



Lessons Learned from Regulatory and Outreach Support for TELA Maize Release in African Countries

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Foreword

The dream and aspiration to see widespread use of biotechnology in Africa's food systems for the greater economic good continues to grow. Within this context, the story of GM maize deregulation in Africa becomes a trailblazer. In the greater GM maize story lies the tale of TELA maize. The pains and gains of making TELA maize available to farmers in Africa can be explained from many angles.

In the words of the editors quoted from the synthesis section in this document, 'Initially, the implementers, supporters, and critics were apprehensive about the success of WEMA and even the TELA Project, as regulatory processes were viewed as the weak points in the proposed implementation process. However, all TELA partner countries have proven this view wrong, as there has been hardly any breach of compliance at any step in any of the numerous CFTs and NPTs during the last 15 years.'

The TELA Project has been operating during an unending debate on GMOs in Africa, with issues ranging from the efficacy of technology, its potential effects on animal and environmental health, and its ownership. This has resulted in rising anti-GMO activities, especially in countries approaching the commercialization and marketing of GMO products. These have led to misinformation on the technology and its effects, diversion of resources from technology development to advocacy and outreach, and delays in getting the technology to those who need it most, the African maize farmers and consumers. Equally important is that, like other African countries, the four Sub-Saharan countries have nascent national biosafety institutions still developing legal tools to help regulate GMOs. Some of these legal tools have been adopted from the north and constantly need adjustment to work in the country-specific legal and social environments. This tends to slow down the speed of decision-making on applications for the various steps toward the commercialization of transgenic technology. In addition to the legal system, the countries faced limited knowledge of the technology and its regulation among decision-makers at the technology developers, policy-making, and national regulatory implementers levels. Thus, time and resources were devoted to educating TELA Project country technology developers on the technology and its stewardship.

The reflections by the TELA maize teams in this document capture the nuances of navigation and the path towards making TELA maize available to farmers in Africa. Their reflections scope the whole spectrum from the capacity of national systems, the role of attitudes and perceptions, and often overlooked economic and trade undertones that drive technology uptake and sustainability – all told in the words of the actual practitioners; all told in an authentic voice.

Dr. Canisius Kanangire,

Executive Director, AATF

Acknowledgments

These learning briefs represent the collective reflections of many people. While it is impossible to list everyone involved, several distinct teams can be mentioned here. The Principal Investigators on the TELA Project in all five countries (Ethiopia, Nigeria, Kenya, Mozambique, South Africa), were the main stewards of the initiatives described in this document. The Regulatory, Advocacy and Outreach (RAO) teams in each country are the main storytellers in this document. They designed and implemented the activities, recording wins and acknowledging losses. The

technical partners in the TELA Project (Bayer, International Maize and Wheat Improvement Center (CIMMYT)) provided backstopping on multiple occasions during project reviews during which many of the lessons mentioned here began to crystalize. The main funding agencies, the Bill and Melinda Gates Foundation and the United States Agency for International Development (USAID), not only provided the resources for the initiatives but actively encouraged learning and reflection among the teams. All these teams' voices are reflected in the subtleties of the lessons documented here.

List of abbreviations and acronyms

AFAN	All Farmers Association of Nigeria
ARC	Agricultural Research Council
ΔSNI	Agricultural Society of Nigeria
RMCF	Rill and Melinda Cates
DIVICI	Foundation
DCNI	Riotochnology Society of Nigoria
CET	Confined field trial
	International Maire and Wheat
	International Maize and Wheat
ידירו	Improvement Center
	Diougni tolerant
D02	Distinctiveness, uniformity, and
	Stability
EDV	Essentially derived varieties
EGS	Early generation seed
EIAR	Ethiopian Institute for
	Agricultural Research
EMCA	Environmental Management and
	Coordination Act
EPA	Environment Protection
	Authority
FAW	Fall armyworm
GM	Genetically modified
GMO	Genetically modified organism
GSN	Genetic Society of Nigeria
HT	Herbicide tolerance
IBC	Institutional Biosafety
	Committee
KALRO	Kenya Agricultural and
	Livestock Research Organization
KEPHIS	Kenya Plant Health Inspectorate
	Services
MAAN	Maize Association of Nigeria
MADER	Ministry of Agriculture and
	Rural Development
MLT	Multi-location trial
МоА	Ministry of Agriculture
MOU	Memorandum of understanding
NABRDA	National Biotechnology Research
	and Development Agency

