCIATED WITH GE CROPS IN AFRICA

The global community is concerned that modern agricultural biotechnologies such as genetic engineering, like other new technologies, may hold risks for the environment and/or human and animal health. For this reason, crops and products developed through genetic engineering are regulated to the extent of possibly making it the most regulated of all agricultural technologies (Braun and Ammann 2003). Concerns that are generally raised imply that the cultivation of GE crop varieties could negatively impact the environment through unintentional transfer of novel genes and traits to non-GE plants. This could result in the development of herbicide resistant weeds and/or more invasive weed species as well as the development of resistant pests. In addition, more specific concerns have been raised in Africa. It is thought that GE crops might have a negative impact on African traditional crops and land races and on the local biodiversity. This would result in an increased dependency of smallholder farmers on multinational seed companies. Africans fear that such a situation would give multinational companies full control on the continent’s genetic resources.

Many other misperceptions and myths are being spread in the continent with regard to GE technology. Some feel that the fact that Cartagena Protocol on Biosafety deals with potential risks means that GE products are risky. Others argue that if GE crops were safe, Europeans would not have adopted their current restrictive attitude. One parliamentarian stated that “we fear this technology and will continue to fear it because it is new and we don’t know the long term effects”. Another argument insists that Africans’ lack the capacity to fully assess and properly manage any risks associated with GE crops. They compare African states with those in developed countries which possess necessary resources to address any issues, should they occur. For example if a particular GE product is found unsafe after it is released to public in developed countries, it is easily recalled; whereas in Africa this may not be possible. In some cases there is expression of lack of trust (Obidimma and Rotman 2012) and advocate the development of “home-made” GE products with the feeling, “Why should it come from outside the continent?” It is also claimed that biodiversity in Africa is very complex that it makes the risk assessment process much more difficult with a higher level of uncertainty (African Union and GIZ, 2011).

KEY PRINCIPLES OF ENVIRONMENTAL RISK ASSESSMENT OF GE CROPS

Extensive scientific research has led to systematic protocols to measure the potential risks posed by GE crops to the environment. Assessment of these risks is based on the logical definition of risk being a function of hazard and exposure. This follows the same fundamental principles as other risk assessment schemes.
Unfortunately, hazard is often perceived to be the only function of risk. However, unless exposure is taken into consideration, hazard is a poor assessment of risk. For example, electricity or fire can be major hazards only if exposure is not carefully controlled.

The typical logical framework designed for risk assessment entails the following key steps:

- Identification of hazards;
- Evaluation of the magnitude and duration of identified hazards;
- Estimation of the likelihood of occurrence of identified hazards; and
- Account for the nature and importance of the scientific uncertainty in each phase of the process.

Thus for each concern raised about a genetically engineered organism (GEO), scientists identify the hazard at the root of the concern; the likelihood that this hazard will materialize; the consequences should it materialize; and whether risk management measures can be applied to reduce any identified risk. When the level of risk is known for all the identified hazards the decision makers determine whether the risk is acceptable for local communities. Biosafety reviewers around the world rigorously follow these logical steps to arrive at credible estimates for risk and to define management measures as proper management of risk leads to safety. African scientists are a part of this network and African decision makers need to trust their national scientists who are working in partnership to achieve international safety standards.

There is consensus that three fundamental questions must be addressed in conducting risk assessments, regardless of where the biotech crop will be grown and the local levels of biodiversity. These are:

1) Whether GE technology will increase plant invasiveness or weediness and cause the transgenes to exhibit a competitive advantage (be more fit) over the natural forms and disturb local ecosystems;
2) Whether GE crops or derived plants will have a negative impact on non-target species present in the environment; and
3) Whether GE crops will negatively impact the non-living components of the environment, damaging or polluting the air, soil or water.

In addressing these concerns there is also consensus that a science-based environmental safety evaluation must focus on:

- The nature of the crop plant;
- The characteristics of the introduced trait;
- The characteristics of the environment where the GE crop will be released; and
- The interactions among these components (Cartagena Protocol on Biosafety 2000; Lu et al., 2012).

Gene movement from GE crops to non-GE relatives, wild or cultivated, is an important consideration, taking into account that the level of gene flow is influenced by the proximity of sexually compatible relatives and the pollination of the biotech crop, especially the degree of outcrossing and the level of viable seed and progeny (Hancock et al., 1996). This information is known for most of the major crop species grown in Africa.

In addition to concerns expressed about the natural environment, biotech crop cultivation has also raised issues about coexistence between GE and non-GE crops and about pest-management. As with pollen flow, guidelines have been developed to address these issues.

**CRITICAL INFORMATION FOR THE ESTIMATE OF GENE FLOW AND WEEDINESS POTENTIAL OF GE CROPS IN AFRICA**

It is important to note that the GE crops being cultivated or under development in Africa are not new to African scientists or farmers. They are African crops in which specific traits are incorporated to improve their tolerance to pests or abiotic stresses, or to enhance their nutrient content. Only three or four of the
thousands of genes in a GE crop are modified. Wide knowledge and familiarity with these local crops makes it possible to conduct science-based risk assessments focusing on the characteristics of the crop species, the introduced traits and the local environment in which the GE crop will be cultivated.

Each crop species may have compatible relatives in the growing area with which hybridization can occur. Developers, including African scientists, provide information on the potential for outcrossing from a GE crop via pollen flow to other plants of the same species or to wild relatives in the environment. Cultivation of GE crops that do not have wild relatives in Africa does not pose an environmental threat associated with gene flow to wild species. Further risk analysis of the impact of pollen flow is only needed to understand gene flow to the same crop species in the release area. For example, there are no wild relatives of maize in Africa, therefore, pollen flow from GE maize to wild relatives is not an issue. However, Africa is the centre of origin for sorghum, so the impact of pollen flow from GE crops to wild species needs to be addressed wherever wild species are present in growing areas and are sexually compatible.

The mode of pollination, the level of self-fertilization and the viability of seed from outcrossing are important considerations. Sorghum for instance, a predominantly self-pollinated species, outcrosses readily with its sexually compatible wild and weedy relatives when grown in close proximity, have overlapping flowering times and share a common pollination mechanism. This implies that genes from GE sorghum would most likely escape into the native populations. The overarching question here, therefore, is what would be the consequences of such a transgenic trait in the wild and not whether gene flow actually occurs. On the contrary, other self-pollinated crops such as cotton and cowpea have a very low probability of hybridizing with neighbouring relatives, so isolation distances of less than 100 m should effectively prevent pollen-mediated gene flow from GE cowpea. Other species, such as banana and many sweet potato varieties, are predominantly sterile, making hybridization with relatives highly unlikely. Levels of self-fertilization and the viability of hybrid seed are particularly important issues to consider when developing strategies for managing coexistence of GE and non-GE crops.

In performing safety evaluations, newly introduced traits are assessed for their potential to increase plant fitness or produce substances that could be toxic to non-target organisms. Pest resistance traits such as those conferred by Bt genes can only have an environmental impact if the populations of the wild relatives are controlled by the same pests in the natural environment. Nevertheless, it has been recently proved that the widespread adoption of Bt cotton and the subsequent reduction of the usage of broad spectrum insecticides have significantly promoted the biological control services in ecosystems in Northern China (Lu et al., 2012).

Herbicide tolerance traits generally do not increase the fitness of progeny from cross pollination with wild species since herbicides are not applied in unmanaged environments. Abiotic stress tolerance traits such as drought tolerance or salt tolerance may have an environmental impact since they allow crops to grow where they might otherwise have been restricted by the abiotic stress. Typically, nutritionally enhanced traits (e.g. iron, zinc or vitamin A) are not known to produce toxic substances and would, therefore, not be expected to have negative effects on the environment.

EXAMPLES OF GE CROPS IN AFRICA AND THEIR BIOLOGY ELEMENTS NECESSARY FOR THE ESTIMATE OF GENE FLOW AND WEEDINESS POTENTIAL

Following are some genetically engineered crops that are of particular interest to Africans and are either commercially cultivated or under development. The key biological elements necessary for biosafety regulators to assess their potential for gene flow and weediness are also summarized.
**Banana (Musa spp.)**

Bananas are not only a staple food for millions of Africans but also they are a source of income, especially in East and Central Africa (Viljoen, 2010). Currently genetic engineering is being used to improve the level of iron and vitamin A in bananas (Wall 2006) and also to improve yield through enhanced resistance to a number of pests including bacterial wilt, nematodes and weevils (FARA website, http://www.fara-africa.org/biotech-management-africa/; Kasozi, 2010). Transgenic banana trials are taking place in Uganda and Kenya.

Banana has its centre of origin in Southeast Asia, but its primary centre of genetic diversity is in the lowlands of West Africa and South East Asia while the secondary centre of genetic diversity is in East Africa. No close wild relatives and no free-living populations of bananas are found in Africa. Though banana pollen is dispersed by insects, cultivated bananas are sterile triploids and therefore do not outcross. Banana is not propagated by seeds or rhizomes and therefore cannot pose a weed problem. In conclusion, based on almost zero potential for gene flow combined with very low potential for weediness and invasiveness the overall assessment leads to the conclusion that GE bananas have negligible potential impact on the environment as far as gene flow and weediness are concerned. However, its potential impact on non-targets organisms needs to be assessed on a case-by-case basis, taking into account the products of the new gene inserted and the trait conferred.

**Cassava (Manihot esculenta)**

Cassava is a drought and heat tolerant crop that contributes to the food security of millions of people in Sub-Saharan Africa (Hillocks, 2002). Nevertheless, cassava farmers are faced with two major challenges. First, cassava production is hampered by several pests such as the cassava mealybug (Phenacoccus manihoti) and cassava green mite (Mononychellus tanajoa) which can cause up to 80% crop loss. Secondly, cassava roots have a relatively low nutritional value, especially with respect to vitamins and other micronutrients (Sayre et al., 2011) and this is a problem for the millions of people who rely on cassava as a staple food. Efforts are underway using genetic engineering to develop cassava varieties resistant to the Cassava Mosaic Virus (CMD) and Cassava Brown Streak Disease (CBSD) (Taylor et al., 2012) as well as cassava with enhanced vitamin A. Field tests are currently taking place in Uganda, Kenya and Nigeria (Taylor et al., 2012, The Donald Danforth Plant Science Center, www.danforthcenter.org/science/programs/international_programs/bcp/).

In evaluating the potential of GE cassava for gene flow and weediness it is worth noting that cassava originates from South America but has close wild relatives in Africa. Cassava is cross pollinated by insects but
its pollen flow into native relatives is considered highly unlikely because of incompatibility issues and its mode of propagation is by stems cuttings.

**Cotton (Gossypium hirsutum)**

Cotton is the major source of cash income and foreign exchange in Sub-Saharan Africa (Hillocks, 2009), but insect pests, especially cotton bollworms and also weeds constitute the major constraints to cotton production (Hillocks, 1995; Javaid, 1995). Fortunately genetic engineering has allowed the development of not only varieties such as Bt cotton, that are effective against the cotton bollworm, but also a number of varieties tolerant to herbicide. In Africa, Burkina Faso and South Africa have commercialized Bt cotton for some years already. Other countries including Kenya, Uganda, Cameroon and Malawi are currently conducting field testing of Bt cotton varieties.

Cotton has its centre of origin in Central America but several centres of genetic diversity are located in West-Central and Southern Mexico, north-east Africa and Arabia, and Australia (Seelanan, T., A. Schnabel and J.F. Wendel, 1997). Cotton has close wild relatives that are present in Africa, especially in Eastern Somalia and South West Africa. These are *Gossypium herbaceum ssp africanum*, *G. trifurcatum*, *G. arboretum*, *G. anomalum* and *G. triphyllum*. The crop (*G. hirsutum*) and its wild relatives show different numbers of chromosomes as well as other genetic incompatibility barriers. This causes an extremely low possibility of inter-fertility between them. Furthermore, although insects, especially bees, ensure the dispersion of cotton pollen, outcrossing is extremely low due to the fact that cotton is predominantly self-pollinated and the pollen remains viable for less than 30 hours. Cotton is known not to persist in the natural environment and is not naturally invasive, therefore does not pose a weed problem. Moreover cotton is not known to produce substances that are toxic to humans or animals or to be a source of human allergens, therefore GE cotton presents an extremely low potential for gene flow, weediness and invasiveness.

**Cowpea (Vigna unguiculata)**

Cowpeas are drought tolerant crops that provide food and legumes in Sub-Saharan Africa (Langyintuo et al., 2004). While cowpeas are a good source of proteins, vitamins and mineral nutrients (Timko and Singh, 2008), production is limited by a number of insect pests including the pod borer, *Maruca vitrata* (Dugje et al., 2009). GE cowpea lines have been developed to express resistance to the pod borer and are currently undergoing field trial evaluation in Nigeria and Burkina Faso (AATF, 2012). The GE cowpea field trials in Ghana (CSIRO Plant Industry 2010) received regulatory approval in 2013 and are now ready to be commercialised.
Cowpea is native to Central West and Southern Africa and was first domesticated in West Africa. For cultivated cowpea the centre of genetic diversity is West Africa while the centre of genetic diversity for the wild species is South-eastern Africa. The closest wild species of cowpea are *Vigna unguiculata var. rhomboidea*, *V. unguiculata var. protracta*, *V. unguiculata var. congolesis*, *V. unguiculata var. huillensis*, *V. unguiculata var. ciliolate*, *V. unguiculata var. grandiflora* and *V. unguiculata var. dekindtiana*. These are found throughout Africa. Cowpeas are highly inter-fertile but do not easily cross because of the high degree of self-pollination which is over 90%. Insects, especially bees and wasps, are the main pollinators of cowpeas. Cowpeas grow fast and can easily shade other competitors within a very short time, but they rarely become dominant in a plant community. Overall, though cultivated cowpea has inter-fertile wild relatives in Africa its potential for gene flow is considered to be low because of its high degree of self-fertilization. Cowpea’s potential for weediness/invasiveness is estimated to be moderate because it does not aggressively spread in spite of its fast growth.

