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Putting GM technologies to work: public research pipelines in selected African countries

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Can public policies and research institutions in African countries provide safe and useful genetically modified (GM) food crops? This is an urgent question, recognizing that advancing GM food crops can be difficult, affected by global debate, and various regulatory protocols. Reaching farmers has been achieved in several countries only for GM cotton for insect resistant while approvals for food and feed crops lag behind. To address this question, we identified and examined public research pipelines for GM crops in Egypt, Kenya, South Africa and Zimbabwe. Genetic transformation events are reported for 21 crops. Findings are presented for events nearing final stages of development, analysis of the crops, traits and genes involved, and details regarding biosafety. The paper concludes with a summary offering various policies, institutional and regulatory suggestions.

Key words: Africa, biosafety, biotechnology, genetic modification, public research.

INTRODUCTION

Over the past 10 to 15 years, scientists have applied new genetic technologies to a diverse range of crops. Many of these technologies hold promise for addressing productivity constraints faced by smallholder, resource-poor farmers. This is accomplished by transforming local or foreign (imported) plant varieties to provide new opportunities for socioeconomically diverse farming systems. Public institutes in developing countries, which rely to various degrees on national, international and private partners, lead this research.

Most studies regarding the impact of genetically modified (GM) crops have focused on commercial biotechnology products used primarily in four industrialized nations (Falck-Zepeda et al., 1999, 2000) [Genetic modification allows selected individual genes to be transferred from one organism into another, including genes from unrelated species. The technology can be used to promote a desirable crop character or to suppress an undesirable trait (Nuffield Council on Bioethics, 2003)]. This study focuses on GM crop pipelines from public research in 4 African countries: Egypt, Kenya, South Africa and Zimbabwe. It provides essential information regarding GM crops under development, status of biosafety approvals, implications of genes to be deployed, distribution of seed or improved planting material, and the range of partnerships available.

Currently, the number of GM crops that have been approved and are cultivated in the developing world is largely limited to insect-protected cotton in Argentina, China, India, Mexico, and South Africa. Virtually all of this improved seed is available from commercial providers, with the exception of China, where publicly developed seed is available as well (Huang et al., 2002). Growers in these countries include poor, smallholder farmers (Thirtle et al., 2003).

One reason why the approval and use of insect-protected cotton is widespread is that cotton is not a food crop, but rather used for fiber, oil and livestock meal. Consequently, most regulatory authorities in developing countries have found it easier to approve this crop because they are not required to assess food safety—an area in which few developing country regulatory authorities feel competent. The exceptions to this are South Africa and the Philippines where assessments have been conducted.

Much has been accomplished with the investments in public agricultural biotechnology research. A study was implemented to assess the state of publicly developed GM crops in 16 developing countries (Atanassov et al.,

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2004). [In this context, publicly developed GM crops are those developed by public or national institutes, including universities, agricultural research organizations, or biotechnology institutes]. This research shows for African countries, that 13 public institutions have stably transformed 21 crops, incorporating a wide range of genes for insect, fungal, viral, and bacterial resistance; protein and quality improvements; herbicide tolerance, and salt and drought stress.

However, the primary source of GM crops continues to be the private sector. Multinational companies lead in the development of GM technologies and, given the technology's market potential, have invested significant resources in facilitating technologies through regulatory processes. With the exception of cotton in China, public research products lag behind.

This study addresses these points by examining in detail GM food crops, with the inclusion of cotton since it is a valuable cash crop for some small-scale, resource-poor farmers, emerging from public research pipelines in Africa.

METHODOLOGY

This study highlights expectations and limitations on public GM crops and traits in Egypt, South Africa, Zimbabwe and Kenya, providing crop research data through 2003. To ensure that relevant knowledge, experiences, and insight were captured in the study, an expert survey approach was used. Given the fact that the development of biotechnology products is knowledge and resource-intensive, the survey was directed to pre-selected experts with unique expertise and knowledge due to their position and involvement in their countries. The study team analyzed the information and consulted further with scientific and research leaders in their respective countries. Collection of information was coordinated with key national research organizations. A methodology was developed for analysis.

