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Commercialization of genetically modified crops in Africa: Opportunities and challenges

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Genetically modified (GM) crops offer potential for enhancing agricultural productivity for smallholder farmers in Africa. After nearly three decades of research and development collaboration and regulatory capacity strengthening, several countries in Sub-Saharan Africa (SSA) are moving towards commercializing GM crops for the benefit of smallholder farmers. South Africa approved genetically modified (GM) cotton, maize and soybeans in the 1990s. Nigeria, Ethiopia, Kenya, Sudan, Eswatini and Malawi recently approved general release of GM crops, including GM cotton, GM cowpea, GM maize, and GM cassava through public-private partnerships. Collected data from a diverse group of 30 stakeholders from 14 countries in Africa and results indicated that while progress has been made towards commercializing GM crops in several countries in Africa, some key challenges and downstream issues remain to be addressed. These include building functional regulatory systems, vibrant seed systems, local seed production, effective extension services, reliable credit/financial and marketing services, and improved access to markets for smallholder farmers. Unless these downstream issues are effectively addressed, smallholder farmers in Africa will not benefit from GM crops.

Key words: Agricultural Biotechnology, genetically modified crops, commercialization, technology transfer, technology deployment, Africa.

INTRODUCTION

Advances in modern biotechnology such as genetic modification and genome editing offer new opportunities for improving crops and enhancing agricultural productivity worldwide. In 2018, about 17 million farmers, 95% of whom are smallholder farmers, planted 190.7 million hectares of GM crops globally (Noisette, 2021). In Africa, several countries are now commercializing GM crops that are appropriate for African farmers and farming constraints. South Africa was the first African country to enact a regulatory framework that allowed GM crop cultivation, import and export. South Africa is the largest GM crop producer (2.7 million ha) in Africa, followed by

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Sudan (243,000 ha), Ethiopia (1,300 ha in 2021), Eswatini (250 ha) and Kenya (1500 ha in 2021) (Silas et al., 2022; USDA, 2020; ISAAA, 2018). To date, the governments of 12 countries in SSA have a functional biosafety regulatory framework. The governments of seven countries - Ethiopia, Eswatini, Kenya, Malawi, Nigeria, South Africa and Sudan - have approved the general release of GM crops (Turnbull et al., 2021; Gbashi et al., 2021).

Currently, there are 13 GM crops in different stages of research and development in 13 African countries, with 13 different traits (ISAAA, 2018). Cotton (*Gossypium* spp.), maize (*Zea mays*), cowpea (*Vigna sinensis*), rice (*Oryza sativa*), sorghum (*Sorghum bicolor*), potato (*Solanum tuberosum*), sweet potato (*Ipomea batatus*), cassava (*Manihot esculenta*), banana (*Musa sapientum*) and sugarcane (*Saccharum officinarum*) are either being tested in confined field trials (CFT) or are approved for general release (Akinbo et al., 2021). Since 2018, four countries have initiated commercial production after approval for general release (ISAAA, 2020): Ethiopia (Bt-cotton), Malawi (Bt cotton), Kenya (Bt cotton) and Nigeria (Bt cotton and insect resistant cowpea). Burkina Faso and Egypt, both earlier adopters of GM crops, faced challenges after commercialization and suspended production. In Burkina Faso, Bt cotton commercial production was suspended in 2016 due to fiber quality. Egypt suspended production of GM maize through a Ministerial decree in 2012 (Turnbull et al., 2021) over concerns about trade with the EU.

Overall, close to three million hectares of GM crops were planted across Africa in 2021. Despite considerable global advancement of GM crops, progress in commercialization in Africa has been slower than expected (Gbashi et al., 2021; Azadi et al., 2015). After nearly three decades of safe use of GM crops and documented benefits for smallholder farmers (Kouser and Qiam, 2011; Bennett et al., 2006), governments of many African countries are still debating and delaying the use of GM crops.