NARS	National Agricultural Research
	System
NASC	National Seed Council
NBA	National Biosafety Authority
NBAC	National Biosafety Advisory
	Committee
NBMA	National Biosafety Management
	Agency
NCPB	National Cereals and Produce
	Board
NEMA	Kenva National Environmental
	Management Authority
NPT	National performance trial
NPTC	National Performance Trials
	Committee
NSA	National Seed Authority
NVRC	Ethionia National Variety
	Release Committee
NIVPC	National Varieties Release
	Committee
NIVDO	National Variaty Poloago
INVIC	Committee
	Open Forum on A grigultural
OFAB	Distasha slow in Africa
	Biotechnology in Africa
R&D	Research and development
RAO	Regulatory, Advocacy and
	Outreach (team)
RR	Roundup Ready
RRI	Regional Research Institute
RSA	Republic of South Africa
SIB	Seeing-is-believing
SMME	Small, micro, and medium
	enterprises
SOP	Standard operating procedure
TPT	Trait Pipeline Team
USAID	United States Agency for
	International Development
VCU	Value for cultivation and use
WEMA	Water Efficient Maize for Africa

Chapter 1 Introduction

he TELA Maize Project is a public-private partnership coordinated by AATF that brings together the national agricultural research organizations of Ethiopia, Kenya, Mozambigue, Nigeria, and South Africa, Bayer, International Maize and Wheat Improvement Center (CIMMYT), seed dealers, and farmers. Started in 2018, the project builds on the Water Efficient Maize for Africa (WEMA) Project that sought to address the issue of drought and insect pest management through the strategic combination of conventional breeding and transgenic technologies. To date, 124 conventional drought-tolerant hybrid varieties of maize, trademarked DroughtTEGO® (TEGO®) and five transgenic TELA® insect-resistant hybrid varieties have been released to farmers through the two projects. The TEGO varieties, referred to as the 'Magic Seed' by farmers, are being planted in 15 African countries, while TELA® varieties have so far been commercialized in South Africa and Nigeria. In efforts towards sustainable agriculture, and food and nutrition security for the continent, the TELA Maize Project is progressing the transgenic technology with a concentration on developing and releasing products to farmers that combine drought tolerance and resistance to stem borer and fall armyworm (FAW) insect pests. The damage by insect pests is costing the continent over 20 million metric tons of maize annually, enough to feed 100 million people, not to mention reducing the quality of the grain. The TELA products benefit farmers by providing higher income arising from increased yields. They have also been proven to be safe for human and livestock consumption and the environment.

However, in many countries of Africa, policy framework hinderances are delaying approval, release, and scaling out the 38 available TELA hybrids, thus denying farmers the benefits. This bottleneck does not mirror the stated commitment by African governments to prioritize science, technology and innovation in empowering the agricultural community with the tools they need to thrive in farming and transform Africa's food systems.

A lesson is an experience that acts as a warning to you or an example from which you should learn. It is something from which useful knowledge or principles can be acquired. A lesson learned is, therefore, defined as a knowledge or understanding gained by study or experience. The experience may be either positive or negative. Further, a lesson must be significant in that it has a real or assumed impact, valid in that it is factually and technically correct, and applicable in that it identifies a specific design, process, or decision that reduces or eliminates the potential for failures and mishaps or reinforces a positive result. Therefore, capturing lessons learned includes the key challenges encountered when implementing the plan targeting expected outcomes.

Chapter 2 Case Studies: Country Learnings

A lesson is an experience that acts as a warning to you or an example from which you should learn. It is something from which useful knowledge or principles can be acquired. A lesson learned is, therefore, defined as a knowledge or understanding gained by study or experience. The experience may be either positive or negative. Further, a lesson must be significant in that it has a real or assumed impact, valid in that it is factually and technically correct, and applicable in that it identifies a specific design, process, or decision that reduces or eliminates the potential for failures and mishaps or reinforces a positive result. Therefore, capturing lessons learned includes the key challenges encountered when implementing the plan targeting expected outcomes.

2.1: The Regulatory journey for commercialization of the first transgenic maize in Ethiopia: Lessons learned

Authors: Tesfaye Disasa, D. Teshome, T. Daba, J. Watiti, J. Njuguna. A. Mathagu, S. Mugo, F. Nang'ayo, N. Muchiri, and S. Oikeh

Overview

The TELA-Ethiopia Regulatory and Outreach team set out to support the TELA Maize Project and facilitate the regulatory approval for the environmental release of insect-protected Bt maize Event MON810 and drought-tolerant maize Event DT MON87460 and the approval of confined field trial testing of Bt maize Event MON89034 maize transgenes in Ethiopia.