**Maize (Zea mays L.)**

Maize is the most widely grown staple crop in Africa providing food for more than 300 million people (Smale et al., 2011). Maize production in Sub Saharan Africa, however, faces various constraints amongst which drought is considered one of the most important. Insect pests and diseases are other limiting factors (FARA 2009). Using genetic engineering techniques efforts are currently underway to improve maize productivity through the development of drought tolerant varieties and also varieties with resistance to devastating insect pests and virus diseases such as stem borers and maize streak virus (MSV) (AATF, www.aatf-africa.org/projects/aatf_projects/wema, Mugo et al., 2002; Shepherd et al., 2007; Thomson et al., 2010). A number of GE varieties including MON 87460 have been developed for drought tolerance and are under confined field testing in South Africa, Kenya and Uganda (Thomson et al., 2010).

Maize originates from Mexico, and does not have any compatible wild relatives in Africa. Maize shows a high degree of outcrossing with pollination ensured by wind and insects. Maize does not spread outside agricultural areas and is not invasive. It therefore does not pose a weed problem.

**Rice (Oryza sativa)**

Rice is one of the most rapidly growing food crops in Sub-Saharan Africa, especially in urban areas (WARDA/ FAO/SAA 2008). Rice production is constrained by a number of factors including drought, salinity and limited fertilizer use (AATF, www.aatf-africa.org). Efforts are currently underway using genetic engineering techniques to develop rice varieties that will use the available nitrogen and water more efficiently as well as exhibit tolerance to saline soils (AATF 2012).

Rice is native to the inland delta of the Upper Niger River and has its center of genetic diversity in the West coast of Africa. Rice has a close wild relative in Africa, *Oryza barthii*, which is found in the West coast of
Africa. Rice pollen is dispersed by insects and wind, but the plant is predominantly self-fertilized, with less than 1% of plants being cross-pollinated. Cultivated rice and its wild relatives are compatible and readily produce viable seeds in artificial hybridization. However, under natural conditions, the levels of introgression are very low, and less than 0.01%. Cultivated rice is not naturally invasive, but the wild relative poses a weed problem in agricultural fields. Overall, the potential for gene flow associated with rice is considered very low, due to the high level of self-fertility and the low rate of introgression. However, the potential for invasiveness and weediness is high.

**Sorghum (Sorghum bicolor)**

Sorghum is a staple crop in the semi-arid areas of Africa (Ashok Kumar *et al.*, 2010); but, unfortunately sorghum has a low iron and zinc content, low pro-vitamin A and poor protein digestibility (Ng’uni *et al.*, 2011). However, vitamin A deficiency is one of the most prevalent problems in Sub-Saharan and is responsible for a high mortality rate. To improve the nutritional status of sorghum, scientists are using genetic engineering to develop biofortified sorghum with improved iron, zinc and pro-vitamin A content, and with higher protein quality and digestibility. The work is being conducted under the African Biofortified Sorghum (ABS) Project (ABS, [www.biosorghum.org](http://www.biosorghum.org)). Such improved sorghum varieties have been undergoing confined field trial evaluation in Nigeria and Kenya and are planned for South Africa, Burkina Faso and Egypt (Wambugu *et al.*, 2012). Regulatory approval was granted by the National Biosafety Agency in Burkina Faso but the trial has still to commence.

The center of origin and diversity for sorghum is in the Ethiopia-Sudan region of Africa (Kimber, 2000). Gene flow occurs readily between cultivated sorghum and its wild/weedy relatives. Genes from cultivated sorghum, even considered as neutral i.e. without selective advantage or disadvantage, may introgress and persist in wild sorghum populations. Therefore, transgenes from GE cultivated sorghum are likely to be transferred to and persist in the wild populations, as with other genes from conventional cultivated sorghum (Karen *et al.*, 2010). To complete the environmental risk assessment, it is necessary to determine the likelihood or frequency of gene flow to wild relatives, and to assess the consequences when the transgenes enter the wild populations via gene flow (Karen *et al.*, 2010).

**Sweet potato (Ipomoea batatas)**

Sweet potato is a very important food crop that produces large amounts of food per unit area in Sub-Saharan Africa (Mwanga *et al.*, 2011). It is a very good source of carbohydrates, vitamins A, B and C, iron, potassium, zinc, protein and fiber (Low *et al.*, 2009). However, sweet potato production is limited by diseases and pests such as the sweet potato virus disease, *Alternaria* blight, and insect pests like the weevil (*Cylas spp.*) (Mwanga *et al.*, 2011). GE sweet potatoes expressing *Bt cry* proteins for the control of the most important weevil species in East Africa (SASHA, 2012) are being developed. Transgenic sweet potato lines have undergone greenhouse evaluation and await confined field trial evaluation (SASHA, 2012).
Sweet potato is native to Central / South America (Srisuwan, Sihachakr and Siljak-Yakovlev, 2006); but has its center of genetic diversity in East Africa (Ethiopia) (Gichuki, Berenyi, Zhang, Hermann, Schmidt, Glossl and Burg, 2003). Sweet potato does not have close relatives in Africa. Cross-pollination is the main method of reproduction with insects as primary pollen dispersers over very short distances. Sweet potato is not known to be naturally invasive, but it does produce substances (furanoterpenoid) that are toxic to human and animals (Boyd and Wilson 1972). Overall, sweet potato has no potential for gene flow, due to the absence of wild relatives in Africa, as well as for weediness/invasiveness.

PEST MANAGEMENT ISSUES ASSOCIATED WITH GM CROPS IN AFRICA

The development of resistance in target pest populations is a concern for all methods of crop pest management. Resistance to chemical pesticides is well known. The cotton bollworm, Helicoverpa armigera, for instance, is the insect species with the highest number of resistance cases reported around the world. Resistance of this insect to chemicals negatively affected the cotton sector in Burkina Faso in the 1990s and prompted the Government of Burkina Faso to explore the use of Bt cotton. Cotton farmers in Mali, Chad, Cameroon and Togo are still facing these resistance issues with chemical pesticides.

Even with GE pest protected crops, resistance to Bt toxins has been reported in a number of countries, including South Africa. This indicates that even with products of agricultural biotechnology resistance can arise; but this situation has been successfully managed using different means of delaying the development of pest resistance including high dose, refugia and gene stacking strategies as well as the adoption of integrated pest management.

COEXISTENCE ISSUES ASSOCIATED WITH GE CROPS IN AFRICA

The issue of coexistence of GE crops with conventional and organic agricultural crop production is not a safety issue. It is market driven and is directly related to choice of consumers and agricultural producers.

The accidental mixing of GE materials with non-GE products, also referred as “adventitious presence”, occurs through physical mixing of seed and pollen. Many countries, including the European Union, have defined acceptable levels of adventitious presence and have determined segregation measures that enable the cultivation of GE crops while protecting farmers from adverse economic consequences of accidental mixing of GE materials.

In Africa, coexistence with GE crops could become an issue for high value cash crops exported to countries where the threshold for adventitious presence has been defined and standards need to be met. However, segregation measures, including isolation distance, can be efficiently applied to meet different thresholds. For each crop species, isolation distances have been defined based on their reproductive biology.

CONCLUSION

The adoption and cultivation of GE crops is growing worldwide thanks to the development of efficient regulatory systems that are able to evaluate the inherent risks and set up appropriate measures to manage those risks. Concerns raised with respect to the safety of the environment are the same all over the world. These concerns centre on whether GE crops and any derived progeny will become more invasive and out-compete other plant species in the environment or whether they will produce substances that could be toxic to non-target organisms. Biosafety guidelines and methodologies have been developed, based on rigorous scientific approaches that carefully assess the identified risks. Knowledge of crop biology and the geographical distribution of wild relatives are key to properly assessing the potential for gene flow and weediness, as part of the environmental risk assessment process. African scientists and farmers have a strong knowledge base having worked with these crops for many decades.
It has been argued that because of the large biological diversity in Africa, assessing potential risks of GEOs would be more complex and the scientific uncertainty will be higher. As a consequence, there is a notion that more precaution should be taken in African countries to deal with any potential risk associated with GEOs. This overly precautionary attitude has denied most African countries access to safe and potentially beneficial modern biotechnology. The risk assessment strategies being used outside of Africa are applicable to this continent and risk assessment can be used effectively for countries with any level of biodiversity. The right question is whether it makes sense for Africa to be denied access to the benefits of modern technology simply because of safety concerns that can be addressed. To what extent other risks would be increased if the benefits offered by advanced agricultural biotechnologies are delayed? Finally, what is the value of biodiversity if it is not protected by sustainable agriculture and used sustainably to support the economic and social growth of local communities?

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http://www.danforthcenter.org/science/programs/international_programs/virca/


Chapter 4. Food safety issues associated with foods derived from Genetically Engineered crops in Africa

INTRODUCTION

The world’s population is estimated to reach the 9 billion by 2050 and Africa is projected to contribute the biggest proportion of this increase. As water scarcity, soil salinity, and other abiotic and biotic stresses continue to increase, compounded by the effects of climate change, the need to produce and maintain high yields of important food crops through techniques such as genetic engineering (GE) will become even more imperative to Africa and the world in general. Genetically engineered food is becoming an increasing part of the global food supply (James, 2012). As Africa cautiously embraces the technology (Okeno et al., 2013), progress is hampered by the perceived safety risks associated with this new gene technology (Ezezika et al., 2012) and corresponding delays in passing regulatory laws and developing regulatory systems. At a global level, there is a general consensus of the food safety issues associated with GE foods and how they are assessed (Codex, 2003). This chapter will discuss the safety issues associated with foods derived from GE crops and point out key considerations in assessing foods derived from these crops to assure safety. A detailed discussion of safety assessments beyond the scope of this chapter but can be found in a number of publications (Snell et al., 2012; EFSA, 2011; ILSI, 2004; Kuiper et al., 2001).

GENETICALLY ENGINEERED FOOD CROPS IN AFRICA

Foods derived from GE organisms are among a number of biotechnological developments intended to improve shelf life, nutritional content, flavour, colour, and texture, as well as agronomic and processing characteristics (NRC, 2004). In Africa, only South Africa, Egypt, Burkina Faso and Sudan have commercialized biotech crops (James, 2012). However, increasing biotechnology research and development activities on important African food crops currently at the experimental phase on the continent attest to a slow but gradual awakening to its possibilities in addressing long standing food and nutrition security challenges in Africa. Table 1 summarizes some of the GE food crops, staple to Africa, that are at various experimental stages – laboratory, greenhouse or confined field trials – in different countries and the different genetic traits that are being introduced (ISAAA, 2012).

Table 1. On-going Biotech Research on Important Food Crops in Africa (ISAAA 2012)

<table>
<thead>
<tr>
<th>Trait</th>
<th>GE Food Crops</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutritional enhancement</td>
<td>Sorghum</td>
<td>Burkina Faso, Egypt, Kenya</td>
</tr>
<tr>
<td></td>
<td>Cassava</td>
<td>Egypt, Nigeria</td>
</tr>
<tr>
<td></td>
<td>Banana</td>
<td>Uganda</td>
</tr>
<tr>
<td>Herbicide tolerance</td>
<td>Maize</td>
<td>South Africa</td>
</tr>
<tr>
<td>Drought tolerance</td>
<td>Maize</td>
<td>Kenya, South Africa, Uganda</td>
</tr>
<tr>
<td>Viral resistance</td>
<td>Cassava</td>
<td>Kenya, Uganda</td>
</tr>
<tr>
<td></td>
<td>Sweet potato</td>
<td>Kenya</td>
</tr>
<tr>
<td></td>
<td>Tomato</td>
<td>Egypt</td>
</tr>
<tr>
<td>Bacterial resistance</td>
<td>Banana</td>
<td>Uganda</td>
</tr>
<tr>
<td>Insect resistance</td>
<td>Maize</td>
<td>Egypt, South Africa</td>
</tr>
<tr>
<td></td>
<td>Cowpea</td>
<td>Burkina Faso, Nigeria</td>
</tr>
<tr>
<td></td>
<td>Sweet potato</td>
<td>Kenya, Uganda</td>
</tr>
<tr>
<td></td>
<td>Pigeon pea</td>
<td>Kenya</td>
</tr>
<tr>
<td></td>
<td>Potato</td>
<td>South Africa</td>
</tr>
</tbody>
</table>
SAFETY ISSUES ASSOCIATED WITH GE FOODS

As far as the safety of foods derived from GE organisms are concerned, the major question to be addressed is “may the improvement of a plant variety through transgenesis result in unintended effects which may impact the consumer and animal health”? The following discussion addresses this question as well as the possibility that the intended changes might also have adverse health effects.

**Definition of food safety**

According to the United Nation’s Food and Agriculture Organization (FAO) and World Health Organization (WHO), food is considered safe if there is reasonable certainty that no harm will result from its consumption under the anticipated conditions of use (FAO/WHO 2000). However, almost any single definition of safe food will be overly simplistic, because food safety is a complex, multifaceted concept (Seward, 2003). Food safety issues are as old as mankind and humans have developed strategies to ensure that the food they eat does not harm them.

An absolute guarantee that a food is safe is virtually impossible. This holds true for foods and ingredients made by conventional methods as well as from GE organisms. All foods are composed of a complex and variable mixture of numerous substances some of which may be toxic to the health of humans if present in sufficient amounts. However, in most cases the foods consumed today are generally viewed as safe, based on their long history of use with no obvious evidence of harm (Constable et al., 2007).

**Gene safety**

There has been public concern about the health impact of consuming a foreign gene in a food; in this case the new gene or DNA introduced through genetic engineering. In contrast to vertical gene transfer, where DNA is spread from a parent to offspring, horizontal gene transfer is the transfer of DNA between cells of the same generation where genetic material is transferred directly to a living cell or an organism followed by its expression (Kelly et al. 2008). The process of DNA uptake has been extensively reviewed (Dubnau, 1999). The consumption of the transgenic DNA itself is not a threat to the consuming organism since it is quite rapidly degraded in the digestive tract and acts as a nutrient (van den Eede, 2004). In humans, daily dietary intake of nucleic acids in the form of RNA and DNA vary widely but are typically in the range from 0.1 to 1.0 g per day (Flachowsky, 2007). Any concerns over the presence of novel DNA in a GE food consumed in the human diet must take into consideration that this DNA would represent less than 1/250,000 of the total amount of DNA consumed (Lemaux, 2008). In view of this and the digestibility of dietary DNA, the probability of transfer of intact genes from GE plants to mammalian cells is extremely low (WHO, 2000).