Numerous reports from health and environmental safety research have confirmed the safety and benefits of GM crops and their derived products (Gbashi et al., 2021; Oloo et al., 2020; Bayer Crop Science, 2020; EU Report, 2010; ISAAA Biotech Update, 2010). Such scientific evidence has not removed lingering public perception and controversies about the environmental and food safety concerns of GM crops (Mbabazi et al., 2016).

Public safety concerns have limited GM crop development, and there are many other barriers to commercialization of already approved products. After CFT, which focus on event selection and regulatory data collection, GM cultivars, like conventional cultivars, are subject to further evaluation through national performance trials (NPTs) and verification studies to meet national cultivar release requirements (Akinbo et al., 2021). National research programs, biosafety authorities and other regulatory agencies work in parallel to evaluate safety and performance results, complete risk assessments, release and register GM crops.

After safety approval and cultivar registration, the roles of regulators diminish and commercialization processes become the focus. The private sector, seed systems, extension systems and business methods function to deploy new GM crops and this transition to commercial deployment is complex and rarely smooth. In Africa, commercialization needs to take into account the prevalence of an informal seed sector, the importance and needs of smallholder farmers, the role of the public sector in producing and supplying improved planting material and extension services, and how the private sector will work alongside these systems. Additional commercialization responsibilities for GM crops must be addressed, including the promotion of new products, obtaining wider acceptance for GM technology, ensuring farmer access to sustainable new products, maintaining product quality and responsible introduction through stewardship.

Roadmap for commercialization of GM crops

Since the first field trial of a GM product in South Africa in 1989, progress has been made on the adoption of biotechnology products. In Africa, the number of laboratory and field trials for product development has increased reflecting scientific optimism for the benefits of the GM crops in the midst of prolonged controversy surrounding modern biotechnology (Waithaka et al., 2015). Along with product development and commercialization, product stewardship is implemented across the process to support the responsible release of safe, innovative GM products (ETS, 2017).

Bringing a conventional or GM crop cultivar to market requires many years of systematic development, testing, and selection. Private and public sector developers apply stepwise review and decision-making processes to monitor the development of new products and to ensure that only good events are moved through to commercialization and into the hands of farmers. These roadmaps for product development and commercialization ensure that important considerations are investigated at each step of development (Cooper, 2006). Re-evaluation takes place at the end of each development step for each product. This reevaluation includes a review of product performance, business fit with existing strategy goals, marketing plans, intellectual property management and licensing, regulatory requirements, product stewardship, and the commercialization strategy.

Input on each of these areas informs the Yes/No decisions that are essential for effective product