The major achievements include: 1) the availability of new drought-tolerance and insect-pest protection solutions that can help farmers improve their productivity and protect their harvests; and 2) the building of capacity in Ethiopia to manage the development, deregulation, and deployment of subsequent transgenic crop products by the end of 2024.

The TELA Maize Project was built on the progress made by the AATF-led Water Efficient Maize for Africa (WEMA) initiative, which Ethiopia joined in 2018. TELA Maize Project aimed at contributing towards food security by making available high-yielding transgenic maize hybrids that are tolerant to drought stress and with auto-protection against stem borers and fall armyworm insect pests. TELA Maize Project aims at testing, deregulation, and initiation of deployment of at least two transgenic drought-tolerant and insect-pest protected TELA maize hybrids by smallholder farmers. Its goal was to open modern technology choices for Ethiopian farmers to allow them to increase their food security and incomes and thereby contribute to an inclusive agricultural transformation.

The TELA Project was needed in Ethiopia because maize is one of the most important staple crops in the country. It is produced by about 10 million households and directly benefits over 50 million people (Central Statistical Agency – CSA, 2022). Maize production is second in land area coverage only after teff but ranks first among cereals in productivity and total grain production. Maize, however, faces challenges with drought stress and insect pests which the TELA Project promised to provide solutions to.

The TELA Maize Project is coordinated by AATF, with technical support from Bayer and the International Mize and Wheat Improvement Center (CIMMYT) and funded by the Bill and Melinda Gates Foundation and the United States Agency for International Development (USAID).

Why a Regulatory, Advocacy and Outreach team?

The overall goal for the Regulatory, Advocacy and Outreach team in the TELA Project in Ethiopia, known as the RAO team, was to support the full regulatory pathway for the environmental release of Bt MON810, DT MON87460, and MON89034 maize transgenes in Ethiopia through the sustained engagement and information sharing with policymakers, regulators, professionals, and the public. The experience highlighted key lessons learned during implementing activities towards compliance with conditions set by regulators during the development and testing of the Bt and DT transgenic maize in Ethiopia. The Ethiopian experience demonstrated the capacity to deregulate genetically modified organism (GMO)-based food crops (TELA products/MON810) through the existing regulatory system in Ethiopia. It equipped the project team with key insights that can inform future initiatives involving biotechnology-derived food crops in the country and beyond.

Lessons learned

1. Leveraging political goodwill and support for harnessing TELA maize in Ethiopia was important

The team recognized that policy-level support and political goodwill were critical to the regulatory pathway for the environmental release of Bt MON810 and DT MON87460; and submitting the dossier for Bt MON89034 maize transgenes in Ethiopia. To fully utilize the existing policy support and political goodwill, the TELA team deployed various information-sharing and awareness-creation strategies, targeting policymakers and high-level leadership as champions for the technology. This engagement was sustained throughout the application and follow-up processes and was meant to convey consistent, timely and correct information to the relevant decision-makers. Overall, the early engagement of regulators and the Ethiopian National Biosafety Advisory Committee (NBAC) helped establish smooth communication among the applicants, regulators and influencers.

2. A supportive biotech policy environment and proven collaboration among key institutions are important for the timely processing of applications for the environmental release of biotech products

A supportive biotech policy environment is crucial for the successful employment of modern biotech research for development technology in addressing food and nutrition security. This supportive environment is established when every institution involved has a clear mandate. a situation that prevents interference and delays in the decision-making process due to either conflicting or overlapping institutional roles and responsibilities. For instance, as part of the informationsharing initiatives. discussions were held on the regulation schemes helped distinguish between trait deregulation based on biosafety assessment and the release of transgenic maize varieties based on hybrid performance. The forum also helped define the array and demarcate the respective mandates of the Environment Protection Authority (EPA) and the Ministry of Agriculture (MoA). This eased the approval process by avoiding duplication of responsibilities that can create a conflict of interest. thus leading to a prolonged process and a decision that is unfavorable for the applicant. The application dossier preevaluation by the Institutional Biosafety Committee (IBC) of the Ethiopian Institute for Agricultural Research

(EIAR) helped its ease of acceptance by the regulators. The TELA team's proper and timely responses to the Environment Protection Authority (EPA)'s requests for clarification also eased the moving forward of the approval process by the regulator.