The probability of transfer of antibiotic resistance genes present in plant GE varieties as selectable markers to the indigenous gut micro-flora of humans is a second aspect of horizontal gene transfer and one which is of major concern to the public. However, there is general consensus among scientists that this kind of horizontal gene transfer requires several improbable steps and is thus extremely unlikely, though it cannot be entirely excluded (WHO 2000). Furthermore, the antibiotics in question are typically not of clinical importance because resistance genes against these antibiotics already exist in the environment. As a result, any small additional transfer that might occur through transgenic foods would be negligible in both scope and medical impact. However, due to the controversial nature of antibiotic resistance marker genes, there is continuing pressure for product developers to use other selectable markers and indeed other markers are already in use (van den Eede, 2004).

**Toxicity and anti-nutrients**

Concerns have been raised about the possibility of introducing or elevating naturally occurring toxins or anti-nutritive substances in GE foods to levels that are harmful to human health. All foods, whether or not they
are genetically engineered, carry potentially hazardous substances and as it is currently the case, those without a history of safe use must be properly and prudently assessed to ensure a reasonable degree of safety. The definition of plant inherent toxicants and anti-nutrients is still not entirely harmonized. Usually antinutrients are understood to be substances that inhibit or block important pathways in the metabolism, especially digestion. Antinutrients reduce the maximum utilization of nutrients such as proteins, vitamins or minerals, and consequently may obstruct the optimal exploitation of the nutrients present in a food and decrease its nutritive value (Watzl and Leitzmann, 1995). However, it should be noted that many antinutrients may also be toxic beyond a certain dose, for example oxalate found in amaranth, spinach and tomato may react with calcium and iron in the diet and eventually lead to the formation of kidney stones. Furthermore, most of the deleterious effects of antinutrients are caused by raw plant material and most of the anti-nutritive substances become ineffective by heating, soaking, germination or autoclaving (Novak and Haslerger, 2000).

Naturally occurring toxins are also found in plants and subsequently in food derived thereof; for example cyanogenic glycosides in some staple African food crops including cassava, yams, and sweet potatoes, and glykoalkaloids in potatoes (Noak and Halergier, 2000). The amounts and natural variation of toxic and antinutritive substances in one plant species can differ considerably since they are strongly influenced by the state of ripening, year of production, storage, varietal differences, and growing conditions and also stress or pathogen infection (Ene-Obong, 1995). Literature data sometimes show very wide variations in typical concentrations of inherent plant toxins and antinutrients (Füllgraf, 1989).

The possibility of elevating naturally occurring toxins or anti-nutritive substances or introducing new ones is precluded by the fact that as part of the safety assessment of GE crops, the levels of the naturally occurring toxins in the GE food are compared to those of the conventional food to ensure that these substances are not elevated above their natural levels or no new associated constituents are present. A list of the most frequent and important classes of these constituents, their occurrence and their nutritional effects is given in Table 2.

### Table 2. Classes of the most frequent inherent plant toxins and antinutrients (Adopted from Novak and Haslberger, 2000)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Occurrence</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyanogenetic glycosides</td>
<td>Manoik, cassava, yams, sweet potato, fruit, millet, lima beans</td>
<td>Blocking of cell breathing, gastrointestinal symptoms. Influence on carbohydrates and Ca transport. At high intake doses iodine deficiency</td>
</tr>
<tr>
<td>Glucosinolates (goitrogen):</td>
<td>Cassava, kale, peanut, soybean, onion, radish, cabbage, mustard seeds</td>
<td>Strumatic effects (forming goiter): thyroid gland increase, thyroxin synthesis, metabolism impairment, ↓iodine absorption, ↓protein digestion</td>
</tr>
<tr>
<td>sinapsin, sinigrin, progoitrin,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>arachidoid,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glykolakaloids (solanine and</td>
<td>Potato, tomato</td>
<td>Inhibition of cholinesterase: gastrointestinal symptoms, haemolysis, inflammation of kidney</td>
</tr>
<tr>
<td>Tomatine)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gossypol</td>
<td>Cottonseeds</td>
<td>Binds metals, ↓iron absorption, inhibitor of enzymes</td>
</tr>
<tr>
<td>Lectins</td>
<td>Legumes, cereals,</td>
<td>Inflammation and damage of the intestinal epithels, ↓resorption of nutrients and N retention →, ↓ enzyme activity, ↓B12 and lipid resorption</td>
</tr>
<tr>
<td>Oxalate</td>
<td>Spinach, amaranth, tomato</td>
<td>Ca metabolism impairment</td>
</tr>
<tr>
<td>Phenols (flavonoids, isoflavone</td>
<td>Vegetables, fruit, cereals, soybeans, potatoes, tea, coffee, plant oils</td>
<td>Destruction or inhibition of thiamine, metal complexes, ↓availability of trace elements, estrogen effects, hypcholesterolaemic activities</td>
</tr>
<tr>
<td>Chlorogenic acid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phytate</td>
<td>All plant seeds, cereals, legumes</td>
<td>Complexes: ↓bioavailability of Ca, Mg, Fe, Zn, Cu, Mn, ↓ utilization of protein and starch, ↓activity of amylotic and proteolytic enzymes</td>
</tr>
<tr>
<td>Protease inhibitor</td>
<td>Legume seeds, peanut, cereals, rice, maize, potato, apple</td>
<td>Inhibition of trypsin and chymotrypsin, caboxypeptidases and pancreas elastase, ↓digestion of proteins</td>
</tr>
<tr>
<td>Compound</td>
<td>Occurrence</td>
<td>Effects</td>
</tr>
<tr>
<td>----------</td>
<td>------------</td>
<td>---------</td>
</tr>
<tr>
<td>Saponin</td>
<td>Spinach, asparagus, soybean, tea, peanuts</td>
<td>Complexes with proteins and lipoides, haemolytic, gastroenteritis, most saponins harmless</td>
</tr>
<tr>
<td>Tannins</td>
<td>Widespread: all fruits, tea, coffee</td>
<td>Inhibition of pancreatic enzymes, cobalamin↓ resorption, ↓ thiamine utilization, ↓ availability of protein and iron</td>
</tr>
</tbody>
</table>

**Allergenicity**

One particular area of concern with respect to safety of GE foods is the potential introduction of an allergen not previously present or an increase in the level of inherent allergens above the natural range within the crop. A food allergy is a reaction of the immune system to an otherwise harmless food or food component. Food allergies are relatively rare (perhaps 2% of adults suffer from a true food allergy) but they are still of concern because extreme reactions can lead to death through anaphylaxis (Kanny et al., 2001; Sicherer et al., 2004). Overall, approximately 90% of all food allergies are associated with a small number of specific proteins represented by eight major allergenic foods: peanuts, tree nuts, cow’s milk, hen’s eggs, fish, crustacean, wheat, and soybeans (Metcalfe et al., 1996).

Since the primary product of gene expression is protein and almost all food allergens are proteins (Bush and Hefle, 1996), there exists a possibility that any novel protein introduced into a plant might be an allergen. Also, if a conventional crop that contains allergens is genetically engineered, the GE food may contain those allergens, just as the conventional food does. For example, soy naturally contains proteins that cause an allergic reaction in some people. Unless these specific proteins are removed, they will also be found in GE soy varieties. Therefore, the possibility of introducing new allergens or enhancing the level of existing allergens is a primary concern and subject of extensive food safety evaluations carried out during development of a GE crop.

**Unintended effects**

Genetic engineering is the newest in a range of genetic modification techniques including traditional hybridization and breeding, and mutation induction by radiation that may be used to alter the genetic composition of plant, animal or microbial organisms to affect a specific result. All these modifications bring about changes that are intended to be beneficial, but also may result in unintended changes. Unintended effects here refer to unexpected alteration(s) beyond the primary expected effect(s) of introducing the targeted gene(s). Unintended effects are not restricted to genetic engineering, traditional breeders observe off-types (undesirable variants) due to unintended effects and they methodologically eliminate these plants through selection during the evaluation process, long before commercialization (NRC, 2004). In addition, unexpected or unintended effects do not imply a health hazard, although obviously a plant expressing novel and unexpected characteristics warrants closer inspection prior to commercial release. Although there have been documented cases of desirable unintended effects in GE crops (Munkvold et al., 1997), this chapter focuses on the undesirable effects.

Genetic engineering is considered a more precise method of altering or introducing genes into a plant compared to most conventional methods e.g. traditional breeding and random mutagenesis, that introduce many uncharacterized genes along with the desired gene(s) or result in multiple mutations of an unknown nature. Even so, there is currently no way to predict the integration region of the gene into the cellular DNA and therefore it is not possible to predict any pleiotropic (multiple) effects of the genetic modification process e.g. through disruption of existing gene or regulatory sequences. Thus, the expression of constituents of crops such as inherent plant toxins, allergens, and antinutrients, and thereby their concentrations in a genetically modified plant, may eventually be influenced by pleiotropic effects (Kuiper, 2001).
Upon random insertion of specific DNA sequences into the plant genome (intended effect), the disruption, modification or silencing of active genes or the activation of silent genes may occur, which may result in the formation of either new metabolites or altered levels of existing metabolites (Novak and Haslberger, 2000). These effects could increase the synthesis and activity of the naturally occurring biochemical metabolic pathways, augmented synthesis caused by increased gene activation, decreased synthesis of catabolism enzymes, or reduced decomposition (Koschatzky and Massfeller, 1994). In addition regulatory elements in the plant DNA can influence the expression of the inserted genes and random insertion events may disrupt or modify the expression of existing genes in the recipient plant. However, it is possible that the activation of genes encoding enzymes in pathways may produce deleterious secondary plant compounds that raises the most concern for food safety (Lang, 1979). Therefore assessment of the unintended effects is an integral component of the safety assessment process.

Nutritional concerns

The risk of health hazards that may be brought about by nutrient excesses, deficits or imbalances as a result of genetic engineering is also an issue that may be of concern and is also addressed before the marketing of foods derived from GE crops. These nutritive issues may arise due to the compositional changes of the food as a result of the genetic modification. The deletion or enhancement of essential nutrients from foods has the potential of influencing the risk of nutrient deficiencies or toxicities, respectively, in a section of the general population, depending on exposure patterns. In this context, it should be noted that to date most of nutrient toxicities are due to elevated nutrient levels in excess of normal physiologic needs, achieved through fortification or due to the excessive consumption of nutrient supplements (NRC, 2004).

SAFETY ASSESSMENT OF FOODS DERIVED FROM GENETIC ENGINEERED CROPS

In order to assure safety, all foods derived through modern biotechnology must undergo a comprehensive safety evaluation as part of the regulatory approval process before entering the market and becoming part of the human or animal food supply (Codex, 2003; FAO, 1996; FAO/WHO, 2000; OECD, 1997; WHO, 1995). The source of the gene is routinely investigated to ensure that the gene product itself has no harmful effects. Furthermore, the safety evaluation process requires the newly expressed product, typically a protein, be investigated to demonstrate that its properties are similar to those of thousands of proteins that are safely consumed on a daily basis and are dissimilar to known toxic proteins.

Substantial equivalence

Safety assessment is structured, step-wise and based on a comparative approach commonly referred to as “substantial equivalence” that was originally proposed by the Organization of Economic Cooperation and Development (OECD, 1993). This concept means comparing a transgenic crop to its nearest isogenic relative using molecular characteristics and agronomic metrics, as well as compositional analysis to determine whether the genetic modification has produced any unintended pleiotropic effects (Sidhu et al., 2000; Ridley et al., 2002; Obert et al., 2004; Herman et al., 2004; McCann et al., 2007; Drury et al., 2008; Lundry et al., 2008).

Animal feeding studies are another way to assess potential adverse pleiotropic effects that may not have been detected from composition testing (Delaney, 2007). However, it is important to note that the assessment of substantial equivalence is not in itself a safety assessment. Rather, it is the first step in the assessment process that provides a platform on which to make a comparison between the GE crop and its traditional counterpart and identify any significant differences. The concept of substantial equivalence is, therefore, considered the starting point of the safety assessment process (Codex, 2003). Careful interpretation and further studies may or may not be necessary to establish safety if biologically significant differences are observed.
Molecular and compositional analysis

To be considered as safe as the conventional counterpart, a modified food would need to be tested to show that the genetic modification had not inadvertently introduced or increased levels of harmful compounds. A detailed description of the molecular characteristics of the recombinant-DNA plant is required. This information includes the composition, integrity and stability of the inserted DNA, the number and genomic location of the single or multiple sites of insertion, and the level of expression of the introduced protein(s) over time and in different tissues and environment. This is important to evaluate the potential effect of the insertions (OECD, 1993).

When the substantial equivalence of GE organisms with their parental organism is analysed, the natural variation in content of inherent plant toxins and antinutrients has to be taken into consideration. Special attention in the analysis of substantial equivalence has to be focused on inherent toxic and anti-nutritive constituents, since genetic modification could affect the expression of gene products not addressed by the genetic modification (unintentional pleiotropic effects) and thereby alter the content of constituents (Kuiper et al., 2001).

Currently, the risk assessment of GE crops includes the analysis of 50-150 analytes that have been identified by OECD (OECD, 2006). If these analytical tests indicate no major differences in the levels of well-known key constituents, the chance of other metabolic alterations leading to the production of significant amounts of other inherent plant toxins and antinutrients is considered unlikely (Belitz and Grosch, 1992).

In addition, ‘-omics’ techniques including transcriptomics, proteomics, and metabolomics have been used as an additional tool for the detection of unintended effects. According to Ricroch et al. (2012), analysis of data from ‘-omics’ profiling publications comparing GE and non-GE crop varieties, with or without intentional metabolic changes, show that transgene insertions produce few unintended effects thus reducing chances of unintended deleterious effect that might occur in the GE crop and/or food. However, such approaches are not required for regulatory purposes.