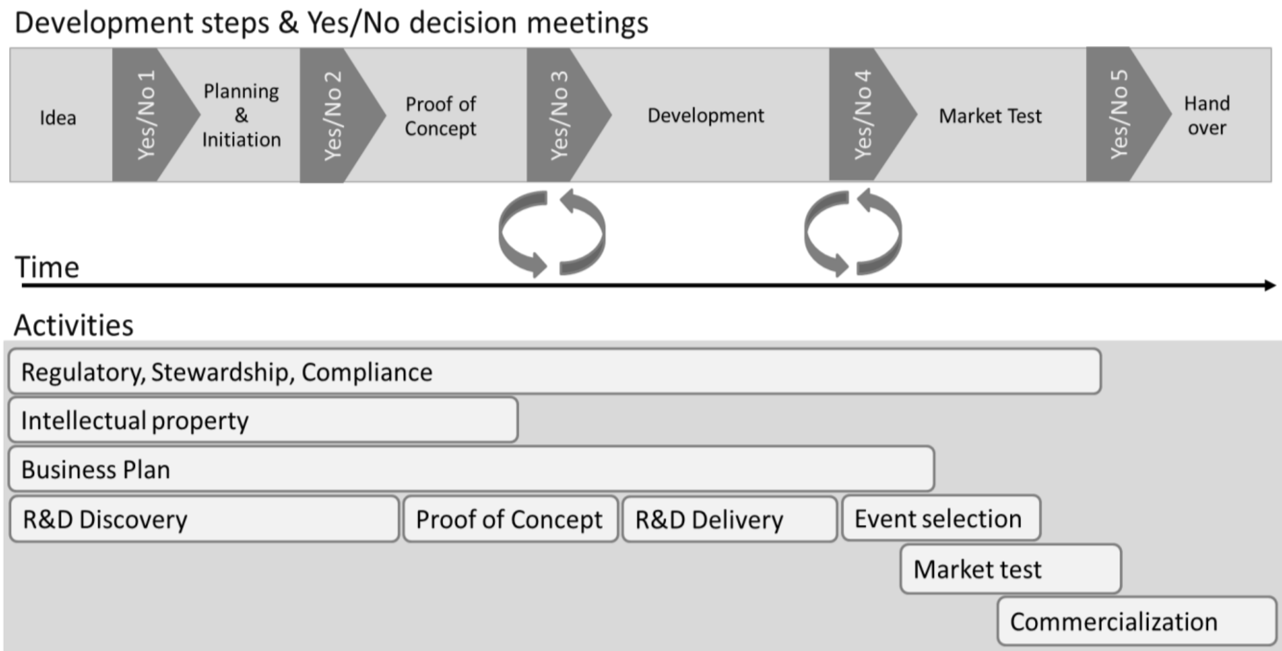

Figure 1. Outline of a product commercialization process for a GM plant cultivar.

development (Figure 1). At all the decision meetings, the product data are reviewed and a decision is made on whether to continue or halt the development of the product. Sometimes a decision to continue may include a step back to repeat and address certain activities that will help ensure the quality needed for a successful product.

Successful commercialization of a GM cultivar requires a well-planned strategy with input from experts in a wide range of fields such as agronomy, molecular biology, entomology, pathology, plant transformation, biochemistry, food science, legal, regulatory, stewardship, seed production, communication, business, marketing, economics, environmental sciences and social sciences. Coordination of the steps and expert input requires effective project management and clear criteria for the decisions that are taken at each step in the development process. Missing one area of expert input or indecisive decision-making at any one stage can lead to costly oversights and a considerable waste of money and time. In general, the process outlined in Figure 1 takes 10 to 15 years and can cost upwards of US$ 50 million for a new GM cultivar depending on the crop, traits, technology, markets, and efficiency of the regulatory approval processes.

Since GM crop commercialization in the mid-1990s, enhanced capacity for regulatory compliance and product stewardship became critical to help ensure safe and sustainable use of biotechnology products. Effort was made in some countries to establish research and development capacity, which are lacking in most countries in Africa. Stakeholders have identified several factors causing delay to commercialization of GM crops, including socio-economic constraints, high cost of technology or seed, fear of corporate monopolies contrasting with weak private sector involvement, and inadequate awareness of best practices for commercial release of new planting material (Mbabazi et al., 2020; NASAC, 2015, in preparation). The need for stronger public-private partnerships in research, product development and product commercialization has emerged as a key success factor for commercializing GM crops in developing countries (NASAC, 2015).

Weak seed systems and weak financial/credit systems can also limit farmer access to technology and new products. A recent study on Bt cotton hybrid seed access by African farmers indicated that weak coordination among various stakeholders along the seed value chain exacerbated the problem of sustainable supply and hindered wider utilization of the approved GM crops (Mbabazi et al., 2020; Alhassan et al., 2018). Stakeholder lack of awareness, inadequate demonstration of new technology to farmers and poor handling of the new technology by farmers, including poor extension systems all contributed to slow commercialization of improved planting material (Turnbull et al., 2021; Mbabazi et al., 2020). More efforts are needed to establish partnerships at national, regional, and international level to bridge the knowledge gaps in research, regulation, extension, commercialization, communication, marketing and trade (NASAC, 2015).

Table 1. Participants of biotechnology and biosafety and food safety courses who were surveyed for this paper.