3. Maintaining compliance with regulatory conditions is critical for the acceptance of TELA maize in Ethiopia

Compliance-dependent processes such as the application for deregulation of Bt maize MON810, and the conditions set by regulators during the development and testing of the technology place a premium on the demonstration of timely and complete adherence to processes. The TELA Ethiopian team managed the confined field trials (CFTs) and national performance trials (NPTs) well to obtain compelling and convincing data on the hybrids evaluated there. This was done while ensuring unequivocal regulatory compliance with conditions which facilitated fasttracking the environmental release process for Bt MON810. These conditions included observing genetic and material confinement, training all staff, and raising awareness in the community in the vicinity of the testing sites as well as keeping excellent records.

4. Demonstration of excellence and performance of the technology helps in acceptance and demand for the product The team ensured that there was compelling and convincing CFT and NPT data, which showed highly contrasting Bt and non-Bt maize plots (TELA and conventional maize plots) and unequivocal regulatory compliance with conditions which facilitated fast-tracking the environmental release process for Bt MON810. Proper selection of FAW

hotspot sites to conduct NPTs helped generate quality data.

5. Consistent outreach to regulators and other stakeholders was important in this process

The team acknowledged that consistent information sharing with the relevant regulators and key audiences would achieve the dual goals of showing openness and compliance and keeping leadership informed about progress. Key decision-making audiences targeted included the NBAC, the Environment Protection Authority (EPA), the Ministry of Agriculture (MoA), the Ethiopia National Variety Release Committee (NVRC), and the Ethiopian Institute for Agricultural Research (EIAR) leadership. Key strategies to reach these groups included symposia, 'seeing is believing' (SIB), 'eating is believing', and benchmarking tours for policymakers to countries where the GM maize technology was already working, such as South Africa.

The team made deliberate plans to reach professional and special interest groups (seed companies, the media fraternity, and regional research institutes) with information on TELA. This was done to raise awareness and to increase the participation of these diverse groups during public participation and comment as requested by NBAC. TELA information was disseminated during plenary sessions, 'seeing is believing' visits and awareness-creation. The information shared included biosafety. CFT results, NPT testing results, and transgenic technology in general. 'Seeing is believing' visits were made to NPT sites. Training and awareness-creation forums were conducted for private seed companies, journalists, and media

outlets. The engagement of the Regional Research Institute (RRI) leaders also helped to get easier access to NPT trial sites for outreach work.

The project team in Ethiopia identified and recruited a group of biotechnology advocates, including respected former State Ministers. former EIAR Director Generals, and university professors associated with the Open Forum on Agricultural Biotechnology in Africa (OFAB)-Ethiopia nodes. This network of champions helped raise awareness and support for science and technology in national development, especially for TELA transgenic technology, by communicating key messages through media appearances and public comments. The OFAB platforms facilitated public comments, which led to over 98% positive support for approving the Bt trait. The combination of various outreach and information-sharing approaches contributed to positive policy support for TELA maize in mainstream public discourse.

The team conducted sustained engagement with the Ethiopian mainstream media through outreach and capacity building, helping counter negative reporting on agricultural biotechnology and contributing to neutral and positive tones even in Ethiopia's emerging social media space.

6. Normal institutional changes can present real risks and challenges

The team noted that recurring communication gaps due to high staff turnover, including at the level of research institute leadership, often affected the quality of engagement and information flow. To sustain momentum, this necessitated repeat onboarding and sensitization of new teams. This was a resource-intensive but necessary exercise, which required the team to strike a balance between cost-effectiveness and the need for continuous awareness creation. Continuous engagement contributed to better understanding and confidence among decision-makers.

2.2: The journey of Bt maize Event MON810 approval for environmental release and market placement in Kenya: Lessons learned

Authors: James Karanja, F. Maritim, M. Mwirigi, Brenda Waithaka, J. Watiti, J. Njuguna, A. Mathagu, S. Mugo, F. Nang'ayo, N. Muchiri, and S. Oikeh

Overview

The TELA Kenya Regulatory, Advocacy and Outreach (RAO) team set out to support the commercialization of insect-protected Bt maize Event MON810 hybrids in Kenya. This followed the environmental or biosafety release of the Bt maize Event MON810 trait or transgene in Kenya in 2016. The support was through creation of an enabling environment for favorable regulatory decisions on the commercialization of TELA maize in Kenya.

