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Regulatory challenges for GM crops in developing economies: the African experience

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Abstract Globally, transgenic or genetically modified (GM) crops are considered regulated products that are subject to regulatory oversight during transboundary movement, testing and environmental release. In Africa, regulations for transgenic crops are based on the outcomes of the historic Earth Summit Conference held in Rio, Brazil two decades ago, namely, the adoption of the Convention on Biological Diversity (CBD) and the subsequent adoption of the Cartagena Protocol on Biosafety. To exploit the potential benefits of transgenic crops while safeguarding the potential risks on human health and environment, most African countries have signed and ratified the CBD and the Cartagena Protocol on Biosafety. Consequently, these countries are required to take appropriate legal, administrative and other measures to ensure that the handling and utilization of living modified organisms are undertaken in a manner that reduces the risks to humans and the environment. These countries are also expected to provide regulatory oversight on transgenic crops through functional national biosafety frameworks (NBFs). While in principle this approach is ideal, NBFs in most African countries are steeped in a host of policy, legal and operational challenges that appear to be at cross-purposes with the noble efforts of seeking to access, test and deliver promising GM crops for use by resource-limited farmers in Africa. In this paper we discuss the regulatory challenges faced during the development and commercialization of GM crops based on experiences from countries in Sub-Saharan Africa.

Keywords GM crops · National biosafety frameworks · Regulatory challenges · Regulatory policy · Sub-Saharan Africa · WEMA project

Introduction

The agricultural sector in Africa is a very important driver of the economy as it employs 65 % of the continent's labor force and accounts for 32 % of its gross domestic product. While the performance of this crucial sector of Africa's economy has appeared to improve from an average of 2.3 % per year in the 1980s to 3.8 % per year in the late 1990s, this growth is considered to be modest. Africa's current farm yields remain the lowest in the world due to a combination of constraints, some of which are historical and structural while many others are climatic and biotic in nature. African farmers, who are

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predominantly smallholders, make a living from small plots of family gardens, typically measuring <2 ha, on soils that have over the years become impoverished and in tropical environments prone to frequent drought, soil erosion and floods. Cereal crop yields in Sub-Saharan Africa have stagnated, averaging only 1 ton (t) per hectare over the last 40 years, while the meager harvests are further reduced by pests and diseases (Omanya et al. 2007). Farm inputs, such as chemical fertilizers and pesticides, are prohibitively expensive and are therefore hardly ever used at the recommended rates.

Addressing these problems is neither an easy nor a straightforward task. Rather, it is clearly a challenge which calls for a number of imperative actions that span macro-economic policy prescriptions and technological interventions, with the aim of ensuring the access of vulnerable rural populations to technologies that are able to catalyze adequate food production. For example, it is known that some technological applications can certainly raise farmers' yields, reduce excessive use of pesticides and other agro-chemical inputs, increase the nutritive value of basic foods and contribute to the development of elite crops adapted to tolerate drought, salinity and low soil nutrients. If smallholder farmers in Africa were to have easy access to these tools and products, their livelihoods would be clearly improved.

One such tool of modern biotechnology, i.e. genetically modified (GM) crops, offers the potential of raising agricultural productivity in developing countries, especially in those African countries that are currently reeling from the constraints outlined above. Elsewhere in the world, the adoption of biotech crops has progressively increased by nearly 100-fold since 1996 when GM crops first became available commercially, making modern biotechnology one of the most rapidly adopted technologies in history (James 2012). The estimated value of GM crop products in 2010 was conservatively estimated to be US$ 150 billion, and in 2012 alone, a total of 17.3 million farmers in 28 countries grew biotech crops on an estimated 170 million hectares (James 2012). Despite this impressive account of GM crops in industrialized and developing countries, efforts to roll out GM products in African countries during the past decade have noted little progress due to the number of monumental challenges associated with national policies, legislation and public concerns about the safety of GM products to human, animal and environmental health. We discuss these challenges in this paper.