Experts collected data across five categories:

1. Information Collection. Continent, country and lead institutes provided details on GM crop development. Table 1 shows the total number of events included in the final assessment for each country [For this study, a single, unique transformation event represents a combination of crop, transgene, lead research institute, and the specific country of origin, thus recognizing both the transformation event and its institutional context].
2. Description of crops under research, transgenes deployed, and the desired phenotypic trait. Crops were categorized and sorted following the FAOSTAT crop classification. Transgene data were gathered as specifically as possible for each gene, but in a few cases such detail was either not clear or listed as "confidential" (http://apps.fao.org/faostat/form?version=ext&collection=Production.Crops.Primary&Domain=Production&language=EN&servlet=1&axis=item&xsl=areareflist). Information was also collected for phenotypic trait expression. Where possible, detailed information at the gene level was obtained [Phenotypic traits were categorized as per USDA APHIS classification. "Phenotype/Phenotype Category - the nature of the introduced trait. Each is assigned a two-letter code which describes the category into which the trait falls, as determined by the Animal and Plant Health Inspection Service (APHIS)" See http://www.nbiap.vt.edu/biomon/datacat.cfm].
3. Types of genetic resources used for transformation were reported to determine whether a public institution or private firm developed these resources, and whether their origin was local or foreign (imported).
4. The relation between regulatory processes and GM research. To accomplish this, data were collected by regulatory stage, emphasizing the most advanced events possible. Four stages were used: experimental, confined field trial, scale-up, or commercial release. For experimental stage entries, experts were asked to identify only highly developed biotechnologies coming from laboratory, greenhouse, or glasshouse.
5. The type of collaboration developed (if any), and plans for dissemination of research outputs. Questions asked included the number of institutions involved, the type of collaboration developed and the plans for dissemination. The study team developed data collection and validation methodologies for information about specific countries, crops, and gene/technology combinations. This led to classification of data as unique transformation events[3]. Not all possible events are summarized here, as the study is designed to be illustrative of trends, not an attempt to capture each and every transformation event under testing or production in the participating countries.

Table 1. Number of transformation events by country.

Country	Number of Events
Egypt	17
Kenya	4
South Africa	28
Zimbabwe	5
Total	**54**

A very high standard for the laboratory/greenhouse stages was set, as we cannot account for all the technologies in the research pipeline, particularly before proof of concept has been presented. As such, the survey cannot measure the flow of technologies from one stage to the next, nor can it tell whether technologies are getting stuck in a particular stage.

PIPELINES FOR GM CROPS AND TRANSGENES EMPLOYED

To date, our research includes 54 transformation events from 13 scientific institutes in 4 countries (Table 1). These countries maintain an ongoing commitment to biotechnology research, supported by universities and agricultural research institutes with good laboratory and agronomic capacity.

Transformation events organized by crop groups are shown in Figure 1. While transformation of cereals predominates, there are significant numbers of transformation events for vegetables, roots and tubers, and sugar, with each group representing a fairly diverse set of crop species. The greatest numbers of transformation events are for: maize (17.0 percent), potatoes (13.0 percent), with sugar and tomatoes at (11.0 percent) each.

The percentage distribution of events by phenotypic groups is presented in Figure 2. Virus and insect resistance cover over half of the 54 events surveyed, and interestingly for Africa none of the traits were stacked.

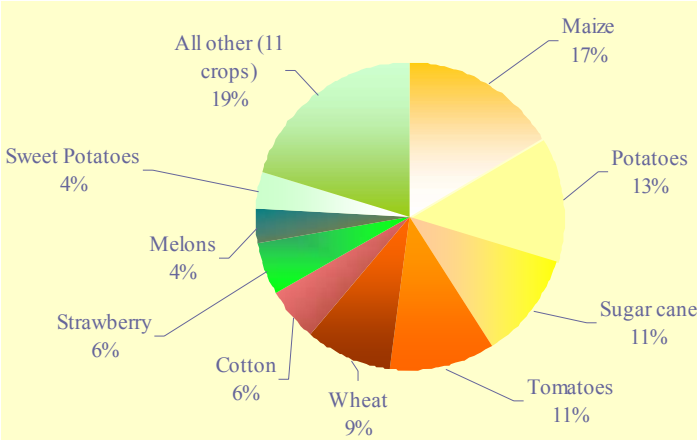

Figure 1. Transformation events distribution by crop groups.