Country and participants (number)	Affiliations[1]			
	Regulatory	Academic	Research	NGO
Burkina Faso	2			
Cameroon	1			
Cote D'Ivoire		1		
Eswatini	4	2	2	
Ethiopia	7		4	
Ghana	15			2
Kenya	2			2
Mali	1			
Mozambique	3			
Niger			2	
Nigeria	7			
Rwanda	3			
Senegal	3			
Togo		3	1	
USDA-FAS[2]	7 participants from USDA in 7 countries			

[1] "Regulatory" includes regulators, policy makers and lawyers.[2] USDA-FAS = United States Department of Agriculture, Foreign Agriculture Service.

This paper reports on stakeholder assessment of the support needed for successful access to and utilization of GM crops in Africa.

METHODS

We collected four sets of data from 74 African stakeholders (including 7 USDA country representatives) that attended two Michigan State University (MSU) international short courses in 2021: (1) a pre-course survey using semi-structured questionnaire, (2) an 'end of course' evaluation, and (3) in-course enquiry from course 1, and (4) in-course enquiry from course 2. The two courses were on agricultural biotechnology and biosafety and food safety. Countries represented and number of participants is shown in Table 1. In the two courses, participants represented a diverse group of stakeholders including regulators, policymakers, scientists, academic specialists, lawyers and representatives of non-governmental organizations. The questionnaire was distributed prior to the start of the course to 30 participants of the first course for participants representing 14 countries from Africa: Burkina Faso, Cameroon, Cote D'Ivoire, Eswatini, Ethiopia, Ghana, Kenya, Mali, Mozambique, Niger, Nigeria, Rwanda, Senegal and Togo. The survey included questions on biotechnology, biosafety, regulatory needs and commercialization of biotech crops.

The survey questionnaire had 100 questions containing multiple choice answering options where respondents replied choosing "Not important", "Somewhat important", "Very important"; or "Strongly disagree", "Somewhat agree", "Strongly agree" based on the situation in their respective countries. Specific questions were related to challenges, concerns, commercialization, public perceptions, personal experiences and other issues pertaining to biotechnology and biosafety.

The pre-assessment survey questionnaire was supplemented with written and oral enquiries and end of course evaluation questions (160 questions) raised by stakeholders that attended the short courses. The questions were recorded and categorized into representative themes: product development, regulation, technology transfer (including IP, licensing, scaling up, seed systems), communication and outreach, public acceptance and trade to understand stakeholders areas of concern. The information included in this paper is part of a needs assessment survey on biotechnology and biosafety development, level of awareness of advances in the biotech product commercialization and genome editing technologies in developing countries, as well as the challenges faced and capacity building needs for commercialization and adoption of GM crops.

RESULTS

The survey assessed stakeholders experience with GM products and found that 96% of the 30 respondents have some level of awareness about GM crops. Most of the respondents (84%) had some level of awareness about genome editing (Table 2). About 54% recognized they had consumed food containing GM products and a third (35%) did not know if they had ever consumed any GM food product. Asked if there is a delay in commercialization of GM crops, most agreed (85%) that there was an undue delay in commercialization of useful GM crops in their countries. The results reflect the high anticipation of stakeholders for biotech progress in their home countries. Stakeholders also showed optimism towards improving public perception and attitude towards GM crops.

Stakeholders' understanding of issues that delay wider

Table 2. Stakeholder awareness of agriculture R&D and their assessment of public perception towards GM crops in Africa.

Attribute	Responses		
	Yes (%)	No (%)	Don't know (%)
Engagement in agriculture R&D	68	32	0
Awareness of GM crops	96	4	0
Awareness of genome edited crops	84	16	0
Consumed food containing GM content	54	12	35
Presence of delay in GM crop adoption	85	15	0

Table 3. Stakeholder perception of issues that delay adoption of GM crops in Africa.