Policy perspectives and challenges on GM crops in Africa

The advent of modern biotechnology, especially GM technology, was associated with the potential to resolve several agricultural constraints that range from inherently low crop yields to stress-related constraints caused by pests, diseases and drought, among others. Although the application of GM technology is hailed as a major success in many parts of the world, there are persistent concerns about the safety and ethical and trade-related aspects of GM products to consumers and the environment, necessitating the need for their regulation. In formulating a national regulatory policy for GM technology and GM food, countries often take into consideration both the opportunities presented by the GM crops and the potential risks associated with them. In Africa there are 55 nation states with diverse political persuasions, trade considerations and environmental interests. As such, Africa is characterized by a mosaic of national policy positions on GM technology, ranging from those which can be considered to be permissive to those which are more pre-cautionary and ultimately to those which are prohibitive to the adoption of GM crops (Paarlberg 2000).

Permissive policy approach on GM crops

Only a few African countries, inspired by potential benefits of modern biotechnology, have adopted GM crops without much equivocation. Of these, South Africa stands out as a classic example of a biotechnology leader in Africa (Department of S&T 2001). The first commercial cultivation of GM crops in South Africa took place in 1998, and by 2001 South Africa had adopted a National Biotechnology Strategy (NBS), a comprehensive policy framework formulated by government agencies that created incentives for the advancement of the biotechnology sector (Department of S&T 2001) with active participation of other government departments. Within the purview of the NBS, a commitment of more than US$ 300 million per year was made to finance a variety of biotechnology initiatives (Mugabe 2003). Not surprising,

South Africa is one of the four African countries that have commercialized GM crops. The total area of land planted with transgenic crops in 2012 stood at 2.2 million ha, making South Africa the only mega biotech country in Africa today (James 2012).

In spite of this impressive record of South Africa's official adoption of GM crops, not all cases of biotech crop development in South Africa have been smooth. For example, the development of the *Bt* potato took over a decade of investment in research and field trials by the Agriculture Research Council in collaboration with Michigan State University to demonstrate complete control of the target pest (potato tuber moth; Douches et al. 2008). However, to date, *Bt* potato has yet to be commercialized for cultivation in South Africa for reasons not related to product safety or agronomic performance (Douches et al. 2008). This demonstrates the urgent need for science-based policies in promoting GM crops in Africa.

Taking cue from South Africa and encouraged by the prospect of revitalizing its cotton sector to make it more globally competitive, Burkina Faso adopted a policy on biotechnology and biosafety through a Ministerial Decree in June 2004 that enabled the development of regulations and guidelines on biosafety. This step was followed by the enactment of the biosafety law in the National Assembly in early 2006. The law established L'Agence Nationale de Biosecurite (ANB) as the national competent authority on biosafety with a mandate to provide biosafety oversight, thereby fulfilling Burkina Faso's obligations as a party to the Cartagena Protocol on Biosafety. The ANB regulates activities on GM crops with the advice of governmental and inter-sectoral advisory committees, a function that has been successfully executed to date.

Burkina Faso is the only Francophone West African country with a fully functional biosafety regulatory system. After several years of field trials, the country approved the commercial growing of *Bt* cotton in 2008. However, in recent years, heightened by anti-GM lobby efforts, Burkina Faso was compelled to draft an amendment to its biosafety law ostensibly to strengthen the legal status of ANB and increase its autonomy. This move, which culminated in the passage by Parliament of the revised biosafety law in December 2012, almost brought into effect the application of strict liability and other restrictive provisions on potential damage arising from GM organisms (GMOs) were it not for the timely intervention of relevant biotechnology stakeholders. The official implementation of this law would have stifled the gains achieved to date in biotech R&D activities in the country had the initial demand by activists been allowed to take effect.

Precautionary policy approach on GM crops

A number of African countries are signatories to the Cartagena Protocol on Biosafety and thereby exercise a guarded and precautionary approach to the implementation of GM technology to ensure safety during the transfer, handling and use of living modified organisms (LMOs), with a primary focus on protecting biological diversity. This group comprises countries such as Kenya, Nigeria, Uganda, Ghana and Malawi which have in recent years moved forward to embrace research in GM crops, albeit in a highly cautious manner. While these countries believe that this approach addresses fairly the risk/benefit considerations associated with GM technology, undue precaution in handling GM crops has in some instances turned out to be an Achilles heel that has hampered progress in some of these countries. For instance, the recent precautionary measure in the form of a decision to ban GM food imports into Kenya is a move that appears to be manifestly dysfunctional in a country that adopted a national biotechnology development policy in 2006 and enacted a biosafety law in 2009. Similarly, in Uganda, where several GM crops have been field-tested in confinement for several years, advances in the biotechnology agenda are potentially at risk of stagnation if precautionary considerations fueled by the on-going sensational GM debate delay the passage of the biosafety bill that is currently in Parliament [Science Foundation for Livelihoods and Development (SCIFODE) Uganda; personal communication]. In both countries, several GM crops, including *Bt* cotton, GM cassava, transgenic water-efficient maize and GM banana (Uganda), among others, have been tested successfully in confined field trials (CFT). However, these GM crops cannot be commercialized due to the inherent regulatory problems outlined above.