Animal feeding trials have also been used as a tool to assess unintended effects (Snell et al., 2012), particularly 90-day rodent dietary studies, but Ricroch et al. (2012) suggest that long-term and multigenerational animal studies should only be conducted on a case-by-case basis for GE food/feed safety and nutritional regulatory assessment if some reasonable doubt remains after a 90-day rodent feeding trial. Such feeding studies are currently not a routine requirement for GE safety testing. According to the European Food Safety Authority (EFSA), when molecular, compositional, phenotypic, agronomic and other analyses have demonstrated equivalence of the GE food/feed, animal feeding trials do not necessarily add to the safety assessment (EFSA, 2011). However, animal feeding studies may provide additional and useful information to complement safety and nutritional value assessments of whole GE food and feed, especially when unintended effects are suspected.

Evaluation of protein safety

It is recognized that certain proteins are toxic or allergenic if consumed (Delaney et al., 2008). Therefore, as part of the safety assessment, the safety of the proteins encoded by the introduced genes is evaluated. Proteins are not known to be capable of genotoxic interactions (Pariza and Johnson, 2001), nor are they known to be carcinogenic or teratogenic when consumed in a diet (Delaney et al., 2008). Proteins are structurally quite different from industrial chemicals since they are large macromolecules and their size limits systemic absorption from the gastro-intestinal tract. Unlike most chemicals, proteins are also degraded by proteases which cleave the peptide bonds that hold the protein together (Hammond and Jez, 2011). However, as part of the safety assessment process, data is required to establish whether the newly introduced protein has toxic or allergenic potential.
The safety assessment of proteins includes a bioinformatics analysis of the amino acid sequence to confirm that the protein is not related to known mammalian toxins and allergens, an assessment of the protein’s potential for digestion when incubated in vitro with proteases, and an evaluation of the protein’s history of safe use in food (Delaney et al. 2008). Where appropriate, a dietary risk assessment may also be carried out with the introduced protein to estimate potential human dietary intake (Hammond and Cockburn, 2008). Additional risk characterization is determined on a case-by-case basis and may involve acute (1-14 days) or sub-chronic (at least 90-days) animal feeding toxicological studies (OECD, 1998), depending on the outcome of the previous risk evaluations.

**Safety assessment of genetically engineered events combined by conventional breeding**

The early commercialized GE crops contained a single event e.g. herbicide tolerance or insect resistance, but the current trend is to combine or “stack” two or more single GE events to provide growers with a combination of traits that increase flexibility and improve performance. This “stacking” can be done using two approaches: by conventional plant breeding, where parents with single GE events are bred to produce progeny with the combined GE events; or by molecular-based methods where two or more traits are simultaneously or sequentially transformed into a recipient crop (Halpin, 2005). Most often, conventional plant breeding is used to combine GE events and in the past several years, multiple new combined GE event crops have been commercialized globally (James, 2009, 2012).

There has been debate on the level of rigor that should be applied to the safety assessment of these stacked GE crops and especially in situations where the individual events have already been approved. There is no global consensus for the regulation of previously approved GE events combined by conventional breeding. Indeed the guidelines provided by Codex do not explicitly address combined GE events generated through conventional breeding (Codex, 2003). Consequently, individual regulatory agencies have devised their own requirements. The regulatory approach taken by US, Canada and Australia/New Zealand does not require additional data for combined GE events by traditional breeding methods that are unlikely to interact (EFSA, 2007; CFIA, 2004; OGTR, 2007). However, other countries including Mexico, Colombia, Taiwan, Philippines, Japan, South Korea, South Africa, and the European Union require additional information (Pilacinski et al., 2011).

The World Health Organization concludes that substantial equivalence should be maintained in a combined GE trait variety if substantial equivalence had been demonstrated for each of the parents (WHO 1995). Additional international groups, including FAO and WHO (FAO/WHO, 1996), the International Seed Federation (ISF, 2005), and Crop Life International (CLI, 2005) similarly advocate basing the safety of combined GM events on the safety of the parental GE events. Pilacinski et al. (2011) argue that additional safety data only become necessary if two or more of the traits present in the combined GE event product are likely to interact in a manner that would in some way change prior safety assessments. In this case, appropriate experiments should be designed to address the anticipated interaction.

**CONCLUSION**

On a global basis, several organizations, including the FAO, WHO, and OECD, have established the food safety issues to be addressed by the safety assessment of GE foods. There is general consensus among these organizations and other regulatory agencies around the world that GE products are not inherently less safe than those developed by traditional breeding. Further, food safety considerations are similar to those arising from the products of traditional breeding which are subject to different regulations and testing procedures that are much less stringent than those applied to GE products. More rigorous assessment procedures are currently being utilized to evaluate GE products compared to their conventional counterparts to ensure
safety. It is debatable whether this should continue after establishing a reasonable history of safety for some of these GE foods (Herman and Price, 2013).

From past and recent publications (EC, 2010; Lemaux, 2008; Cockburn, 2002) and as far as the author is aware, for the past 16 years that GE foods have been consumed there has not been a single documented case to indicate that these foods pose any greater risk than their conventional counterparts to humans and animals that consume them. Although this cannot exclude low-level or rare events that might not have been recorded, it would be reasonable to suppose that the current regulatory framework for evaluating food safety has been effective in ensuring that the GE foods currently in the market are as safe as their conventional counterparts. However, vigilance should be maintained as more GE crops continue to be developed. It is important that African scientists and regulators have access to the available GE food safety literature. The ability of African regulators to understand these safety issues, and evaluate and provide scientific opinion to decision makers on the safety of GE crops will, in-part, determine the rate of adoption of this technology. This, in turn, will impact the continent’s ability to address the food and nutrition security challenges afflicting it.

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Chapter 5. Legislative and policy issues associated with GE crops in Africa

INTRODUCTION

Biotechnology, defined broadly as the use of living organisms or parts thereof in the production of goods and services, has revolutionized many human endeavours that rely on biological processes. Activities in agriculture, health, environment and industry have had a radical facelift as a result of developments in biotechnology. These developments have brought together advances in disciplines such as engineering, chemistry and biology, to hasten processes, and to enable the development of processes and products that were not imaginable before the advent of these technologies. African countries are employing various levels of biotechnology (as detailed elsewhere in this book) in a wide range of fields, which include agriculture, environment management, forestry, health care and industry. The potential of the technology to deal with some of the challenges facing the countries of Africa has been documented in national development strategies, especially agricultural, science and technology and industrial policies, and some steps have been taken towards harnessing the technology.

As they wrestle with the perennial challenge of feeding their populations, African countries have had to contend with the contested benefits and risks presented by new technologies such as gene-based biotechnologies (Birner and Linacre, 2008). Indeed, like elsewhere in the world, African countries have engaged in the debate on the pros and cons of modern biotechnologies and products thereof for a greater part of the last two decades (Paarlberg, 2000). However, for African countries, the debate continues to change irreversibly and fundamentally in content and nature as a result of situations such as food emergencies which force countries to make decisions in the face of regulatory uncertainty and humanitarian crises (Mugwagwa, 2008). The debate continuously reveals the limited preparedness within countries, and the continent in general, to deal with these crises despite the many years of individual and collective efforts to develop and implement effective regulatory systems. Meanwhile, the fact that there is no unanimity at sub-national, national and continental levels on the technology and how to regulate just adds to more confusion to an already disorderly situation. This chapter identifies and discusses some of the legislative and policy activities to harness and effectively regulate modern biotechnology across Africa.

THE NEED FOR BIOSAFETY LEGISLATION

From a biological science perspective, the concept of biological safety (or biosafety) has paralleled the development of the science of microbiology and its extension into new and related areas (e.g. tissue culture, recombinant DNA, animal studies, among others). The knowledge and skill gained by microbiologists to isolate, manipulate and propagate pathogenic microorganisms required parallel development of containment principles, facility design, and practices and procedures to prevent occupational infections in the biomedical environment or release of the organisms to the environment. However, as used under the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD), the concept of biosafety refers to the legal actions that an importing country is entitled to take under international environmental law with the aim of protecting the biological diversity of its conventional plants and animals against the risk of contamination through imported varieties or species consisting of so-called Living Modified Organisms (LMOs) (cf. Mackenzie et al., 2003). These actions consist primarily of preventive or precautionary trade measures. Such restrictions or bans include the elaboration, negotiation and implementation of pertinent standards, and the institutionalization and international ‘harmonization’ of the
related regulatory framework and procedures. They also take into consideration the legally less clearly circumscribed concerns over related public health issues and socio-economic considerations. All these provisions aim at a non-hierarchical and mutually supportive relationship with other international agreements, especially with World Trade Organisation (WTO) rules, with the Codex Alimentarius Commission standards on food safety and with the International Plant Protection Convention.

The Biosafety Protocol

The Cartagena Protocol on Biosafety was adopted in January 2000 as a supplement to the Convention on Biological Diversity (CBD) to serve as the global framework on biosafety. The Protocol addresses the safe handling and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity, taking into account risks to human health and focusing specifically on transboundary movements (CBD Secretariat, 2007). Countries are given authority by the Protocol to assess the risks posed by LMOs before they accept them. Their acceptance or rejection of the products is enshrined in the advance informed agreement, and the precautionary approach emphasised by the Protocol. A communication mechanism for exchange of information and experiences on biosafety with the world community is provided via the Biosafety Clearing House (BCH) Mechanism.

The Protocol makes it clear that Parties to the Protocol must develop or have access to the “necessary capacities to act on and respond to their rights and obligations”. National capacities are seen as a necessary prerequisite for the successful implementation of the Protocol, hence many national, regional and international agencies have been engaged in assisting countries, singly or in groups, to develop the necessary technical and regulatory capacities. The efforts of the three supranational organisations are seen as some of these many efforts towards equipping countries for implementation of the Protocol and strengthening their risk management and decision-making with respect to biosafety.

Even before the advent of the CPB, there were many efforts to build regulatory and technical capacity in African countries for the development, enforcement and safe use of biotechnology. However, since its entry into force in September 2003, the Protocol has served as a key driver of both national and international processes in the handling of products of modern biotechnology. In addition, and looking specifically at countries in Sub-Saharan Africa, many policy and regulation models used elsewhere in the world have been adopted by key stakeholders, governments and organisations as a basis for policy development (e.g. the ISNAR and UNEP models and the African Model Law on Safety in Biotechnology, cf. Paarlberg, 2000). Lessons have also been drawn from the European and American experiences.

LOCAL LEVEL REALITIES FOR BIOSAFETY

Biosafety is a collective term used in reference to policy frameworks and actions for assessment and management of the safe application of modern biotechnology, frequently referred to as “genetic engineering.” Concepts of safety are applied with respect to hazards that modern biotechnology may pose to human and animal health as well as to the environment. The risks include related non-technological concerns of a social, ethical or political nature (Persley et al., 1993; Persley and Doyle, 1999). In this context therefore, biosafety is a concept that is being applied to regulate situations in which products of biotechnology are introduced into the environment directly as genetically engineered crops, animals and microbes or through derived products such as food, cosmetics, drugs and other biologicals. Biosafety is, therefore, applicable to the food industry, public health, agriculture and the environment, where it is applied in research, production, conservation, marketing and trade.
Among the key issues and realities for biosafety are that while there is a significant level of agreement on the potential risks associated with GE technology - for example, environmental risks from gene flow to non-cultivated plants, agronomic risks from resistance problems in the GE crops and in weeds, co-existence challenges between fields of farmers using GE crops and those not using them; among others - there is still considerable disagreement within and across countries regarding the importance of these risks and the scientific possibilities for adequately assessing and addressing them (Birner and Linacre, 2008). Add to this the disagreements on the so-called non-scientific issues, such as labelling of food and feed derived from GE crops, and socio-economic issues around the technology, and one begins to understand the emergence of a continuum of regulatory systems, ranging from the ‘stringent’ EU system on one end to the ‘permissive’ US system on the other end (Levidow et al., 1996, Paarlberg, 2000). As noted by Arcuri (2001), a ‘regulatory divide’ has emerged, championed by ‘technocrats’ on one hand, who believe in a rational application of the science to identify and manage the risks; and a ‘deliberative’ philosophy on the other hand, which embeds scientific knowledge within policy and societal debates (Birner and Linacre, 2008). African countries have to contend with these realities in their efforts to harness and effectively regulate the technology.

DEVELOPING AND IMPLEMENTING NATIONAL BIOSAFETY SYSTEMS

According to the UNEP-GEF Project, a national biosafety framework is a system of legal, technical and administrative mechanisms established to address the safety of modern biotechnology. Biosafety frameworks can be tailor-made to meet specific country needs but the main three tenets that must be present in any biosafety regulatory system are:

- An administrative system to handle application for permits for releases and research on GEOs/LMOs;
- A decision making system including risk assessment and management for the release of GEO/LMOs;
- Mechanisms for public participation.

Article 2(1) of the Cartagena Protocol on Biosafety requires each party to take the necessary and appropriate legal, administrative and other measures to implement its obligations. It further states that parties shall ensure that the development, handling and transport, use, transfer and release of any GEO/LMO is undertaken in a manner that prevents or reduces risks to biological diversity, taking into account risk to human health.