Issues causing delay	Strongly agree (%)	Somewhat agree (%)	Strongly disagree (%)
Lack of access and availability of new technology	82	9	9
Lack of information	81	5	14
Lack of marketing	77	18	0
Lack of political will	68	18	9
Food safety concerns	67	19	0
Cost of technology/seeds	65	15	5
Poor regulation	59	13	18
Environmental safety	59	23	9
Absence of distributors	57	24	10
Lobbying by GM opponents	52	14	10
Trade concerns and loss of market access	38	29	10
Farmers lack of interest	27	27	46
Technology not promising	25	20	35

adoption of GM crops is an important consideration of the assessment (Table 3). Most stakeholders agreed that lack of access and availability of GM crops (82%) and lack of information and awareness (81%) contributed most to delayed adoption of GM crops. Other issues such as political will (68%), safety concerns (67%) and costs of seeds (65%) are among the key bottlenecks that participants agree are challenging expanded use of GM crops. Only a few stakeholders strongly believe the delays in adoption were due to unpromising technology (25%), or low interest from farmers (27%).

Stakeholders identified key global issues that likely influence the adoption of modern biotechnology in their home countries (Figure 2). The stakeholders' responses indicated that most (80-84%) agree food security and climate change are critical drivers for adoption of modern biotechnology in Africa

The assessment also showed that top ranking causes of favorable attitudinal changes in the context of future acceptance of GM products by public would include, among others, scientific advancement (77%), better public awareness (74%), rising demand for food feed (67%), impacts of climate change (65%) as well as experiences from GM-adopting countries (65%) (Table 4).

Most stakeholders agreed the barriers for GM crop adoption come from socio-economic, ethical and socio-political concerns (76%), environmental concerns (62%), GM opponent pressure (61%) and perceived food safety and health concerns (57%). Participants identified these as likely reasons for slow adoption of GM crops and weak public acceptance (Table 5).

Analysis of 160 questions raised by 74 participants and recorded during the two courses at MSU indicated that close to 47% of stakeholder interest was about regulatory related issues (Figure 3). These questions were about risk assessment, biosafety approval processes, safety standards/protocols, authorization, product approval, legal issues, and safety considerations related to the environment, health, food and feed. Interest in technology development was the second highest issue raised (25%) by stakeholders who also expressed the need for more training support and capacity building in this area (Figure 3).

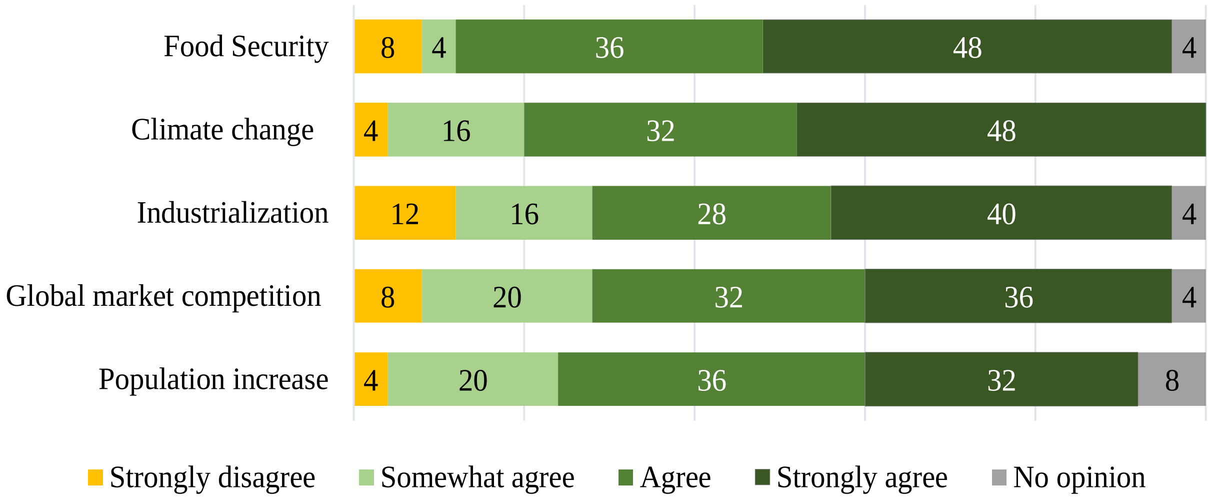

Figure 2. Global issues identified as likely drivers of biotechnology adoption (percentage responses).