Prohibitive policy approach on GM crops

A number of African countries have taken the extreme policy of either consciously or inadvertently positioning themselves to prohibit the adoption of GM crops. During the past decade, several countries are on record

for having declared bans or moratoria on GM crops and their products within their territories. In 2004, Angola banned imports of all GM food products, except for food which would only be imported in milled and other processed forms. The United Nations World Food Program, the World's major supplier of food aid, reported that the additional cost of milling had the consequence of discouraging a number of food donors and in effect left a sizeable hunger-stricken population without food aid (UNEP 2006). Two years earlier, Zambia had also banned the importation of all GMOs, citing concerns over their environmental impact and effect on human health even as millions of its population suffered from widespread grain shortage brought about by severe drought. The Benin Republic has maintained a series of 5-year moratoria against activities in GM crops, including R&D, since 2003. Unfortunately, this extreme policy position that merely sought to prohibit GM food imports and all other R&D activities in Angola and Benin Republic was based on perceived rather than practical risks to human and environmental safety. Such extreme policy positions have unintended consequences on the promotion of GM crops.

Some other African countries have adopted stringently protective policy approaches which inadvertently have had the consequence of curtailing research in the fields of modern biotechnology. The case of the strict liability and redress regulatory regimes that are currently enforced in Ethiopia, Tanzania and Togo serve to illustrate this point. In legal parlance, strict liability preassigns fault to a specific party and imposes absolute legal responsibility for an injury or damage on the suspected wrongdoer regardless of whether that party is at fault or has taken the necessary care. Ironically, these three countries are among those which have recently suffered adverse climatic conditions characterized by severe droughts—and where GM technology, such as the transgenic water-efficient maize being advanced through the Water Efficient Maize for Africa (WEMA) project, could be tested and deployed to mitigate the effects of drought on maize. Unfortunately, the WEMA project has been unable to conduct transgenic CFT in Tanzania since the inception of this policy in 2009.

Legislative challenges on GM crops in Africa

African countries, as parties to the Cartagena Protocol on Biosafety, are obligated to take the necessary and appropriate legal, administrative and other measures to ensure the safe transfer, handling and use of LMOs (SCBD 2000). There are two practical avenues for realizing this requirement. On the one hand, countries may elect to have the regulatory oversight for GM crops domiciled in their existing legislation, regulations and standards for plant quarantine, variety testing and release, with the introduction of certain amendments. On the other hand, a national regulatory system for GMOs could also be anchored on a completely new legislation with a defined scope and institutional framework for assessing and managing potential risks associated with GMOs. Both avenues are plausible provided they create a system that is functional and accords the country a protective regulatory oversight that optimizes the benefits of GMOs while safeguarding against any potential risk (UNEP–GEF Biosafety Projects 2005).

According to Jaffe (2004), the purpose of a national biosafety regulatory system is to scientifically assess the safety of genetically engineered (GE) organisms to humans and the environment, manage any potential risks and authorize the development and marketing of safe GE organisms and their products. To develop such a regulatory system, a government can use existing laws or develop new statutes. Any national biosafety regulatory system that is proposed, however, must not only be functional and protective but also comply with international trade standards that are evolving in recognition of the growing importance of GE organisms at the World level (Jaffe, 2004).