The main purpose of a biosafety system is three-fold. It enables a country to:

- Make informed choices on decisions to import GEOs/LMOs,
- Devise tools to assess, evaluate and manage potential adverse effects associated with transboundary movement, transit, handling and use of GEOs/LMOs on conservation and sustainable use of biological diversity accounting for risks to human health as well as socio-economic considerations
- Meet the international requirements of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

THE POLICY ENVIRONMENT

Public policies are statements of intent on what is to be done by states or agencies, and they are defined as outcomes of interactions between the states or agencies and civil society (Ushewokunze-Obatolu, 2005). Policies are therefore intended to serve the public interest. They are expressed as acts of parliament or regulations that attempt to state in very clear and specific terms, what is to be done under various circumstances surrounding an issue. Policies may further be explained for relevance through statutory instruments, guidelines, strategy documents and action plans. Policy-making in most African countries has tended to be prescriptive and top-down rather than participatory with the public. This is due to the low level of literacy of the general population, ignorance about the purpose of policies and regulations, the absence of skills in participatory development techniques and the anxiety by administrations to bring about changes without committing too much time and financial resources, thereby implementing by force rather than by
voluntary co-operation. While a top-down approach may have worked with most past policies, development of biotechnology/biosafety policies in many African countries has ushered in a new era where consultative processes have become the norm rather than the exception (Mugwagwa et al., 2013). This has introduced inertia and momentum in the processes, but overall, there is agreement that for the adoption of this technology, there is need for it to be well understood by the public.

Biotechnology policies should strike a balance between promoting research, development and applications and ensuring human safety, national security and biodiversity conservation. Modern biotechnology is not sector specific - it includes the entrepreneurial life sciences/biotech companies that use modern biotechnological techniques to develop products or services, research institutions, regulatory bodies and standards development bodies, traders and consumers, among others. An ideal country policy environment will thus need to strengthen and balance the capabilities of these various stakeholders in their contribution to and derivation of benefits from modern biotechnology (Mugwagwa and Makinde, 2012). Realising this goal is not only in the outputs, but also in the processes of coming up with the policies, both of which should be reflective of local contextual realities.

The problems that biotechnology addresses are social, present and economic, in the domains of food availability, nutritional quality, enhanced yields, incomes, entrepreneurship, reduced cost of inputs, and reduced costs and predictable availability and quality of vaccines and drugs. A wide range of stakeholders thus needs to understand the implications of the technology in order to accept and promote its products (Ushewokunze-Obatolu, 2005). Due attention is therefore required to these factors if effective policies are to be developed and, with the support of the public, to be executed through self-policing and self-regulation.

LEGAL ISSUES TO CONSIDER

There are many legal issues that a country will encounter when it attempts to implement and comply with the Cartagena Protocol on Biosafety (Kiplagat, 2009).

**Liability and Redress**

Liability is the obligation of a legal entity, such as a person, corporation, or government office, to provide compensation for damage caused by an action of that legal entity for which that legal entity is responsible. Liability will arise when an action contravenes legal rules and causes damage. There is a causal link between the action and the damage and responsibility for the action can be attributed to that legal entity. Within the context of the Cartagena Protocol, liability and redress refers to whether there should be an international liability and redress system for any environmental damage caused by a transboundary movement of an LMO. Currently, there is a significant difference in ideologies between countries who favour a strict liability regime, and those who favour a liability and redress regime that takes cognizance of existing liability and regimes within the legal systems of member states (Kiplagat, 2009).

If a country opts to develop a separate national liability and redress regime to deal specifically with living modified organisms, the specific challenges will be defining exactly what constitutes damage, determining an adequate timeline for ascertaining damages, and defining who should be liable for the determined damages. A country might also opt to use its existing liability and redress regime for environmental damage. This issue, however, will remain uncertain for countries until the debate on the international regime for the Cartagena Protocol is finalized.

**Socio-economic Considerations**

The Cartagena Protocol allows the possibility of including socio-economic considerations in biosafety regulatory approval processes for LMOs. Article 26 of the Protocol provides that Parties may take into
account socio-economic considerations in reaching a decision on import of LMOs, but only to the extent consistent with that country’s other international obligations. These obligations could include any international agreements and treaties that a country is party to. The Protocol further limits what may be taken into account by describing socio-economic considerations as those “arising from the impacts of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.”

By definition, socio-economic assessments are *ex-ante*—before the fact procedures—for those products in the regulatory approval process. There may be some cases where a biosafety regulatory system may require post-release monitoring and evaluation of socio-economic impacts, but this instance clearly falls under the realm of *ex-post* assessments, where there is a long and well-established literature and experience for assessments after environmental release (Kiplagat, 2009).

The Protocol in itself does not define socio-economic considerations and the interpretation of this Article has been left to individual parties. If a country decides to include socio-economic considerations in its regulatory process, a clear definition on what issues will constitute socio-economic considerations and how they will be factored into the decision making process should be included in the law, regulations or guidelines.

**Public Participation**

Article 23 of the Cartagena Protocol encourages Parties to “promote and facilitate public awareness, education and participation in the safe transfer, handling and use of LMOs...” The Protocol further provides for consultation with the public to be part of decision-making and necessarily unique to each country’s legal system and regulations. In addition, any public participation that is permitted in a country with respect to biosafety decision making should not differ in any material way from participation permitted in that country on other matters that may impact conservation and sustainable use of biodiversity. The legal challenge will be to ensure issues on public participation with regard to implementation of the Cartagena Protocol will be treated in the same manner as any other public participation mechanism currently in use within a country.

As the Cartagena Protocol does not give guidance on the public participation procedures to be used in the decision-making process, it is important that when engaging in public dialogue each country should consider the level of education, the language of communication and the medium to be used.

**Transparency and Confidentiality**

Article 21 of the Cartagena Protocol allows certain information provided by a notifier (applicant) to be treated as confidential. The Protocol provides that the name and address of the notifier; a general description of the living modified organism or organisms; a summary of the risk assessment; and any methods and plans for emergency response shall not be treated as confidential. This information is considered to be information that must be supplied in the public interest. The onus is on the notifier to specify the information it considered to be confidential.

However, not all information identified by the applicant as “confidential” qualifies to be treated as such. Countries need to provide clear guidelines on confidentiality in their laws and regulations since this issue is linked to transparency. Information that may have an adverse economic impact on the business of the developer should be kept confidential as this information may provide a competitor an unfair advantage. Trade secrets, the gene construct and the efficacy data are types of information considered to be confidential material. The location of field trials and the personal information of the applicant are also treated as confidential in most instances. Countries should strive to reach a balance on what information can
be kept confidential and what should be made available to the public. The public needs to be educated on why some information will remain confidential as this is important in the decision-making process.

Transparency is an integral part of a regulatory process as it ensures that the regulatory process within the country is clear to the applicant, the Government, regulators and the general public. Countries should therefore ensure that the regulatory process has legal rules that set forth the application process, including the information required on the application, the parties involved and the office responsible for the activities to be undertaken. Those regulations or guidelines should ensure that decisions are availed to both the applicant and the public. A mechanism of how the application and decision documents can be made available to all interested parties should also be developed. The legal challenge will be to create a balance between the competing interest of the applicant and the information to be available to the public.

CONCLUSION

The challenge for African countries will be to ensure that the laws developed address issues that have not been clearly defined by the Cartagena Protocol yet are important in its implementation at the national level. Clear and concise rules will go a long way in ensuring an adequate level of protection for transboundary movement of LMOs. Overall, countries should enhance their policy and regulatory capacities in order to be able to unpack and confront the challenges facing development and implementation of biosafety systems. There is a need for a more nuanced and context-driven approach to biosafety as a platform for raising stakes for success and making best use of available resources. Failure to adequately define and delimit policy and legislative issues and embed them within a science-based assessment of biosafety causes more harm than good to efforts by countries to develop and implement biosafety systems.

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Chapter 6. Socio-economic issues associated with GE crops in Africa

INTRODUCTION
The challenge of the new millennium is to provide solutions for a growing population including attaining food security and food safety, managing climate change and the limited fossil fuel resources while combating disease, hunger, malnutrition, poverty, and inequity. The nature of the challenge is not only to increase global future production but also increase it \textit{where it is mostly needed by those who need it most...with special focus on smallholder farmers, women and rural households and their access to land, water and high quality seeds ... and other modern inputs} (FAO, 2008). This resonates particularly with Africa, a continent recognized for its high agricultural potential yet low productivity characterized by low product diversity and the existence of biotic and abiotic stresses. As a consequence, Africa is a net importer of food. The three basic economic problems to resolve for any system are what to produce, how to produce it and who gets what is produced. Concerning how to produce to meet societal needs, modern biotechnology has been identified as a tool for agricultural productivity and food security in meeting the global needs for food, feed, fiber, and fuel. Proponents argue that biotechnology could be used to address challenges that have been difficult to resolve using conventional approaches.

The NEPAD Planning and Coordinating Agency, among other objectives, seeks to eradicate poverty, place African countries on a path of sustainable growth and development and halt the marginalization of Africa in the globalization process and enhance its full and beneficial integration into the global economy. A thriving African bioeconomy within the global market place is possible if premised on enabling biosafety laws and an ability to make timely and appropriate regulatory decisions. Economics is one of the key drivers of change within a bioeconomy and plays a major role in assessing and improving a regulatory process (Figure 1).

\textbf{Figure 1: Drivers of Change}

Africa urgently needs strategic repositioning in the modern era of technological advancement and bioinformatics.

SOCIO-ECONOMIC BENEFITS AND CONCERNS FOR ADOPTION OF GE CROPS
Area under biotech crops and the number of countries and farmers planting biotech crops globally have been monitored since commercialization in 1996. James (2013) in his annual report on the global status of commercialized GE crops observes an annual growth rate of 6\% for the 18-year period of commercial cultivation and that there was a more than 100-fold increase in biotech crop area from 1.7 million hectares (ha) in 1996 to 175.2 million ha in 2013. By 2013, 18 million farmers in 27 countries of which more than 90\%
were resource-poor farmers in developing countries had planted GE crops. The report estimates that the global value of the biotech crop market in 2012 was US$14.84 billion and this represented 23% of the US$64.62 billion global crop protection market. The share of biotech crop seeds in the estimated US$34 billion global commercial seed market was 35% in 2012 (James, 2013). This valuation of the global biotech crop market was based on both the sale price of biotech seed and associated technology fees. Brookes and Barfoot (2009) also noted that the direct global farm income benefit from biotech crops was $10.1 billion in 2007 and that since 1996, farm incomes have increased by $44.1 billion. About $20.5 billion of the total cumulative farm income benefit (46.5%) was attributed primarily to yield gains and to some extent facilitation of a second crop while the remaining 53.5% was due to reductions in the cost of production. The contribution of GE insect resistance technology to the observed yield gains was estimated at 68% while GE herbicide tolerance contributed the remainder.

Of the 27 countries that commercially cultivated GE crops, 19 were from developing countries while 8 were industrial countries. The cumulative economic benefits from 1996 – 2012 for developing countries was US$59 billion compared to US$57.9 billion (46.5%) for industrial countries. For 2012, the economic benefit for developing countries was US$8.6 billion and US$10.1 billion for industrial countries (Brookes and Barfoot 2014, forthcoming; cited in James 2013). The US had the largest share of global biotech crop plantings in 2013 accounting for 70.1 million hectares. Other major growers were Brazil with 40.3 million ha, and Argentina with 24.4 million ha. Other notable mentions were India, Canada, China, Paraguay, South Africa and Pakistan. The eleven GE crops deployed in 2013 were alfalfa, canola, cotton, maize, papaya, poplar, soybean, squash, sugar beet, sweet pepper and tomato. Of these, maize, cotton and soybean were the most cropped in terms of number of adopter countries (Figure 2).

![Figure 2: Number of Countries Growing Various GE Crops in 2013](image)

Source of data: James 2013

The three crop traits adopted were herbicide tolerance, insect resistance, and stacked traits. Available statistics suggest stacked double and triple traits appear to be increasingly more popular with farmers compared to insect resistance traits alone. Double stacks conferred pest resistance and herbicide tolerance while the triple stacks conferred resistance to two insect pests plus herbicide tolerance. In 2013, 13 countries planted 47 million hectares to GE crops with stacked traits (James 2013).
Some Continent Specific Statistics

Currently, farmers in the US grow more GE soybean, maize, cotton and canola than conventional varieties. The scenario is not different in Canada for GE soybean, maize, and canola. The benefits accruing to adopter farmers in these countries are well documented (see James, 2009; Brookes and Barfoot, 2009). Five EU countries namely Spain, Portugal, Czech Republic, Slovakia and Romania planted a total of 148,013 hectares of biotech Bt maize in 2013. Spain alone accounted for 93% of this total.

At present, only 3 African countries (South Africa, Burkina Faso, and lately Sudan) commercially cultivate GE crops. From an initial 197,000 hectares in 2001, the area planted to GM crops by South Africa increased over the years to 2.85 million hectares in 2013. Of the three GM crops grown, Bt maize is the leading crop in terms of hectarage under cultivation with a share of 82.9 per cent of all GM crops. In 2013, Bt maize occupied 86.6 per cent of all land cultivated to maize, be it conventional or GM with HT soybeans occupying 92% of total area of 520,000 ha planted to soybeans while the total area of 8,000 ha under cotton represented a 100% adoption rate. The net benefits from biotech crops for South Africa was estimated at US$98 million in 2011 while the accumulated benefits from 1998 to 2011 was US$922 million (Brookes and Barfoot, 2009). Maize accounted for US$891.1 million, soybean US$34.4 million and cotton US$7 million of these accumulated benefits. Cotton is the leading cash crop in Burkina Faso and is second only to gold as an export commodity. The sector however was beset with pest control issues in the 1990s with reported crop losses between 30 to 90% in some growing areas (Goze et al., 2003; Vaissayre and Cauquil, 2000; personal communication, 2013). Pyrethroid resistance was observed in major pests with more than €3 million loss in 1998 and increased number of insecticidal sprays from 6 up to 12 with decreased effectiveness. To address resistance to pesticides and decreased cotton production, Burkina Faso adopted Bt cotton. In 2008, 8,500 ha was planted to Bt cotton for certified seed production and a modest 15,000 ha planted. Area under cultivation increased to 125,000 ha in 2009 and by 2013, to 474,229 ha. Sudan commenced Bt cotton commercialization in 2012 and put 20,000 ha under cultivation. This increased to 62,000 ha in 2013.