The TELA Maize Project was built on the progress made by the AATF-led Water Efficient Maize for Africa (WEMA) initiative, which Kenya joined at its launch in 2008. The project aims to contribute to food security by making available high-yielding transgenic maize hybrids that are tolerant to drought stress and with auto-protection against the various stem borer species and maize fall armyworm insect pests. The project aims to test, de-regulate, and initiate the deployment of at least two transgenic drought-tolerant and insect-pest-protected TELA maize hybrids by smallholder farmers in Kenya.

Biotechnology-derived crops addressing different production constraints are the most rapidly and widely adopted agricultural

technologies globally of which maize occupied more than 40 million hectares by 2023 (ISAAA, 2024). Genetically engineered (GE) maize-producing insecticidal proteins (mainly Cry proteins) from Bacillus thuringiensis (Bt) have been used to effectively control distinct species of stem borers (e.g., Chilo partellus and Busseola fusca), fall armyworm (Spodoptera *frugiperda*), and other lepidopteran insect pests. Given the significant levels of stem borer and fall armyworm insect pests, Kenyan farmers should be allowed to reap the enormous benefits of TELA maize. This is to enable them to produce high-quality and safe food and feeds with increased yield at reduced production costs due to limited application of insecticides. This will secure the country against an over 13 million 90kg bags (1.17 million tons) loss and increased cases of aflatoxin contamination that is associated with insect-pest damage.

Despite all efforts to overcome stakeholders' technical, regulatory, legal, and diverse perception issues, Kenyan regulators have not yet approved Bt maize MON810 hybrid commercialization, largely due to court cases from suits by some stakeholders. Valuable lessons can be learned from the journey of the TELA hybrids. The TELA Maize Project is coordinated by AATF, with technical support from Bayer and the International Maize and Wheat Improvement Center (CIMMYT) and funded by the Bill and Melinda Gates Foundation and USAID.

Why a Regulatory, Advocacy and Outreach team?

The goal of the TELA-Kenya Regulatory, Advocacy and Outreach (RAO) team was to support compliance and information sharing for the successful approval of TELA insectprotected maize Bt MON810 hybrids in Kenya. The experience highlighted several lessons that can guide future practice in Kenya and beyond. Although the Kenya National Biosafety Authority (NBA) approved the environmental release and placement in the market for MON810 hybrids, the final approval and gazettement of the three TELA insect-protected maize varieties by the National Variety Release Committee (NVRC) has not taken place due to several internal and external factors.

Notably, the TELA team had secured regulatory approvals for MON810 TELA maize through strict compliance, only to encounter significant opposition from antibiotech activists, who introduced a series of court cases challenging the lifting of the ban on importation and cultivation of GMOs in Kenya.

Lessons learned

1. Compliance with regulatory conditions is the starting point for a favorable review of the application for environmental release of TELA maize

TELA-Kenya obtained NBA approval for the environmental release of MON810 in 2016. This was a result of consistent compliance with the Confined Field Trial (CFT) standard operation procedures (SOP) and other requirements that ensured fulfillment of the regulatory conditions by NBA and other regulatory bodies, including the Kenya Plant Health Inspectorate Services (KEPHIS) and the Kenya National Environmental Management Authority (NEMA).

Consistent compliance led to the collection of compelling data on biosafety from the two CFT sites, the Kenya Agricultural and Livestock Research Organization (KALRO) Kiboko center and KALRO Kitale center. In these sites, effective control of stem borer and, to some extent fall armyworm, without the use of chemical pesticides was demonstrated. Similarly, consistent compliance with the regulator's conditions at the national performance trial (NPT) levels led to compelling field-testing data and results. allowing for the speedy recommendation for the release of Bt maize Event MON810 hvbrids by the National Performance Trials Committee (NPTC) in Kenya.

2. A thorough review of all applicable laws and regulations is important for expedited review and approval of biotech products

Some compliance challenges arose from the interpretation of the guidelines, emphasizing the need to thoroughly review all applicable laws and regulations before submitting applications for environmental release. For instance, the requirement to implement NPTs under confinement proved to be a challenging, expensive, and time-consuming exercise. However, the team exploited a guideline that capitalizes on the value of the essentially derived varieties (EDV) aspect in variety improvement to facilitate the rapid release of TELA maize. Since the conventional iso-hybrids (the so-called WEMA/Drought TEGO) of TELA maize were already released, the time to test TELA hybrids for NPT and DUS testing was reduced from two to one year only. This saw three TELA maize varieties, WE1259B, WE3205B, and WE5206B, assessed and recommended for release within one year (June 2020 to June 2021).