Nearly all African countries, like many other developing nations in the world, have chosen the route of promulgating new legislation as well as implementing regulations and standards for biosafety. For example, a GMO Act was first passed in South Africa in 1997 and amended in 2006, as was the biosafety law in Burkina Faso in 2006 and amended in 2012. Similar legislation has been passed in Kenya and Togo in 2009; and in Ghana in 2011, to name just a few. However, it must be noted that the promulgation of law is a time-consuming process that is often characterized by side-shows, such as political infighting and actions from numerous interest groups. In a number of African countries, these side-shows have often resulted in delays in adopting the law(s), thereby preventing the timely adoption of GM crops. For example, it took 10 years for Ghana to pass its biosafety legislation, and even to date this legislation

still needs the passage of complementary regulations to aid its implementation. In Uganda, a legislative process to pass a biotechnology and biosafety law that started in 2002 is far from over and is at the risk of stalling the planned commercial approval of GM cassava and *Bt* cotton. Even where legislative formalities are resolved, endorsement of the resulting law through a simple process of assent by the country's head of state can in some cases take years. A case in point is Nigeria, where the biosafety act has not yet received the presidential assent it requires to take full effect of the law years after it was debated and passed by the Upper and Lower Houses of Parliament [National Biotechnology Development Agency (NABDA) Nigeria, personal communication]. This has also stalled commercialization of relevant GM products in the country.

Challenges of institutional capacities for GM crops in Africa

While the existence of a conducive policy and legislative framework is necessary for the advancement of GM crops, both elements can only work when implemented through a matching institutional organization for handling and processing requests and permits related to their testing and release. Equally important are the capacities of the organization set in place for conducting science-based risk assessments to inform decision-making, including ensuring effective monitoring and inspections for compliance once approvals for GM activities are sanctioned. Indeed, a functional biosafety regulatory system does not stop its oversight once a GMO has been approved for confined testing or commercial release. According to Jaffe (2012), administrative systems for the biosafety of GM crops in Africa are still in their infancy. While most countries have established National Biosafety Committees (NBCs) and mandated these as the national competent authorities on biosafety, members of NBCs often work on an ad hoc basis, maintaining concurrent, full-time engagements elsewhere, such as university research positions, but convening for 1 or 2 days to review applications presented to the NBC. In Uganda, for example, all but one member of a team of 13 that constitute the NBC are fully employed in other organizations and only serve on the Committee on part-time basis. Similarly, in Nigeria, only two staff members run its biosafety office on a full-time basis, with all other members of the NBC working on a part-time basis.

This working arrangement, while at best the least costly approach, has never engendered the professional finesse expected to build public confidence in regulatory systems. Furthermore, the critical mass of scientists conversant with risk assessment considerations that can adequately inform decision-making on GM crop approvals remains low even in those few countries that have institutionalized regulatory oversight authorities, such as Kenya and Burkina Faso. Owing to this dearth of expertise in the critical areas indicated above, most approval decisions on GMOs tend to take inordinately long processes to be concluded and are sometimes premised on flawed risk assessment considerations. Africans, rather than being witness to the gradual emergence of functional regulatory systems, are often confronted with a number of dysfunctional national organs with inadequately trained staff that are under-resourced to deliver on their mandates.

To circumvent institutional funding limitations, some national regulatory systems have resorted to charging fees for the processing of applications and trial inspections. While this approach may provide (part of) the funding needed by such offices to function, such fees may be prohibitively high to the point of discouraging well-intentioned R&D efforts on GM crops on the continent, such as the case of an African student who was charged a fee of US$ 2,000 to conduct a CFT on a GM crop. In Burkina Faso, the national competent authority on biosafety charges an equivalent of US$ 10,000 as the fee for processing and issuing a permit to conduct a CFT for one season. This figure could easily assume monumental proportions if trials are repeated for three to four seasons as is currently happening with the on-going efficacy evaluations on *Bt* cowpea in Nigeria, Ghana and Burkina Faso (AATF 2011).