Brookes and Barfoot (2009) report that both small- and large-scale farmers have adopted GE crops and that the size of operation appears not to influence adoption. The four leading countries growing GE crops in Asia are India, China, Pakistan and the Philippines. In India where Bt cotton remains the only commercialized GE crop, 11 million hectares was planted by small-scale farmers to the crop in 2013. With an adoption rate of 93%, India enhanced farm income by US$3.2 billion in 2011 and by US$12.6 billion for the period 2002 – 2011. For the 7.1 million small- and resource-poor farmers who benefited from cultivating Bt cotton in China, studies conducted by the Center for Chinese Agricultural Policy (CCAP) indicated that, on the average, small-scale farmers increased their yield by 9.6%, reduced insecticide use by 60% (which had positive implications for both the environment and the farmers’ health), and generated a substantial US$220/ha increase in farm income (James, 2009) and in 2013, 7.5 million small resource poor farmers in China grew 4.2 million hectares of Bt cotton. Small-scale farmers who grew Bt maize in the Philippines were also reported to have gained from the crop in 2008. A socio-economic impact study reported that these farmers gained an additional farm income from Bt maize of about US$135 per hectare during the dry season and about US$125 per hectare during the wet season of the 2003-2004 crop year (James 2009).

Reasons for the fast adoption

For any agricultural technology, benefits are usually quantified in monetary terms. However, non-monetary benefit considerations including ease of operation, time savings, and lesser exposure to chemicals also inform farmer decisions (Fernandez-Cornejo and Caswell, 2006). Consequently, farmers’ adoption of new technologies is influenced by both monetary and non-monetary expectations of net benefits. Farmers normally choose technologies and practices that they expect to earn the greatest benefits based on yield performance, taste and preferences, farm characteristics, savings in management time, demand for
produce/product, and costs. The observed annual increments and growth in global biotech crop adoption have been attributed to a number of factors including continued increases in the number of countries growing GE crops (adopter countries), additional crop acreage deployment in adopter countries, the introduction of new GE crops and traits, farm profitability, and the introduction of stacked or multi traits (James, 2009; Brookes and Barfoot, 2009).

Similar considerations have driven the rapid increase in the adoption of GE crop varieties in countries that commercialized cultivation. Beyond farm profitability, other less quantifiable (non-pecuniary) benefits have been observed to have had important influences for technology adoption (Brookes and Barfoot, 2009). These benefits have received mention across adopter countries by farmers and were attributed to herbicide tolerant (HT) and insect resistant (IR) crops (Boxes 1 & 2).

### Box 1: Herbicide tolerant crops
Factors influencing farmer adoption of herbicide tolerant crops include:
- Ease of use associated with broad-spectrum, post-emergent herbicides and the increased/longer time window for spraying;
- Reduction in damage to crop arising from the application of post-emergent herbicide;
- Ability to use alternative production technologies such as no/reduced tillage practices;
- Time and fuel savings from the adoption of no/reduced till compared to equivalent conventional crop husbandry practices;
- Ease of weed control leading to cleaner crops hence reduced harvesting costs, and time spent for harvesting. Resultant effect is improved harvest quality and premium price for quality;
- Avoidance of potential damage from soil-incorporated residual herbicides in follow-on crops;
- Improved quality of family life arising from social benefits derived from time savings made from crop husbandry practices.

Sources: Brooke & Barfoot 2009; James, 2009; Karembou et al. 2009; Personal communication 2008 - 2013

### Box 2: Insect resistant crops
Factors influencing farmer adoption of insect resistant crops include:
- Reduced risks from crop loss associated with insect pests;
- Convenience associated with less time spent on crop walking and/or applying insecticides;
- Savings in fuel use – mainly associated with less spraying;
- Savings in the use of machinery (for spraying and possibly reduced harvesting times);
- Improved quality (e.g. lower levels of mycotoxins in GE IR maize);
- Improved health and safety for farmers and farm workers (from reduced handling and use of pesticides);
- Easier crop husbandry practices;
- Facilitated second crop cultivation;
- Triggered subsidiary benefits for bee keepers as fewer bees were now lost to insecticide spraying;
- Improved family welfare and education for women and children.

Sources: Brooke & Barfoot, 2009; James, 2009; Karembu et al., 2009; Personal communication 2008 - 2013

Yet despite this rapid growth, the industry has been beset by a wide-ranging and often emotionally charged debate on issues pertaining to the environment, human health, economics, ethics and politics. The socioeconomic concerns include dependence of farmers on large corporations for seed; unaffordable planting materials; possible unsuitability of GE crops for small-scale farm operations and for resource poor farmers (interestingly 90% of GE crop farmers are small-scale and resource-poor farmers in developing countries);
unethical patenting of life; possible limited access and increased price of seeds due to technology fees; lack of food distribution infrastructure rather than simply producing more; products needed in developing countries not being developed due to market or profit considerations; and developing countries having to eat food others had rejected. It must however be noted that these concerns are not peculiar to GE crops but rather are challenges inherent in the agricultural sector. Discussions on and in-depth analysis of the benefits and perceived risks associated with GE crops are required but have been hindered by lack of information, lack of access to impact assessment analyses and in some cases misperceptions. The goal of public policy is to maximize the welfare of all its citizens and biosafety regulation can help achieve that by providing certainty, stability and disciplinary rigor to the social framework required for risk assessment, management and communication.

Socio-economic Considerations in Biosafety

Regulation has been central to the debate on the use of agricultural biotechnology due to possible safety implications for the environment and human health on one-hand and non-safety implications including socio-economic considerations on the other. Defined as a principle, rule, or law designed to govern conduct, regulations play a critical role in achieving broad socio-economic goals, including assuring safety, achieving equitable distribution of income, ensuring public confidence, improving efficiency of resource allocation, and protecting rights of ownership. In the same vein, biosafety regulations are expected to enable countries to protect human health and the environment while harnessing the benefits of modern biotechnology. However, such outcomes can only be achieved if countries implement functional biosafety regulatory systems. Consequently, the Cartagena Protocol on Biosafety, a legally binding international agreement, negotiated, concluded, and adopted in the framework of the Convention on Biological Diversity, was established to guide parties in developing systems for the environmentally sound management of modern biotechnology practices, focusing specifically on trans-boundary movement of living modified organisms (LMOs) and their impact on biodiversity.

Article 26 of the Cartagena Protocol on Biosafety allows Parties to the Protocol to consider the inclusion of socio-economic considerations in biosafety approval processes and decision making for living modified organisms. Article 26 of the Protocol states that:

1) The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2) The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

A close examination of the provisions of this article reveals that it is fraught with implementational challenges having been cast in a language of constructive ambiguity that presents a number of caveats. These are:

1) Lack of a clear understanding of the meaning of socio-economic considerations in biosafety because the Protocol does not define what these considerations are;

2) Regulators’ lack of information on the socio-economic impacts of biotechnology; and

3) Lack of clarity on the process of incorporating socio-economic considerations in actual decision-making.

Consequently, it is unclear what socio-economic considerations (SECs) are, when they are required, what information should be used for the analysis, how that analysis should be done, and by whom. In addition, a strict interpretation of the text in the Cartagena Protocol suggests an implementation scope that is limited to
impacts of living modified organisms (LMOs) on biodiversity, especially on indigenous and local communities. Nevertheless, the language in some national legislation suggests a broad and undefined inclusion of all socio-economic considerations of LMOs. The Protocol also states that the inclusion of socioeconomic considerations must be consistent with other international obligations. While it is possible for a country to include socioeconomic considerations in its national biosafety regulatory system, it will require a significant amount of work to specify all the details in its laws and regulations that are needed to make the analysis of those considerations consistent with international obligations as well as fair and transparent to biosafety stakeholders (Jaffe 2005, Falck-Zepeda 2009).

Recognizing the implementational challenges, a survey on the application of and experience in the use of socio-economic considerations in biosafety decision-making as provided for in Article 26 of the Cartagena Protocol on Biosafety Scoping exercise on socio-economic considerations (SECs) in biosafety decision-making was commissioned. The survey included capturing experiences of Parties with SECs and the preparation of a draft outline for a toolkit module on socio-economic considerations. The survey was conducted from Oct 14, 2009 to Nov 13, 2009 in English, French and Spanish. A total of 578 completed surveys were received from individuals and organizations. Respondents identified the following as most important socio-economic issues:

- Food security
- Health-related impacts
- Coexistence of LMOs
- Impacts on market access
- Compliance with biosafety measures
- Macro-economic impacts
- Impacts on biodiversity
- Economic impacts of changes in pest prevalence
- Farmers’ rights
- Intellectual Property Rights
- Impacts on consumer choice
- Use of pesticides and herbicides
- Cultural aspects
- Labour and employment
- Land tenure
- Gender impacts
- Rural-urban migration

### Ranking of the level of agreement with statements concerning the evaluation of SECs

<table>
<thead>
<tr>
<th>Rank</th>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>“Socio-economic considerations should be included in all decision-making frameworks for LMOs.”</td>
</tr>
<tr>
<td>2</td>
<td>“Decisions concerning LMOs should incorporate socio-economic information at the same time as scientific risk assessment information is being considered.”</td>
</tr>
<tr>
<td>3</td>
<td>“Socio-economic considerations should be undertaken separately from scientific risk assessments of LMOs.”</td>
</tr>
<tr>
<td>4</td>
<td>“Socio-economic considerations should be part of the scientific risk assessment of LMOs.”</td>
</tr>
<tr>
<td>5</td>
<td>“Decisions concerning LMOs should incorporate socio-economic information only after scientific risk assessment information has been considered.”</td>
</tr>
</tbody>
</table>

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5 UNEP/CBD/BS/COP-MOP/5/INF/10
For inclusion in a methodological toolkit, respondents listed the following assessment methods in order of importance:

- Cost effectiveness
- Macroeconomic impacts
- Cultural, ethical assessment
- Property right assessment
- Benefit-cost assessment
- Economic risk assessment

When asked whether they had ever taken SEC arising from impact of LMOs on the conservation and sustainable use of biological diversity for decision on imports, 29% indicated having done so, 15% had only in some cases and 40% had not.

Regarding if they had cooperated with other Parties on research and information exchange on any socio-economic impacts of LMOs, only 7% had done so. Twenty-seven percent had done so to a limited extent while a staggering 66% per cent had not at all.

Parties to the Cartagena Protocol on Biosafety agreed further discussions were required for conceptual clarity on socioeconomic issues associated with decision-making on LMOs and that Parties that may wish to consider socioeconomic factors in reaching decisions will require assistance in that regard. Consequently, it was agreed to convene a group of experts to develop conceptual clarity on socioeconomic considerations and to convene online discussion groups and regional online real-time conferences to facilitate exchange of views, information and experiences on the issue. COP-MOP 6 therefore established an Ad-hoc Technical Expert Group (AHTEG) on socio-economic considerations (SECs) to:

- Examine the outcomes of the online discussion group, the regional online real-time conferences, and the global overview of information, in order to develop, drawing upon the outcomes, conceptual clarity on socio-economic considerations; and
- Submit a report for consideration by COP-MOP 7.

The AHTEG on SECs recognized there was no single agreed definition for socio-economic considerations hence adopted a descriptive approach to reach conceptual clarity and went ahead to propose elements of a framework that could be adapted as deemed appropriate to national and regional specificities and consistent with international obligations.

The AHTEG on SECs noted that any list of elements of SECs would be indicative and non-exhaustive but should be informed by existing experiences and information which would then contribute to the future development of guidelines on SECs.

**Framework for Socio-economic Impact Assessment (SIA)**

Socio-economic considerations are crucial in safeguarding the interests of indigenous and local communities in technology adoption. However, a lack of comprehension of the regulations governing the inclusion of socio-economic considerations by stakeholders could translate to socio-economic assessments becoming an obstacle to the development and transfer of safe and efficacious products to farmers (Falck-Zepeda, 2009). For biosafety approval processes, assessment of such considerations will require a mechanism for identifying positive and negative socio-economic impacts. Doing this requires a framework that is accessible, transparent, reproducible, predictable, and science-based to ensure that SIA will not become an obstacle to the safe development and transfer of products to end users. The socio-economic impact data could have the social impact component including acceptability, vulnerability, access, gender equity, loss of traditional knowledge, appropriateness, culture, ethics, and religion while the economic impact component covers cost-
benefit analysis, cost of application, cost of compliance with biosafety regulations, cost of new planting material and impact on trade.

The major phases in a GE product development that potentially represent regulatory decision points in a functional biosafety system are the laboratory, greenhouse, confined field trial, commercialization and post-commercialization stages. The central issue is to determine the stage at which to include socio-economic considerations since socioeconomic assessments could be ex-ante i.e. before the fact/event or ex-post i.e. after the fact/event. For biosafety approval processes, socioeconomic assessments tend to be ex-ante and therein lies a limitation regarding methods for assessment. Equally important is whether to have socioeconomic considerations inbuilt into the biosafety decision-making process or have a process that separates risk and socio-economic impact assessments but utilizes SIA before a decision is made (Falck-Zepeda, 2009).

REGULATORY COSTS

Risk and cost considerations bound biosafety assessments and biotechnology decision-making processes (Viscusi, Vernon, and Harrington, 2000). It is also noteworthy that the time value of money lost from regulatory approval delays tend to be greater than the cost of compliance itself (Bayer et al., 2008). The high cost of generating adequate data for regulatory purposes, maintaining functional biosafety regulatory structures, and ensuring regulatory compliance is well documented (Bayer et al., 2010; Bradford et al., 2006; Jaffe, 2005). In the specific instance of discovery, development and authorization of a new biotech crop or trait, the cost is estimated to be US$136 million (McDougall, 2011). A regulatory system must be established in a manner that it is workable, science-based, cost efficient, and does not compromise on acceptable safety standards. Only relevant regulatory data should be requested at any stage of the regulatory process and the regulatory structures and requirements should be efficient and commensurate with the level of risk posed by GEOs. Thus there is the need to clearly define data needs and establish acceptable data sources and methods of validation.

Most African countries and institutions lack the financial and technical resources for mandatory risk assessment and compliance monitoring. However, a false and detrimental premise in establishing regulations is the assumption that foreign multinational companies will be the only developers and users of the technology and will offset the high regulatory costs with profits from approved products. This assumption penalizes public institutions that are interested in applying GEOs that focus on crops and traits of national and regional interest. Many public research institutions in Africa have partnered with foreign public and private counterparts to undertake GE R&D activities, but the products of these initiatives never reach African farmers primarily because of the prohibitive cost of regulatory approval and the long delays associated with regulatory decisions.