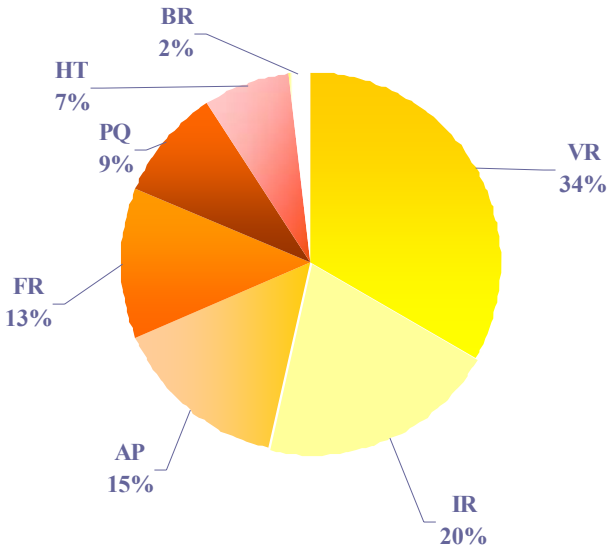

Figure 2. Transformation events distributed by phenotypic groups. **AP**- Agronomic Properties; **BR**- Bacterial Resistance; **FR**- Fungal Resistance; **HT**- Herbicide Tolerance; **IR**- Insect Resistance; **PQ**- Product Quality; **VR**- Virus Resistance.

ENSURING SAFETY IN THE FIELD

To examine the relationship between the transgenic events reported above and biosafety regulations for GM crops, the survey proposed a well-defined set of regulatory stages to classify each product, especially regarding field-testing and advancement. Respondents were asked to indicate in what stage of regulation their respective events were most accurately placed.

Events in the *experimental stage* contain stable research products derived from multiple generations, beginning in the laboratory and moving to the greenhouse or glasshouse. In this stage, the stable expression of the gene of interest is confirmed. In *confined field trials*, expression of traits remains stable in small-scale, single or multi-location confined trials. These trials are designed to mitigate any environmental damage by their containment, thus their regulatory standards are different from those established for subsequent stages.

The *scale-up* stage occurs when products advance from confined trials to pre-commercial trials, requiring the ability to increase seed amounts, and larger areas for testing purposes. These tests may be conducted for environmental safety purposes, efficacy trials, or both. Finally, products are made available to farmers only after *commercial release*, through privately- or publicly-owned seed companies or other institutional mechanisms.

The survey data show that a total of 38 events are at the experimental stage, while 15 are in confined trials, and 1 is awaiting a permit (Figure 3). South Africa is a clear leader in getting events into the field.

In all research pipelines, technologies or products are eliminated due to safety considerations or efficacy questions. However, in the case of GM crops, many countries have only interim guidelines or regulations in place, most of which do not allow for commercial approvals. Other countries, with commercial approval abilities, often lack confidence in their commercial decision-making. Such decisions are influenced by negative public opinion, pressure from anti-GM groups, and the current trade impasse over GM crops between the USA and Europe (Compés López and Carrau, 2002). There may also be physical limitations such as growers' inability to produce adequate seed amounts for large scale testing or for food safety testing.

Those events in the confined testing represent the most promising public research for GM crops (Figure 3). These