Challenges associated with regulatory compliance

Approval decisions on applications for field testing of GM crops are usually accompanied by a raft of recommendations to ensure compliance with the regulations. An important provision in biosafety regulations of some African countries is the mandatory 12-month period for post-harvest monitoring and removal of volunteer plants from the CFT sites. Experience from the WEMA project, a public–private partnership that is

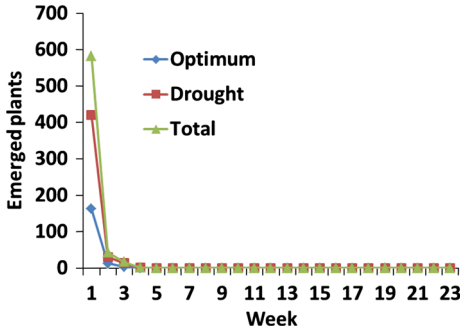

Fig. 1 Post-harvest monitoring of volunteer plants in drought-tolerant transgenic confined field trials at Kiboko, Kenya, 2010/2011

developing and testing drought-tolerant and insect-protected transgenic maize hybrids in countries of eastern and southern Africa (Kyetere et al. 2012), shows that this requirement places a great challenge on the effective use of project resources. For example, during multi-season evaluation of the efficacy of transgenic water-efficient maize, huge tracts of land would need to be opened up to allow for the compulsory 12-month post-harvest monitoring of volunteer plants at CFT sites as is required by the biosafety regulations operative in Kenya, Uganda and South Africa. During such monitoring, the entire CFT area is expected to be frequently watered to induce the germination of volunteer plants. Interestingly, this regulatory provision appears not to take into account the biology of the test crop, maize, which is not known to exhibit seed dormancy. For example, experience in conducting CFTs on the drought-tolerant trait (encoded by *CspB* gene) by the WEMA project in Kenya has shown that within 3 months, all maize seed volunteers would have germinated; consequently, volunteer plants do not require a further 9 months of irrigation and monitoring (Fig. 1). Such time and resources could be better targeted to other fruitful endeavors. However, the project has since requested for a waiver of this mandatory 1-year monitoring of volunteer plants from regulatory agencies in Kenya, South Africa and Uganda.

Public participation in regulatory processes for on GM crops

According to the provisions of the Cartagena Protocol on Biosafety, which many African countries have signed and ratified, a functional national biosafety framework should contain, among other components, mechanisms for capturing inputs and feedback from the public. To a large extent, this interaction with the public is an important demonstration of transparency and fairness in regulatory oversight and goes a long way towards enhancing public confidence in regulatory institutions. Quite a number of national regulatory systems, by law, solicit public views on applications for GM crop trials and release. However, such forums are often dominated, even hijacked, by sensational views from anti-GM lobby groups that have not helped matters other than alarming the public with falsehoods and scares. Rather than there being a dialogue between proponents and opponents of GM technology, a common spectacle is placard-waving anti-GM demonstrators picketing along streets or GM crop testing fields to denounce modern biotechnology, as experienced by the WEMA project in South Africa in 2010 and 2011.

Conclusion

National governments play an important role in ensuring that novel foods and products approved for commercial release are both safe for human consumption and non-detrimental to the receiving environment. The adoption of biosafety regulatory frameworks for GM crops is a challenging task since decision-makers are faced with numerous difficulties, including the ever evolving technological advances that can quickly render specific regulations obsolete. In view of this, countries and policy-makers tend to respond to such circumstances via a raft of measures, including legislative, institutional and/or policy-based strategies. In Africa, the tendency has often comprised the promulgation of new laws and establishment of new institutions to regulate GM technology—twin processes that are inherently time consuming and costly to operationalize. Public opinion on GM technology in many parts of the world, particularly in Africa, is still steeped in controversy. As a result, public policy on GM technology in many African states is laced with precautionary overtones. In these circumstances, regulatory regimes have emerged that implicitly assume that all GMOs present high risks unless proven otherwise, an approach which often requires inordinate amounts of information and data to be included in the safety dossier for regulatory clearance. This

regulatory premise has become a real challenge to the future development and adoption of GM crops in Africa, even when such crops—especially those with traits for tolerance to biotic and abiotic stresses—could immensely benefit smallholder farmers on the continent. Some analysts have rightly observed that setting regulatory safety standards on such an impossibly high threshold is a sure way of keeping GM crops from these countries, thereby depriving their farmers of the benefits of such technologies.

The on-going regional harmonization of biosafety regulations, when pursued vigorously, an improvement in regulatory capacity in terms of number and quality of the regulators and an enhancement of the interactions among technology providers/developers, regulators and the public could play a significant role in addressing some of these challenges to Africa and result in Africans benefitting from the potentials of modern biotechnology.

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