3. Consistent outreach to regulators and other stakeholders was important in this process

A series of outreach and informationsharing activities, including stakeholder engagement at the CFT sites, helped to obtain the support of key institutions. Among the institutions reached were the Ministry of Agriculture (MOA), KALRO, NBA. NEMA. KEPHIS. and the National Cereals and Produce Board (NCPB). For each of these institutions, the Board Members, the CEOs, and key technical leads were all targeted and outreached through field visits to CFTs and NPTs, seeing is believing' tours, and workshops. Communities neighboring the CFT and NPT sites were equally accessed for awareness creation and buy-in. Those reached served as key ambassadors in publicizing the benefits of MON810 insect-pest-resistant maize technology.

4. Clear institutional mandates are essential to the regulatory pathway

Navigating the compliance journey highlighted the challenge of overlaps in institutional mandates governing biotechnology regulation. For instance, a three-year delay (2016 to 2019) in securing environmental release approval to execute the NPTs may have been due to inadequate consultation between the project team and all regulatory agents before the application cycle. Similar hurdles in interpretation emerged from the requirements for a comprehensive post-release monitoring framework that would address both environmental and health elements.

5. Political goodwill can mean everything in the regulatory journey

Political goodwill was critical to the success of the application for MON810 in Kenya. In the early part of the outreach work, the TELA team engaged the then relevant government bodies, to leverage its cross-sectoral convening mandates and roles, as a strategy to secure highlevel government support. However, the challenge of coordinating efforts across departments was evident. The ban on the import, production, and consumption of GMOs had wide-reaching implications for product approvals and promotion requiring high-level political support that regulatory agencies alone could not mobilize effectively.

6. Effective partnership agreements can energize product promotion

To guarantee prompt progress in the project, TELA country National Agricultural Research System (NARS) partners need an all-inclusive agreement that covers research and development (R&D) and commercialization. In addition, NARS need to be familiar with the details of the agreements and contracts before the projects are executed. Clarity in partnership agreements limits disagreements and offers the freedom to operate. Parties should discuss key contract issues before the first draft is shared. This will ensure all parties' concerns are well captured ultimately saving valuable time during implementation.

2.3: Engaging key stakeholders for successful environmental release of TELA maize traits in Mozambique: Lessons learned

Authors: Sónia Nnantubo, Pedro Fato, Manuel Dia, Pedro Silvestre Chauque, Egas Germias Nhamucho, Alice Cambula, Monica Namburete, J. Watiti, J. Njuguna, A. Mathagu, S. Mugo, F. Nang'ayo, N. Muchiri, and S. Oikeh

Overview

The TELA Project Regulatory, Advocacy and Outreach team (RAO) in Mozambique in collaboration with the Trait Pipeline Team (TPT) and the Open Forum for Agricultural Biotechnology (OFAB) lead, and with support from AATF set out to create an enabling environment for a favorable decision on the environmental release of TELA insectprotected maize (*Zea mays* L.) Event MON810 and drought tolerant (DT) maize Event MON87640 transgenic traits in Mozambique.

The major achievements from the RAO initiatives in Mozambique include: (i) attainment of full compliance with NBA conditions for confined field testing; (ii) records of 2022-2023 NPT testing, with the TELA maize (MON810) varieties significantly outyielding the conventional varieties by 36–64%; (iii) stakeholders including highlevel government authorities and regulators engaged through awareness creation and education on the TELA maize products and biotechnology; (iv) environmental release of MON810 and MON87460 in Mozambique; and (v) raised awareness about the technology and the benefits of TELA maize varieties among key stakeholders through visits to CFT and NPT sites.

The TELA Maize Project was built on the progress made by the AATF-led Water Efficient Maize for Africa (WEMA) initiative, which Mozambique joined in 2008. TELA Maize Project aimed at contributing towards food security by making available highyielding transgenic maize hybrids that are tolerant to drought stress and with autoprotection against stem borers and fall armyworm insect pests.