Table 4. Stakeholders identification of factors favoring GM adoption.

Factor	Very likely (%)	Somewhat likely (%)	Not likely (%)	Do not know (%)
Promises of advances in science	77	9	5	9
Raising awareness of policy makers	74	13	4	9
Raising consumer demand	67	14	10	9
Prospect of climate change	65	26	0	9
Positive results from GM-adopting countries	65	13	13	9
Pressure from the scientific community	61	22	9	8
Rising role of media in favor of GM technology	57	17	17	9
Pressure from pro-GM advocates	40	30	13	17

DISCUSSION

Regulatory decisions

The surveys indicated that there is a need to build regulatory and technical capacity in Africa that will strengthen regulatory decision making and build public trust. Informed participants about GM products recognize the presence of delay in regulatory decision making and commercialization of biotech crops. More optimism is reflected in this assessment towards improved public attitude if awareness of stakeholders in GM technology is raised. Participants identified a number of drivers for adoption of biotechnology that include food security and climate change challenges. It has been suggested that linking regulatory decisions to national and United Nations Sustainable Development Goals provides an incentive for regulators to complete risk assessments and align decisions with national economic policy (Raybould, 2021). This focus on applying technology to drive development and sustainability would support regulatory decisions that could facilitate the adoption and commercialization of GM crops in Africa.

Appropriate technology

The key crop production and productivity challenges identified by these stakeholders relate to low adoption of improved technology due to poor access and availability of appropriate technologies that can respond to the farmers' specific production problems as well as poor agronomic conditions such as inadequate water, pests and diseases, poor soil fertility and climate change challenges. Improved genetics and best farming practices can reduce yield gaps and enhance productivity (Anthony and Feronni, 2011). Products derived through modern biotechnology such as GM and genome edited crops are relevant to meeting the needs of developing countries for food, feed and industrial applications (Anthony and

Table 5. Identified barriers to public acceptance of GM crops.

Causes of acceptance delay	Very likely (%)	Somewhat likely (%)	Not likely (%)	Do not know (%)
Fear of socio-economic, ethical and socio-political issues	76	10	10	5
Environmental risks concern	62	14	14	10
Pressure from GMO opponents	61	9	22	9
Concerns of food safety and potential health effects	57	14	19	10
Costly technology and approval processes	52	24	19	5
Inadequate farmers and public demand	52	29	10	10
Risk of market access loss	50	23	23	5
Fear of politicians losing votes	50	5	23	23
Do not perceive GM crops as beneficial	48	19	29	5
Too many actors are involved	33	33	29	5

Feronni, 2011; Gbashi et al., 2021). However, as the assessment showed, socio-economic, ethical or safety are key considerations along GM crops adoption that determines appropriateness of the technologies. Innovative GM crops developed with these perspectives in mind can solve production constraints and provide robust and sustainable solutions to increase food production and nutritional enhancement to help alleviate hunger and malnutrition (Cornish, 2018).

Commercialization and adoption in Africa

Most respondents of this survey replied that technology access and availability are the greatest barriers to wider adoption of GM crops. About two-third of the respondents observed an improving public attitude towards GM crops in recent years, but noted ongoing delays for approval and adoption of GM crops. Despite the availability of some appropriate technology, GM crop adoption in Africa has been slow (Alhassan et al., 2018; ISAAA, 2020). After the approval of Bt cotton in 1997 in South Africa, only Burkina Faso, Egypt, and Sudan commercialized this crop-trait combination 10-15 years later, between 2008 and 2012. The next approvals for Bt cotton in Africa were in Ethiopia, Eswatini and Nigeria in 2018, Kenya in 2019, and Malawi in 2020. Other early approvals for appropriate GM crops were for maize and soybean in 1997 and 2001 in South Africa. Nigeria approved Bt cowpea in 2019 and Bt-drought tolerant maize in 2021. Kenya approved virus resistant cassava in 2021. According to Aldemita et al. (2015), the speed of cultivation approval for GM crops globally from 1992-2014 shows remarkable contrast between Africa and the rest of the world. Between 1992 and 2003 there were 214 approvals in 16 countries globally whereas there were only 10 approvals in Africa all only in South Africa. In the next 14 years between 2004 and 2014, there were 419 approvals globally in 28 countries of which 12 approvals were only in 4 African countries: South Africa (9), Egypt (1), Burkina Faso (1) and Sudan (1).