An additional cost mitigation consideration would be the acceptance of regulatory food safety data from other countries and environmental data from regions with similar agro-ecological systems. If farmers and consumers in Africa are to benefit from improved planting materials, there is the need to build regulatory systems that are an incentive for investment.

Key issues that can lead to disagreement and stymie progress towards implementing functional regulatory frameworks include:
terminology differences; inconsistency with international obligations; inclusion of socio-economic issues; labelling of GE products; and choice of liability and redress regime. Considering that most African countries are parties to the Cartagena Protocol on Biosafety, consistency with provisions of the Protocol is of prime importance and consensus documents from the Protocol can be used to help establish harmonised regulations or processes.

CONCLUSIONS

Regulations are critical for the adoption of good science and for deriving benefits from modern biotechnology without compromising on safety to the environment and humans. For any human endeavour, the adoption of a technological innovation implies a certain amount of risk and managing this risk is an important component of decision-making. Ultimately, a regulatory decision has to be made, and the scientific assessment will have to be balanced against the cost/benefit analysis in risk management.

National biosafety regulatory systems in considering socio-economic issues should address definitional issues and spell out the decision-making rules and regulations upfront and these must be consistent with international obligations. Also needed is a clear indication of when and how “socio-economic considerations” will be analyzed and factored into the decision-making process. Designing a clear, adequate, fair, transparent, efficient and workable national biosafety system requires a significant amount of work and resources. Information exchange on best practices could be useful as a starting point. Currently no blueprint exists on how these issues should be addressed but then it is important for the national regulatory systems to note these challenges and fashion out a workable process that is agreed upon by biosafety stakeholders.

A thriving African bioeconomy within the global market place is possible if based on enabling biosafety laws and an ability to make timely and appropriate regulatory decisions. Functional regulatory systems that demonstrate government leadership in the technology, assure the public safety, ensure public confidence, facilitate public research and corporate collaboration, and promote investment by industry are needed to attain socio-economic goals such as achieving equitable distribution of income, improving efficiency of resource allocation, and protecting rights of ownership. The AU-NEPAD Agency’s African Biosafety Network of Expertise (ABNE) is partnering with other biosafety service providers to assist build functional regulatory systems in Africa. ABNE is achieving this goal by empowering African regulators and policy- and decision-makers by providing science/evidence-based biosafety information, technical assistance and training that will ensure the safe use and management of agricultural biotechnology and the effectual participation of African countries in the global bioeconomy.

REFERENCES


Africa urgently needs strategic repositioning in the modern era of technological advancement and bioinformatics.


McDougall 2011

Chapter 7. Biosafety regulatory systems in Africa

E. JANE MORRIS

INTRODUCTION

At the start of this chapter it seems logical ask the question “why does Africa need biosafety regulation anyway?” Biotechnology and biosafety go hand in hand, and countries cannot develop their biotechnology sector (at least insofar as Genetically Engineered Organisms (GEOs), alternatively known as Living Modified Organisms (LMOs) are concerned, without at the same time ensuring safety. However the majority of African countries are recipients of technology developed elsewhere, and have limited capacity to develop their own biotechnology products. This is starting to change, with Kenya, Uganda, Egypt and South Africa leading the way in biotechnology research, yet even in those countries no GEOs developed by local researchers have reached the stage of commercialization.

The wide range of available biotechnology techniques has only recently started to be taken up by African researchers. Although GEOs continue to attract attention, there are many other emerging technologies with relevance to Africa. These include not only more widely known techniques such as marker assisted selection and mutation breeding, but also new techniques such as RNAi, zinc finger nucleases etc. Biosafety regulation may be seen as a means to ensure governability of the technology, although the rapid pace of technology development threatens to leave the regulatory systems behind. Nevertheless, by managing the uncertain risks, the technology’s benefits for society can be realized (Todt and Lujan 2008). Regulation can also facilitate the process of technology selection, through comparative risk-benefit assessment to facilitate choice between alternative technologies (Morris 2011).

A HISTORICAL PERSPECTIVE

South Africa is probably the most advanced country on the continent in terms of biotechnology research, and was the first country in Africa to enact biosafety regulations. The factors driving this process are informative (Morris 1995). In the early days of genetic engineering, in 1978 an advisory committee known as the South African Committee for Genetic Experimentation (SAGENE) was established. Although this committee initially dealt with laboratory containment issues, its mandate was later widened to include environmental release. Applications for importation of genetically engineered (GE) seeds received by the Department of Agriculture were sent to SAGENE for consideration before permission for importation was granted. The first request for field trial approval of genetically engineered cotton was received by SAGENE in 1990, and a number of other approvals followed subsequently. The limitations of SAGENE became apparent when research on GE crops within South Africa developed to the stage where confined field trials were needed. As an advisory body, SAGENE had no power to make decisions. The Department of Agriculture could apply its plant and quarantine control legislation to imports, but had no power to regulate activities when importation was not involved. This led to a realisation that additional legislation was necessary. As a result of the political turmoil in South Africa there were some delays in developing new legislation, but the Genetically Modified Organisms Act (South African Department of Agriculture 1997) was finally passed and implemented in 1999 when regulations were published. The initiative to develop legislation came from scientists working in the field, who needed an appropriate regulatory environment to facilitate their work.
The South African situation stands in stark contrast to that of most other African countries. Much of the early push to develop biosafety regulations in those countries came through the development of the Cartagena Protocol on Biosafety (CPB) (Secretariat of the Convention on Biological Diversity 2000), amid concerns that developing countries would become testing grounds for novel and potentially risky substances that they had neither the capacity nor the regulatory frameworks in place to deal with (Gupta 2010). Although African policy makers expressed early concern over GEOs, these concerns surfaced in the public mind at the time of the food aid crisis in 2002 (Clapp 2005). African policy makers’ concerns were partially influenced by concerns in Europe over GEOs, as well as a mistrust of the motives of multinational seed companies. During the regional drought in Southern Africa at that time, African governments became concerned about the potential health, environmental and trade effects of importing food aid (Eicher et al. 2006). Biosafety legislation that was developed as a result of these pressures therefore tended to be preventative in nature; the Biosafety Act of Zambia (Government of Zambia 2007) and the Biosafety Proclamation of Ethiopia (Government of Ethiopia 2009) are extreme examples of this.

Some African countries have subsequently developed biosafety legislation in response to other pressures. Burkina Faso wanted to facilitate the local introduction of GE cotton to revive its flagging economy (Vitale et al. 2010), while countries such as Kenya, Uganda and Nigeria have been promoting their own development of biotechnology capacity and have been pushing ahead with confined field trials.

The availability of capacity-building funding from the Global Environment Facility (GEF) for developing countries to draft National Biosafety Framework (NBF) documents after the CPB entered into force in 2003, was another reason for countries to develop biosafety regulations, even though a number of these countries at that stage had little knowledge of, or interest in, biotechnology or biosafety. As discussed in the GEF evaluation report (GEF 2006), the CPB does not prescribe the immediate need for comprehensive legislation, stating instead:

- As an alternative to immediate development of a law addressing the “introduction of LMOs”, parties may decide to directly use article 10 of the protocol, adopting it by reference as an interim measure for implementing the protocol.
- As an alternative, to develop a streamlined decision-making process to address LMOs used as food, feed, or for processing (LMO-FFPs), parties may decide to directly utilize the provisions of article 11.6 of the protocol in the same way.
- Nevertheless the development of draft legislation was seen by most countries as an important component of their NBFs, even though this did not necessarily proceed further once the GEF funding was exhausted.

It is therefore clear that there have been many different underlying reasons behind the development of biosafety regulation in Africa, which at the same time have led to differing approaches to the issue.

**CURRENT STATUS**

A summary of the current status in each African country is provided in Table 1.
Table 1
Status of GM technology and regulations in Africa

<table>
<thead>
<tr>
<th>Country</th>
<th>Draft National Biosafety Framework</th>
<th>Enacted Biosafety Legislation</th>
<th>Draft Biosafety Bill</th>
<th>Biotechnology/biosafety policy</th>
<th>Approved GM laboratory research</th>
<th>Confined field trials</th>
<th>General Release Approval</th>
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<tr>
<td>Benin</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No (GM moratorium recently lifted)</td>
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Note: The information in this table is gathered from a multitude of sources, too numerous to cite. The data are correct according to the best information available to the author, but it is possible that there may be some minor inaccuracies.

As of February 2014, the only countries in Africa that have not yet ratified or acceded to the CPB are Côte d'Ivoire, Equatorial Guinea, São Tomé and Príncipe, and Sierra Leone. Also as of February 2014, there are 56 signatories to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (Secretariat of the Convention on Biodiversity 2011), hereafter termed the “Supplementary Protocol”, of which 13 are from Africa.

It is therefore clear that the majority of African countries are taking the CPB as the basis for their biosafety regulatory systems. In line with the requirements of the CPB, most African countries have adopted the Precautionary Principle (PP) in their regulatory systems, despite the many criticisms as summarized by Vlek (2010), who points to its inherent pessimism regarding uncertain risks.

**African Model Law on Biosafety**

The African Model Law (AML) embodies a strict view of the PP. The PP as framed in Principle 15 of the Rio Declaration (United Nations Conference on Environment and Development (UNCED) 1992), and adopted in the CPB text states:

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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.

The AML was first developed in 2001 but its contents have been controversial because of the strict nature of its provisions, which apply not only to living GEOs (i.e. LMOs) but equally also to the products of GEOs. In spite of this, the African Union (AU) and others have urged that the AML should be adopted as the basis of biosafety legislation by all African countries (Andanda 2009). In an attempt to gain greater acceptance of the AML, and to use it as a basis for harmonizing the positions of African countries on biosafety, there has been some attempt at revising the AML (African Union 2007). The most recent draft of the revised AML (African Union 2011a) however remains extremely strict, and goes far beyond the requirements of the CPB. Its provisions continue to apply equally not only to LMOs but also to sterile organisms and products of GEOs.

The revised AML also requires mandatory labelling of both GEOs and products of GEOs, including the relevant traits and characteristics of the organism. Taken to extremes, this would require not only segregation of GEOs from non-GEOs throughout the production process, but could also require segregation of different GE events in order to ensure that labels adequately reflect the particular traits that might be included in (for example) a cotton shirt.

The AML also addresses the issue of Liability and Redress, which has been the subject of intensive international negotiations resulting in the finalization of the Supplementary Protocol in 2011. The Supplementary Protocol applies specifically to “significant” damage, which is defined to include such items as:

a) The long-term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period of time;

b) The extent of the qualitative or quantitative changes that adversely affect the components of biological diversity;

c) The reduction of the ability of components of biological diversity to provide goods and services;

d) The extent of any adverse effects on human health in the context of the Protocol.

In contrast the revised AML makes no reference to the significance of any harm, and extends the liability to both direct and indirect effects.

However both the Supplementary Protocol and the AML “place the burden of proof on the claimant, meaning the more resources and knowledge a country has the more it will be able to apply the supplementary protocol effectively” (Komen 2012).

It can be unequivocally stated that the adoption of this strict AML will do little to stimulate the adoption of GEOs or the development of modern biotechnology within the countries concerned. As an example, the AML requires that experiments with locally produced GEOs must be carried out in “complete containment”, presumably Biosafety Level 4 – regardless of the results of any risk assessment and the fact that few if any countries in Africa have such facilities. The approach of the AML, although promoted by the AU, seems to be at odds with the report of the AU’s own High Level African Panel on Modern Biotechnology (African Union 2006) that “the AU should adopt the ‘co-evolutionary’ approach in which the function of regulation is to promote innovation, while at the same time safeguarding human health and the environment” and the recent support of African Ministers of Agriculture Science and Technology who endorsed the need “to take advantage of modern technologies such as biotechnology” (FARA Secretariat 2012).
The development of laws, regulations, guidelines or policies relating to biotechnology and biosafety is an ongoing process in many African countries. Progress has been documented at various stages, (Makinde et al. 2009; Mtui 2012; USDA 2011; Wafula et al. 2012; ABNE 2012, 2013, 2014). It is perhaps not surprising that the African countries have been a strong driving force in the development of the CPB (Egziabher 2007). The African Group’s position placed an emphasis on the likelihood that biotech products could result in social and economic dislocations in the global south (Andrée 2005), and hoped that a Biosafety Protocol could help mitigate these disruptions. There were also hopes that the CPB would place added burdens on countries exporting goods to Africa rather than on the receiving countries, hoping to “shift the burden of testing to the exporting countries” (Garton et al. 2006). Despite this, there has been a lack of political commitment to implement the requirements of the Protocol through the development of national legislation. It may be that many countries expected the international instruments of the CPB to remove their responsibilities at national level.

COMPONENTS OF A BIOSAFETY REGULATORY SYSTEM

For countries in Africa to have a workable biosafety regulatory system, the passing of a Biosafety Act or equivalent, or the modification of existing legislation to take account of biosafety issues, is just the start of a long process. The CPB does not require specifically that new legislation is introduced, but it does require some decision making processes to be put in place, which in the majority of cases lead to legislation. Capacity needs to be built at many levels. The NBFs developed under the CPB did make progress in setting the scene to a greater or lesser extent depending on the country, but were insufficient to ensure that a full regulatory system was in place. Obonyo et al. (2011) point out that in most African countries there are many gaps in expertise necessary to implement a workable biosafety regulatory system. Even in South Africa, the country with the most experience on the African continent, many of the issues highlighted below have not yet been fully resolved, leading to ongoing conflicts and uncertainties.

Some of the components of an ideal functioning biosafety regulatory system are discussed below.