The TELA Project was essential for Mozambique, where maize is an important staple food and is the most cultivated cereal crop. Maize has a high production yield potential, estimated at 5 to 8 tons per hectare (Come et al., 2020). However, the current productivity is extremely low, ranging from 0.8 to 1.2 tons per hectare (IAI, 2020). TELA was addressing drought stress and insect pests, which, together with poor genetic varieties, are significant factors that reduce maize production, leading to food insecurity, especially among small-scale farming communities. The TELA Maize Project is coordinated by AATF, with technical support from Bayer and CIMMYT and funded by the Bill and Melinda Gates Foundation and USAID.

Why a Regulatory, Advocacy and Outreach team?

The TELA Regulatory, Advocacy and Outreach team's work was to support the regulatory pathway to obtain environmental release of TELA maize MON810 trait in Mozambique by facilitating information flow from the preparation of the dossier for submission and working closely with the national regulators, GIBBS, National Seed Authority (NSA), the Ministry of Agriculture and Rural Development (MADER) and National Biosafety Authority (NBA), to demonstrate consistent compliance. The team raised awareness with key stakeholders through various outreach initiatives. It supported public awareness about the TELA maize varieties that were being tested at CFT and NPT levels between 2022 to 2024.

The compliance journey enabled the team to learn critical lessons about the Mozambican context for deregulating biotechnologyderived food crops such as GM TELA maize.

Lessons learned

1. In highly regulated technologies such as GM maize, strict compliance is an important ally in the regulatory pathway

Compliance is the state of being in accordance with established guidelines or specifications or the process. In highly regulated processes, such as the application for deregulation of Bt maize MON810 in Mozambique, compliance is key. TELA Mozambique complied with the conditions set by the regulators during CFTs in 2019. This called for the team to observe material and genetic confinement and turn in all required reports and other conditions. A special condition that TELA Mozambique painfully complied with was a new request to the TELA team to conduct multi-location CFTs not contained in the biosafety regulations. The TELA team noted that the requirement for NPTs to be followed by confined multi-location trials (MLTs) was unusual and contributed to a sense of lack of clarity in regulations and their interpretation. Nevertheless, the team complied with it to obtain approvals for the deregulation of TELA MON810 hybrids.

2. Sustained outreach and information flow is an effective tool and a pre-requisite for positive regulatory support

The product, transgenic insectprotected Bt maize Event MON810, and the technology through which it was developed, were both new in Mozambique. Sustained outreach to regulators and other stakeholders was found to be an important pre-requisite for positive regulatory outcomes. From 2019, the TELA Project Regulatory, Advocacy and Outreach (RAO) team in Mozambique worked closely with partners to implement outreach and information-sharing activities with the regulators and key stakeholders that aimed to communicate adherence to compliance requirements for dossier submission. CFTs. and MLTs for TELA MON810 maize. This resulted in the successful biosafety evaluation for TELA MON810 transgenic maize and the conditional environmental release in 2021.

Facilitating timely information flow with the key stakeholders was not without challenges. Efforts to deliver timely information to the key regulatory bodies -GIBBS, NBA, NSA, and MADER - proved slow and complex. Notably, the process began in 2019 and continued until 2021 when a final response was given leading to conditional environmental release. To facilitate the process and to overcome communication gaps, the team pursued several outreach strategies, including, seeing is believing' tours, symposia, workshops, and scheduling in-person presentations to key audiences. These diversified outreach methods helped sustain the intensified interactions, information flow, and support for the application.

3. Appropriately handled mainstream media can be a crucial ally in introducing new products and technology

Mainstream media is very effective in raising awareness and support, especially on issues that have the potential to stir differing opinions in society. Obtaining regulatory support for TELA MON810 maize hybrids in Mozambique took a long time, and it required a deliberate focus on engaging high-level authorities, regulatory agencies, and other critical audiences because the task not only involved demonstrating compliance but also raising awareness and building buy-in for the first GM maize variety in Mozambique. Consequently, key audiences (GIBBS, NSA, NBA, MADER, media) were involved in multiple field and outreach events that helped build a common understanding of the proposed benefits of the technology to farmers, as well as the clear demonstration of human and environmental safety. A crucial ally in this process was the mainstream media. Close working partnerships with journalists, especially science journalists where capacity building, feature stories, field interviews, and approaches were

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deployed, ensured that key messages on the technology were communicated consistently during establishment of CFTs and MLTs, and during harvesting. Additional capacity-building events for the media were organized in partnership with initiatives such as the Open Forum for Agricultural Biotechnology (OFAB).