It took more than 20 years for 7 of 46 SSA countries to adopt a range of improved GM crops. However, after GM crops are approved by national regulatory authorities, deployment of planting material to farmers has its own challenges.

Countries that adopted GM crops early have confirmed that appropriate technology can decrease production costs and increase food production (ISAAA, 2020). For instance, in Asia and Latin American countries, studies consistently confirm the adoption and progress of GMOs has been driven by economic value (Cornish, 2018; Brookes and Barfoot, 2014). In Brazil, GM soybean, maize and cotton varieties reduced farm production costs with an average farm income benefit of $34, $58 and $91 per hectare, respectively (Cornish, 2018). Participants in this survey confirmed that although farmers show interest to grow GM crops, issues of access to new technology, seed cost and market linkage are potential barriers for farmers to adopt GM crops. Piñeiro et al. (2020) similarly indicated that for smallholder farmers, sustainable access and affordability of planting material are important success factors in adoption of GM crops. Therefore, product commercialization requires careful planning from the start to avoid delays and provide sustainable access to high quality planting material for farmers. Discussions on commercialization start early in product development to confirm acceptance and evaluate marketing plans for the final product. When approved GM crops are transferred for adoption in other countries, the commercialization plans need to be adapted and developed considering specific local circumstances to ensure successful dissemination. Potential market value and local desire for the traits should be the driving force for technology transfer. It can be seen from the above assessment that technology access constraints are diverse

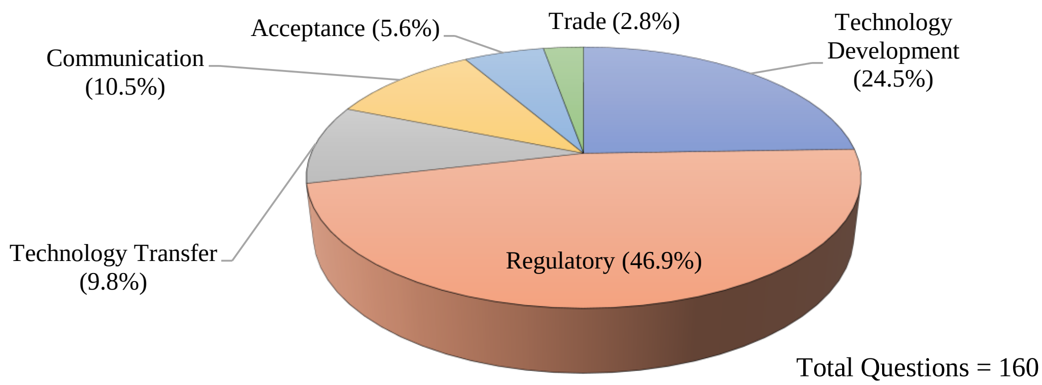

Figure 3. Stakeholder questions categorized by thematic area.

and can effectively hinder the wide adoption of GM crops. In Africa, the presence of functional seed and extension systems, adequate stakeholder awareness, effective technology demonstration, financial schemes to support smallholder farmers and reliable marketing services all require shared responsibility and coordination between developers and government services.