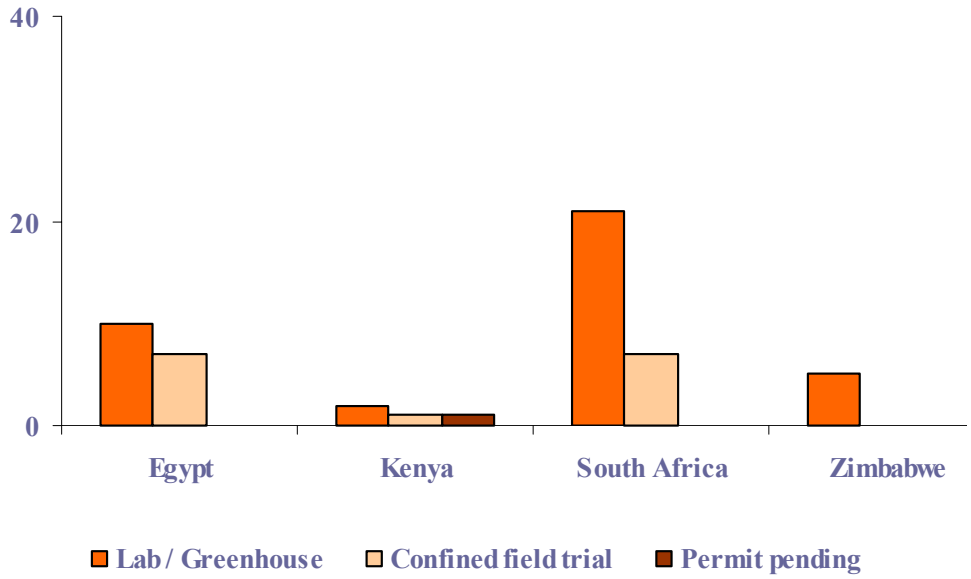

Figure 3. Number of public events classified by regulatory stage by country.

15 events will decline in number during their rigorous evaluation. However, the public sector cannot just monitor confined trials for safety and efficacy. It must also guarantee seed supplies to evaluate product performance on a large scale, and include experiments designed specifically for safety evaluation. Larger tests could be done in partnership with private seed companies or with government seed production facilities. To accomplish this successfully, events should be identified as soon as possible, based on the most reliable field trial data possible.

We do not know the number of initial transformation events required to reach the event records in Figure 3. Are the 15 events in confined testing, spread over many crops, traits and countries, sufficient to select superior GM material, increase seed, biosafety trials, and finally, advancement to commercial use? Implications of these numbers and ratios require analysis among participating countries and institutes. This would better allow institutes to assess their role from a development perspective and not for research alone.

SAFETY, REGULATION, AND REQUIRED ASSESSMENTS

The most important benefit of biosafety regulation is ensuring that biotechnologies deployed in a country are safe and effective. In addition, a well functioning regulatory system can instill confidence in the public that the risk assessment used to evaluate newer technologies, including biotechnologies, are science-based, as presented under Article 15 and Annex III of the Cartagena Protocol on Biosafety (Convention on Biological Diversity (CBD) Secretariat 2000). While the Protocol provides a unifying approach to biosafety, it also states that the cost of the assessment is borne by the notifier (Article 15).

For this reason, the study explores the benefits and costs of regulation, especially those relevant to public institutions providing GM crops in the developing world. These institutions have little combined experience as “notifiers” and are only just beginning to understand the safety costs associated with those required for research and development. As all participating institutes place safety paramount, they wish to understand costs to the notifier as well as to society. These may occur from opportunities lost if biotechnologies having a potentially high social value are not approved, and hence not able to provide its net benefits to society.

To initiate the exploration of safety and the costs of biosafety regulations, Kenya and South Africa were able to give basic estimates of costs they face as they seek to fulfill safety requirements while developing their specific technologies and crops (Table 2). In reviewing this data, some preliminary findings became apparent.

A study by Odhiambo (2002) estimated the cost for an insect resistant corn event in Kenya at US$ 160,000. The major component of which is the cost of containment structures. Quemada (2003) estimated that the total cost for the biosafety regulatory compliance of virus resistant potatoes in South Africa amounted to US$ 830,000.

Little data exists in African regarding food safety testing needed for regulatory approval. While there were not many examples of such tests, the need for food safety information, the policy and regulatory decisions affecting these requirements, and the severe lack of capacity for

Table 2. Preliminary estimates of average per year per event costs of biosafety regulations for two African countries.

Country	Average per year regulatory Cost per Event (Million US$)	Crops	Source
Kenya	0.16	Insect resistant maize	Odhiambo (2002)
South Africa[1]	0.83	Virus resistant potatoes	Quemada (2003)

[1]The data presented for South Africa is from a paper developed by Quemada (2003). Very preliminary data for South Africa was presented in the Next Harvest conference by Brink and Koch (2002). Estimate for South Africa's virus resistant potatoes are for the total regulatory span.

Table 3. Classification by gene group.