National Policy

A national policy is required to frame a country’s unified approach to biotechnology and biosafety. Problems arise when one sector of government has a positive approach to the development of biotechnology (often led by ministries responsible for agriculture or science), whereas other ministries (often those responsible for the environment or trade) adopt a negative view. This has happened, for example in South Africa, where the Department of Science and Technology is responsible for the National Biotechnology Strategy (and the more recent Bioeconomy Strategy), while the Department of Agriculture administers the GMO Act, but the Department of Environment Affairs is responsible for the administration of the CPB, as well as for the National Environment Management Act (NEMA) and the National Environment Biodiversity Act (NEMBA) (South African Department of Environment Affairs 1998; 2004). NEMA and NEMBA collectively confer the ability to block the issuing of permits for release of GMOs applied for under the GMO Act. The diversity of approaches of different government departments leads to considerable uncertainty and can be considered partially to blame for regulatory delays and poor decision making (Janssen van Rijssen et al. 2013).

Legislation

Although some countries are operating with interim existing sectorial legislation (Wafula et al. 2012), the majority of countries in Africa are moving towards new biosafety legislation, with varying degrees of success. “Inexpertly drafted legislation that ....creates insufficient or legally uncertain permits and
processes, for example - may deter external investors and importers from future attempts to act within the country” (Global Environment Facility, 2006). Legislation comprises not only an approved Act governing biosafety, but also associated Regulations and Guidelines. The government ministry responsible for any new legislation must be agreed and confirmed, and that ministry is then responsible for drafting the Regulations that are required to bring the Act into force. It is not uncommon for there to be a delay of some years between the passing of an Act and its coming into force. The wording of the Act and Regulations should be aligned with the approach outlined in the Policy.

Administrative arrangements

Biosafety legislation is meaningless if there is no appointed body to administer the legislation, with appropriate resources at its disposal. There needs to be a central point where application forms are developed and disseminated, and where applications can be received and processed. The processes for handling applications, for receiving inputs on risk assessments, and for the final approvals and issuing of permits need to be defined. There also needs to be a clear mechanism by which applicants who are dissatisfied with the results of their application can apply for recourse, usually through an appeals process. There must be a central point where reports are received and evaluated, and where monitoring processes are undertaken to ensure adherence to permit requirements.

Risk assessors and agreed approach to risk assessment

Those involved in risk assessment are usually scientific experts who are independent from the decision-making process. In many African countries there is a scarcity of experts with the required expertise, but additional international expertise may be available if required. Experts should however be provided with a clear mandate and should follow an agreed methodology. The risk assessment may be undertaken with different perspectives, eg with the intention of complete risk avoidance (Townsend 2006), or through a risk-benefit assessment (Morris 2011). The comparative risks of alternative options for action need to be taken into account. An initial framing step can give direction regarding hazards and identified priorities (e.g. this is where discussions should take place regarding the importance of food security versus the importance of protection of biodiversity). The recommendations may be different depending on the context in which the assessment is undertaken. However the international context, and the country’s adherence to international regulatory requirements such as the CPB, should also be taken into account.

Risk managers and decision makers

Whereas risk assessors are usually scientists operating in an advisory capacity, eventually a decision has to be made as to whether the activity with GEOs/LMOs will be permitted, and if so under what conditions. This puts the burden of responsibility on to government officials. The relevant government officials therefore require training and need adequate support to give them confidence in making decisions. Lack of confidence on the part of government officials is usually reflected in ongoing requests for additional information, delays in issuing permits, or outright rejection of applications.

Extension services

Extension officers play a vital role in introducing the technology to the farmers and advising on “best practice”. They need to be trained in all aspects of the application of GE technology in order to ensure that farmers apply it to best effect. In many developing countries the extension system is unfortunately weak.

Agricultural inspectors
Agricultural inspectors are usually government employees, who inspect the process of growing and making of agricultural products. They can play a vital role in monitoring and inspection, provided they are mandated to do so and are appropriately trained to know what to look for.

**Risk communicators**

It is apparent that for any project involving GEOs to be successfully implemented, effective risk communication within the country is essential (Wangalachi et al. 2011). Communication and dissemination of accurate information appropriate to the audience is critical to reducing negative perception, building trust and winning public confidence in the technology.

**Customs officials**

Customs officials have an essential role to play insofar as the CPB is concerned, since its primary focus is on transboundary movement of LMOs. The five key roles and responsibilities of customs officers have been described as:

(i) ensuring that LMO imports and exports have proper approvals before they are cleared;
(ii) ensuring that LMO shipments are accompanied with appropriate documentation;
(iii) inspecting incoming shipments of LMOs to verify the actual content and cross-check them against the accompanying documentation;
(iv) detecting illegal or unintentional transboundary movements; and
(v) reporting to relevant authorities information concerning shipments of LMOs arriving at the ports of entry (UNEP 2009).

In most cases the roles of Customs officials will be confined to (i) and (ii) above, since the process of physical verification of actual content is time consuming and costly. If the importing country has accepted that certain GE events are permitted, then appropriate documentation is normally sufficient. Actual testing of shipments to verify the content requires clarification on (a) sampling techniques, (b) agreed threshold levels, (c) statistical significance, (d) labelling requirements (see below), (d) testing methodology and (e) procedures for dealing with stacked events. Experience to date in South Africa shows that most international shipments are accepted on the basis of accompanying documentation, and GEO testing facilities are not utilized to full capacity.

**Trained farmers**

For farmers to gain maximum benefit from GE seeds, they must also implement good farming practices. The currently available GE traits still require the use of good agronomic practices. Unfortunately where farmers are unable to access credit for purchase of fertilizers and other inputs, they may fail to reap the benefits of GE crops. Farmers need to understand the reasoning behind the biosafety requirements such as the need to plant non-transgenic refugia around pesticide-resistant crops to prevent the emergence of pesticide-resistant insects. Instances where there has been failure of insect resistance have been linked to lack of adherence to permit requirements particularly in the small-scale farmer environment (Kruger et al. 2009).

**Agreed approach on labelling**
Gruère and Rao (2007) point out the range of different labelling options, from voluntary labelling to
mandatory labelling of all processed products derived from GEOs. “Countries may require labeling for a list
of particular food ingredients or all ingredients that include detectable transgenic material; highly processed
products derived from GE ingredients, even without quantifiable presence of transgenic material; animal
feed; additives and flavourings; meat and animal products fed with GM feed; food sold at caterers and
restaurants; and unpackaged food.”

Threshold levels for labelling need to be established (do they apply to each ingredient, to each transgenic
event or to the food product as a whole?) and the content of labels needs to be specified. If the
requirements are to be enforced by testing, then only products with detectable and quantifiable traces of
GE materials or ingredients should be required to carry a label. But if the labelling requirements specify that
any product derived from GEOs will have to be labelled, despite the lack of detectable transgenic DNA or
protein, then document-based identity preservation systems that track or identify GEOs (or the lack of
GEOs) from their origin to their final packaged form will be required.

Bouet et al. (2010) demonstrated the negative effects on trade and food prices that would result from
introducing strict labelling requirements for LMOs intended for food, feed or processing. Strict labelling
would require that all shipments of LMOs are labelled as “does contain” LMOs and must be accompanied by
a list of all GE events present in the shipment. This would require testing of each shipment to verify the
accuracy of the list. Providing precise information on each shipment would have a significant cost
implication.

Involvement of multiple actors in the supply chain

Farmers, handlers, processors, distributors, and retailers all have to deal with the realities of GEOs in the
supply chain. These role players may have to make segregation decisions, with associated costs (Desquilbet
and Bullock 2009), based on regulatory requirements, labelling requirements and on market preferences
(organic or conventional, GE or conventional, etc).

It is clear from the above that it is not enough just to have legislation, but that all the role players need to be
in place to ensure that legislation can be effectively implemented within an overall policy framework.

DO BIOSAFETY REGULATORY SYSTEMS FACILITATE BIOTECHNOLOGY DEVELOPMENT?

The fact of having a regulatory framework in place is unfortunately not sufficient to ensure that
biotechnology development takes place or that biotechnology products are taken up by the countries
concerned (Kingiri 2011). In the majority of countries in Africa, GEOs developed by multinational companies
are likely to gain regulatory approval ahead of those developed through local technology, even though such
products were not initially targeted towards the African situation. Even where the regulatory framework is
intended to encourage local development, or implementation of internationally developed biotechnology
products, some ongoing barriers to implementation exist, as identified by Kingiri:

- Lack of ongoing funding to ensure regulatory systems are sustainable
- The need for integration of multiple actors with multiple agendas
- Limited access to credit to buy expensive GE seed
- Informal seed trade and possible breach of intellectual property rights
- Inadequate capacity to enforce regulations
- Inadequate inspection and monitoring capacity
- Lack of public awareness
Additional limitations identified by Timpo (2011) are:

- Limited human resources with expertise in biotechnology/biosafety
- Lack of access to accurate information
- Inadequate infrastructure
- Lack of viable seed industries
- Nascent public-private sector partnerships
- Weak linkages between industry and R&D institutions

These limitations pose a major concern to the development of biotechnology and biosafety in Africa, and need to be addressed through broad infrastructure development programmes within the region. Until these barriers are overcome, commercially available GEOs/LMOs are unlikely to be widely adopted by both large and small scale farmers. Nevertheless, there are considerable opportunities to enhance agricultural production in Africa, provided that both the infrastructural and regulatory hurdles can be overcome.

REGIONAL HARMONIZATION STATUS

It is generally recognized that regional harmonization of biosafety regulation is advantageous (Morris 2008). Although the main reasons for harmonization are centred around formal and informal trade issues, there are also a number of research initiatives involving development of GEOs that are being undertaken at a regional level and involve field trials in more than one country. Some of these were outlined by Thomson et al. 2010. They include African Biofortified Sorghum (ABS), Water Efficient Maize for Africa (WEMA), BioCassava Plus (BC+) (Adenle et al. 2012) and Virus Resistant Cassava for Africa (VIRCA) (Taylor et al. 2012).

At the level of the African Union (AU), there is a clear recognition of the advantages of regional harmonization, although there is also an acknowledgment of the complexities. The AU standpoint is laid out in the 2011 Biosafety Report document (African Union 2011b). In support of the AU, the African Biosafety Network of Expertise (ABNE) is an initiative established by the AU/NEPAD’s Office of Science and Technology to build functional biosafety systems in Africa (ABNE 2012).

In moves towards harmonizing biosafety regulation amongst trading blocs, there are a number of sub-Saharan African initiatives aimed at developing regional biosafety policies and guidelines. The West Africa Regional Biosafety Project is funded by the Global Environment Fund (GEF) and the International Development Agency (IDA). It forms part of the West African Economic and Monetary Union (WAEMU) Regional Program for Biosafety. This project has developed a draft regional biosafety regulatory framework, and national and regional consultation workshops have been held. There is an ongoing dialogue with the Economic Community of West African States (ECOWAS) and with the Interstate Committee for Reducing Desertification in the Sahel (CILSS) (World Bank 2012).

The Common Market for Eastern and Southern Africa (COMESA) has developed policies on commercial planting, trade and emergency aid in GEOs and a roadmap to guide development of national biosafety frameworks (Juma 2011; Wafula et al. 2012). These policies were developed with the assistance of USAID Program for Biosafety Systems (PBS) program, and following national consultations were endorsed at the fifth Joint Meeting of Ministers of Agriculture, Environment and Natural Resources in September 2013 (Chambers 2013).

Harmonization in the Southern African Development Community (SADC) may be more challenging, given the divergent positions of SADC members towards the technology (Mugwagwa 2011). At the sub-regional level, guidelines were drafted and adopted in 2003, through the SADC Advisory Committee on Biotechnology and Biosafety, but there appears to have been little or no progress towards implementation.
WHAT ARE THE INFLUENCES ON REGULATORY DECISIONS?

Although risk assessment is essentially a scientific process, African decision makers often take into account a broader range of issues including socio-economic considerations. A framework for decision support can be helpful to enable decision makers to take a wide range of risks and benefits into account in a structured way (Morris 2011).

The multinational companies such as Monsanto are often accused of influencing the regulators in Africa and elsewhere to adopt GE technology against their better judgement. This has been termed “regulatory capture”, which occurs when a state regulatory agency, created to act in the public interest, instead advances the commercial or special interests that dominate the industry or sector it is charged with regulating (Adams et al. 2007; see also the summary on Wikipedia http://en.wikipedia.org/wiki/Regulatory_capture). However even where the multinationals have played a significant role, such as in the adoption of GE cotton in Burkina Faso, the benefits to farmers and to the economy are apparent (Vitale et al. 2010). In South Africa, the economic benefits of GE maize and cotton have been analysed (Gouse et al. 2005; Gouse 2009) and shown to be positive overall.

Despite this evidence, many African countries are resistant to the idea of permitting activities with GEOs to take place in their countries. The danger of loss of exports to Europe has been frequently cited as a negative factor in such decisions, yet Paarlberg (2006) has demonstrated unequivocally that African countries cannot use the excuse of loss of exports to Europe as a reason to impose preventative GE regulations. He states that “by far the largest share of the possibly GE exports…go to other African states”. The potentially negative impact on intra-Africa trade has been cited as a rationale for harmonization of regulatory systems within Africa (Morris 2008). This emphasizes the need for African countries to establish their regulatory systems based on a clear policy towards GEOs. Gruère and Sengupta (2009) and Gruère and Takeshima (2012) have shown that unjustified threats from European or other importers who set GE-free private standards can have a significant influence on regulatory decision making. The lack of a well informed and rationally considered regulatory policy for GEOs can “potentially push policy makers to support irrational and likely detrimental decisions” (Gruère and Sengupta 2009).

It is to be hoped that in future more African regulators will support a rational approach to decision making based on much more than the “fear factor” which continues to dominate the debate and has led some countries to impose a complete GE moratorium.

CONCLUSION

While African countries continue the GE debate, the technology is moving forward. The definition of a “Genetically Engineered Organism” continues to develop with the introduction of some of the new technologies mentioned earlier in this chapter. Indeed, RNAi technology has already been adopted in the VIRCA project. It is imperative that regulators in African countries should not be seen to “bury their heads in the sand”, but should take the lead in determining the best way forward to enhance agricultural production and promote food security.

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