Seed systems in Africa

Dissemination and adoption of improved new varieties in Africa is relatively slow due also to a weak private seed sector and dominant informal seed systems. According to Akinbo et al. (2021), in SSA the informal seed sector accounts for about 80% of the seeds planted and, in most countries, public sector seed programs play a major role in supplying quality seeds for registered and released varieties. A thriving seed system requires a growing demand for seed and well-functioning markets for seed and grain, a robust innovation system for the crop improvement, and an effective regulatory system to sustain an innovative and competitive market (Spielman and Kennedy, 2016). In developing countries, it is hard to find these components fully in place. The case of maize in Asia is a good example of how multinational seed companies with strong R&D programs and product lines played a central role in those markets, operating independently or in joint ventures with domestic seed companies (Spielman and Kennedy, 2016).

The private sector leadership in Asia's maize seed market did not entirely replace the need for public research. In fact, in Thailand, combination of policy reforms and a strong public-sector maize development program in the 1970s transitioned the country into a hub for private R&D investment. The key challenge with the public system, however, is to remain competitive due to limitations in scientific capacity, funding trends, top-heavy organizational structures, and poor research and technology promotion incentives (Schreinemachers et al., 2021; Spielman and Kennedy, 2016).

Commercialization of hybrid seed, open pollinated seed and vegetative planting material has well documented challenges in Africa (Schreinemachers et al., 2021). These authors confirm that seed regulations are easing in a number of African countries to encourage investment and establishment of private seed companies. They encourage policy makers to create favorable commercial and regulatory environments for seed companies; incentives to strengthening investment and capacity in seed research and development; provision of extension programs to encourage adoption of improved farming methods; and infrastructure for access to markets for farm produce. Mbabazi et al. (2020) noted that lack of technical capacity and infrastructure to implement seed delivery systems leads to delayed access to and adoption of improved planting material in Africa.

Technology delivery: Institutional and stakeholders coordination and partnership

Participants of this survey indicated that social, economic and political challenges are critical concerns that affect wider acceptance of GM crops in their countries. Leading up to commercialization, effective demonstration and awareness creation among the extension agents and smallholder farmers determines the adoption of an approved GM crop. Many African farmers do not routinely purchase improved seeds despite the demonstrated potential of these technologies to improve productivity and success. It shows the transfer of GM crop technology to Africa will benefit from strong public-private partnerships that ensure a reliable source of good planting material for farmers and all the support the public sector can give them to bring a good crop to market. This is illustrated in a recent assessment report by WorldTAP Program, MSU (2021) on the challenges of bridging the

Bt cotton seed access gap and ensuring a sustainable supply of seeds to smallholder farmers. Others have also highlighted the role successful public-private partnerships can play in effectively commercializing an approved GM crop (Mbabazi et al., 2020).

Lesson learnt and way forward

Commercialization of GM products is a multifaceted, long-term and expensive undertaking. It takes 10-15 years to commercialize a GM crop with high costs. Private sector has played a dominant role in commercialization of GM crops to date. Public-private sector partnerships are critical to facilitate commercialization of GM crops in developing countries. Although concerted efforts are ongoing to build scientific and regulatory capacity and to deploy appropriate GM crops from the international community, there continue to be delays in regulatory approvals for general release and commercialization of GM crops in Africa.

Lack of political will, safety concerns, fear of change and negative public perception have contributed to delays in adoption. However, during the past three years, there has been a wind of change in Africa with several countries taking positive steps and making favorable regulatory decisions that facilitate the commercialization of GM crops. In this respect, Raybould (2021) reports that many countries have demonstrated political will to assess and harness GM crops. Linking national regulatory decisions on GM crops to national policy goals, such as achieving the United Nations Sustainable Development Goals, will help to clarify which products benefit the local society, the environment, and economic growth. These linkages will reinforce that science is helping to achieve policy aims, not driving its own agenda.

Biosafety regulatory decisions are just one of the many steps involved in the commercialization process that will put GM seeds in the hands of smallholder farmers. Vibrant seed systems, local seed production capacity, effective extension services, reliable financial and marketing services as well as product stewardship strategies are needed to deploy and sustain GM crops for smallholder farmers. Unless these issues are addressed, smallholder farmers in Africa will not benefit from GM crops.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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