Phenotype Category	Gene group (as best could be described)	Transformation events (No.)	Sub totals
AP			**8**
AP	Drought tolerance	6	
AP	Salt Tolerance	2	
BR			**1**
BR	Antimicrobial peptides	1	
FR			**7**
FR	Glucanase, PGIP2	2	
FR	b32, PGIP2 (VOPI), and other selected anti-fungal genes	1	
FR	Chitinase	1	
FR	Glucanase, PGIP3	1	
FR	Grape resveratrol	1	
FR	PGIP1 and PGIP2 - isolated at VOPI	1	
HT			**4**
HT	Pat	3	
HT	EPSPS	1	
IR			**11**
IR	Bt	11	
PQ			**5**
PQ	Higher sucrose	2	
PQ	Nutritional	1	
PQ	Confidential	1	
PQ	Ethylene regulation	1	
VR			**18**
VR	Coat protein	15	
VR	Replicase	2	
VR	Antisense to TYLCV	1	
			54

AP- Agronomic Properties; **BR**- Bacterial Resistance; **FR**- Fungal Resistance; **HT**- Herbicide Tolerance; **IR**- Insect Resistance; **PQ**- Product Quality; **VR**- Virus Resistance.

such in developing countries was also discussed (Cohen et al., 2003). For this reason, among others, the Cartagena Biosafety Protocol envisions the need for capacity building among regulatory bodies as a central activity (CBD, 2001).

These estimates rely on the state of knowledge and the current biosafety regulatory system in the respective countries as presented during the first *Next Harvest* conference in 2002. As knowledge, experiences, and exchange of information continue to grow, increased familiarity with GM technologies will enable regulatory agencies to have confidence to reduce requirements, thereby decreasing the approval costs per event. Participants noted that there has been a shift of regulatory costs to earlier stages of the research process.

This fact highlights the need to rationalize GM research efforts by being more selective as to projects and numbers of events so that safety requirements can be completed. Participants also noted the importance of ensuring that the cost structure and level of regulatory processes are adequate to assure safety, while not hindering the development of potentially beneficial technologies.

PHENOTYPES AND TRANSGENES

Specific transgenes or gene groups were identified and classified according to the phenotype expressed. This allows comparisons of regulatory information available and expected for genes in wide use, or those that are more unique. The entire set of 54 events are grouped under 7 phenotypic groups, (Table 3) of which virus resistance has the highest entries with 18, followed by 11 for insect resistance, 8 for agronomic performance and 7 for fungal resistance.

Worldwide, there are primarily three gene groups with sufficiently robust utility and suitability for wide use, and those are *Cry* genes from *Bacillus thuringiensis* (Bt genes) that provide insect resistance, coat protein genes for virus resistance and thirdly those genes conferring herbicide tolerance. Interestingly for Africa, the first gene group consists of coat proteins of plant viruses used for virus resistance. The second group consists of Bt genes for insect resistance, and the third group consists of genes conferring agronomic performance. Most other gene groups and their associated phenotypic traits have not yet demonstrated robust applicability in the field. For example, no gene group has yet to confer effective fungal resistance, although much experimental activity has been spent on investigating the glucanases and chitinases. For Africa this group represented 7 entries alone.

Table 4. Distribution of phenotypic traits by country.

Continent	Crops (number)	AP	BR	FR	HT	IR	PQ	VR	Total
		Number of events							
Egypt	8	4		1		2		10	17
Kenya	2				1	2		1	4
South Africa	**7**	**4**	**1**	**6**	**3**	**5**	**5**	**4**	**28**
Zimbabwe	3					2		3	5
All	20	8	1	7	4	11	5	18	54

AP- Agronomic Properties; **BR**- Bacterial Resistance; **FR**- Fungal Resistance; **HT**- Herbicide Tolerance; **IR**- Insect Resistance; **PQ**- Product Quality; **VR**- Virus Resistance.

Similarly, no group of genes has been shown to reliably confer bacterial resistance in the field, even though many investigators have studied the effects of antimicrobial peptides, globally, and in Africa only one such event was recorded. While herbicide tolerance ranks third worldwide, it only ranked sixth for Africa, reflecting a totally different trend that might be linked to either the cost of the herbicides on the continent or indeed a cultural reason such as the fact that weeding is primarily carried out by women, and therefore few resources are devoted to this task. An emerging group of traits for Africa is drought tolerance leading at 6 events and 2 for salt tolerance. Thus, there is only limited success in developing crops with traits other than insect resistance, virus resistance, and agronomic performance. The large number of single gene approaches means that researchers are testing numerous alternatives to achieve traits of interest, which may lead to identifying utility of other gene groups. This trend could be a reflection of Africa's diverse ecology and culture.

One gene for product quality was labeled as confidential. Such confidentiality indicates that countries are becoming aware of the need to protect intellectual property rights in the earlier stages of development. These confidential genes could be publicly developed or received from the private sector under confidential agreements.

When developing country scientists use genes made available for research, licensed, or derived from collaborative research, greater amounts of data are available to enable regulatory decisions. The more unique the gene and crop used for transformation, the additional data that will be required during the biosafety review, as well as having fewer options to benefit from other sources.

Among the genes or gene groups listed below, the C*ry* genes, coat protein genes, and herbicide tolerance genes can be expected to move through regulation with fewer requirements for additional data. This is because numerous safety reviews have been conducted on these genes in several countries. However, this does not rule out the need for tests to address specific environmental, cultural or biodiversity concerns, as results of such tests may not be transferable from one country to another.

OTHER FINDINGS

By continent, researchers in four African countries (including North and Sub-Saharan Africa) completed 54 events. While research is underway in the 4 countries surveyed, with the exception of South Africa and Egypt, the rest of Africa is seriously lacking in capabilities and resources to consider such research (Alhassan 2003; UN ECA 2002), and in many cases, countries are just exploring the implications whether to consider research on, or import of, GM crops. Research capacity and potential markets are evolving (such as insect resistant cotton), albeit subject to uncertainties regarding the use and trade of GM crops.

As shown in Table 4 below, Egypt conducts research on the largest variety of crops, followed closely by South Africa. South Africa however has the largest variety of events, compared to Egypt. Bacterial resistance is the most limited, while the single most important group is the expression of virus resistance. As will be discussed later, such commonalities could lead to new forms of collaboration among neighboring countries, including new opportunities for exchanging transgenes and germplasm. The leading countries could help build capacity by providing training, shared experiences and enhance south-south collaboration.

South Africa presents an important case study. South Africa has devoted an appreciable amount of money to biotechnology research and development. Though the South African research program was relatively unfocussed in its early years, it has become more targeted and better coordinated with the enactment of the Biotechnology Strategic Plan and the BRICS (Biotechnology Research Innovation Centers), and under the pressure of reduced financial support for research in the Agricultural Research Council.

Furthermore South Africa's requirement that research proposals be linked to industrial applications or development partners is ensuring that agbiotech products are developed with relevance for end-users. More recently, the government initiated a three-year program to improve Public Understanding of Biotechnology (http://www.pub.ac.za/) that promotes informed decision

making among the population (Koch, personal communication 2004). South Africa has an established biosafety process that reviews all activities with GMOs and has recently ratified the Cartagena Protocol on Biosafety.

While South African research was somewhat unfocused in its early years, the research reported here for Egypt appears focused and clearly targeted for key crops, and a whole variety of traits being exploited. A large number of products are in advanced trials. Egypt has clearly benefited from the collaboration with the private sector as well as the Agricultural Biotechnology Support Program in phase I (ABSP I).

Zimbabwe has a highly developed seed sector, a functional biosafety regulatory system that should lend itself well to the arrival of GM technologies. Zimbabwe has signed the Cartagena Protocol on Biosafety and the ratification process is well underway. The country however does not have a clear policy on GMOs, although plans are underway in the legal fraternity to mount a national policy dialogue on the subject.

Establishment of a fully functional biosafety regulatory system in Kenya is well underway. In recent years Kenya has enjoyed excellent partnerships on several different fronts, including the hosting of the African Agricultural Technology Foundation (AATF) a foundation established to broker royalty-free technology transfer from the private sector to research institutions and resource poor farmers in sub-Saharan Africa, as well as the launch of a Center of Excellence, the Biosciences Center for East and Central Africa (BECA) under the New Partnership for African Development (NEPAD). Collaboration with both Monsanto Company for the virus resistant sweet potato and with the Syngenta Foundation on the insect resistant maize for Africa (IRMA) has brought much needed capacity to the Kenya Agricultural Research Institute (KARI). These projects have helped Kenya build strong capacity in biosafety reviews and infrastructure.

The presence of a functional seed development and delivery system cannot be overemphasized. In many African countries, such stable, market-oriented, and seed distribution networks barely exist, or do not exist at all, creating almost sole dependence on the public sector for agricultural innovation. This is especially true for countries not allowing import, testing and possible approval of commercial transgenic crops. With sole dependence on public sector, and no ability to import GM crops for testing, farmers stand to lose in many different ways.

SUMMARY

Will policies and research in the developing world stimulate the safe use of publicly developed GM food crops? We addressed this question with an analysis that takes readers from North to South on the African continent, and from genes and crops used for transformation. To do so, the paper summarized information for GM crop research conducted by public research institutes in 4 African countries. This information will help scientists, policy makers, and regulators understand their respective countries' public GM research and help address the question above. Further analysis—more in-depth and specialized examination of the key issues— will be conducted in direct consultation with the participating countries.

Research institutes covered in this study demonstrate capabilities across 21 plants, several different phenotypes, and the ability to use transgenes together with available genetic resources. In so doing, scientists have harnessed an assortment of genes in pursuit of traits relevant to farmers. Some have also gained familiarity with regulatory dossiers as needed for biosafety determinations. The range and diversity of these crops is wide, exceeding that carried out through international programs. However, desired phenotypes are few when compared to traits being developed by multinational firms or advanced research institutes in industrialized countries (Nuffield Council on Bioethics, 2004).

The public sector is a viable, but largely unproven, player in the bioengineering of local crops. While on the policy front, regulatory systems and policies have been under development for over 10 years in Africa. Some of these systems have already conducted biosafety assessments, and have determined which crops are acceptable for trials and use. However, even with this progress, regulatory decision-making remains complicated, affected by conforming to the Cartagena Protocol for Biosafety, and, are subject to delays or moratoria. The fact that there are approximately 39 percent of the 38 events in various phases of confined testing indicates opportunities for advancement of public sector research products. However, the longer the waiting period, the more likely the trait and or germplasm becomes ineffective as disease pressures change and more productive varieties are released.

The need for "single window" approaches for regulatory authorities and committees was noted to minimize time delays for approvals, thus making public sector research more efficient (Atanassov et al., 2004). Limited human resources also mean that, in certain cases, the developers of the technology are also the regulators, raising questions of conflict of interest which could further cloud the issue of acceptability and transparency.

A combined policy/institutional issue also arises for public GM crops because so many institutes work alone, without research or development partners. The data and analysis presented here can reduce such isolation by finding commonalities among crops, genes, regulatory stages, and collaboration. With this information, private firms and public research institutes can pursue greater collaboration based on these commonalities and

complementarities.

Moreover, this information can be used to organize greater South-to-South collaboration, a mode of partnership that does not presently exist in any appreciable quantity. Greater South-South collaboration will provide one more way to strengthen inter-institutional research and experiences. This can occur by building on common approaches, genes, and stage of regulatory trials and required safety information.

The information reviewed in this study can also inform readers of parallel research in their own country, in other regions, and internationally. This can be valuable when selecting transgenes, considering regulatory requirements, and genetic resources available, or needed.

Building on these new opportunities to strengthen public GM crop research and exchange experiences, does not mean that all decisions are in the researcher's hands alone. Rather, it is a process involving several policy dimensions concerning the regulatory system, the political and trade environment, the management of development opportunities and partnerships, and keeping in constant dialogue with farmers to address their needs and the needs of specific communities.

However, all of these events and policies can also be used against the very technologies they are there to evaluate and to advance once proven. Delays can mean rising costs, lack of impact at the rural level, regulatory requirements in need of clarification, and more direct accountability. Such concerns are emerging issues in developing countries. The combined effect is delayed impact and uncertainty of the technologies, both of which are used by biotechnology's detractors nationally and internationally.

We have recognized policy, political and institutional changes where efficiencies could be gained, while supporting the need for safety and efficacy testing of GM crops. A combination of these changes and farmer testing of products from public research means a rapid assessment of success or failure. Clearly immense progress has been made on all fronts; but efforts are still needed to ensure that polices and institutes in the developing world stimulate the safe and relevant use of these new technologies for the poor.

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