4. Clarity in regulations and consistency in following criteria in reviewing applications can enhance decisionmaking among regulators

Lack of clarity in regulations and their interpretation by various stakeholders and lack of consistency in decisionmaking led to considerable delays in approvals for the deregulation of MON810 in Mozambique. The considerable delay in arriving at the final decision to approve the conditional environmental release for the TELA MON810 maize (2019-2021) in Mozambique resulted mainly from an unusual request to conduct multilocation CFTs, which are not contained in the biosafety regulations. This indicated a lack of clarity in regulations and their interpretation by various stakeholders. It also showed an inconsistency in decision-making by key agencies. The sensitization of regulators on these issues was done by the involvement of the regulators in all testing activities during NPT implementation. In addition, the regulators were invited to take part in 'seeing is believing' visits in and outside the country, and to take part in exchange trips with other regulatory institutions such as the visit of regulators to Nigeria.

5. Political goodwill is essential for the uptake of biotech-derived food crops Political goodwill is demonstrated by highlevel government support for deploying new scientific technologies, especially for biotechnology-derived crops in

Mozambique. The Minister and the Deputy Minister for Science, Technology, and High Education, the Deputy Minister of MADER, and all provincial governments where implementation of project trials was completed are favorable to the technology as part of the government toolkit to address the effects of food insecurity. Even then, some of the difficulties with clarity in the biotechnology regulation may have stemmed from limited dissemination of biosafety law among key audiences. which resulted in limited knowledge by key constituencies, including politicians and other opinion leaders. Greater dissemination of policies can go a long way in easing the compliance journey for biotechnology-derived crops, as the case of TELA maize has demonstrated.

6. Natural calamities and other unforeseen occurrences can affect even the best plans

Other external challenges that affected the regulatory journey included the adverse and unfavorable effects of COVID-19 (2020-2021), which severely disrupted field activities. The catastrophic flooding at key sites like Chokwe in 2022 destroyed entire trials and limited the use of the facilities and field activities there. High staff turnover in government departments also presents a challenge in maintaining awareness levels.

2.4: Successfully navigating the regulatory pathway for the release and commercialization of TELA Bt maize Event MON89034 in Nigeria: Lessons learned

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Overview

The word TELA is derived from the Latin word 'TUTELA' which means protection. The TELA Maize Project builds on progress made from a decade of excellent breeding work under the WEMA Project. TELA Maize Project is a public-private partnership being conducted in seven African countries. The aim of the project is to help African countries meet the challenge of food and nutritional security by increasing maize production and productivity by providing farmers with transgenic maize hybrids. The average yield of maize in Nigeria is 2t/ha which is far below the global yield potential of 5.8 tons/ha.

The TELA Maize Project is targeted at addressing the twin problems bedeviling maize production in Nigeria – namely drought and insect pests, specifically stem borers and fall armyworm. Nigeria joined the TELA Maize Project in April 2019. The project was granted permit for CFTs in 2020. Three CFTs were successfully completed by 2021. A permit for commercial release of TELA maize genetically modified for drought tolerance, resistance to stem borer and fall armyworm was granted on 8 October 2021. Three DT materials were released in 2021 and 2022.

In January 2024, the Nigerian Government through the National Varieties Release Committee (NVRC) approved the release of four TELA maize varieties with the nomenclature SAMMAZ 72T, SAMMAZ 73T, SAMMAZ 74T and SAMMAZ 75T. The varieties were distributed to licensed seed companies for onward sales to farmers in May 2024. A national product launch of TELA maize was held in June 2024. The project is coordinated by AATF with technical support provided by BAYER and CIMMYT and is funded by USAID and the Bill and Melinda Gates Foundation.

Why a Regulatory, Advocacy and Outreach (RAO) team?

The TELA RAO team in Nigeria was established to support the regulatory pathway for the environmental release of TELA Bt maize Event MON89034 in the country. The approval for commercialization of four TELA maize varieties in January 2024 marked the end of the regulatory journey, which focused on demonstrating the efficacy of the insect-protection trait and compliance with regulatory conditions set by the regulators' requirements. The next frontier is the engagement, incentivization, partnership building, and empowerment of the certified seed companies and last-mile intermediaries to take up the final leg on the commercialization pathway that leads to farmers accessing seed of the insect-protected TELA maize in Nigeria. It will focus on incentivizing and capacitating the early generation seed (EGS) and certified seed companies to produce enough highquality transgenic seed of MON89034 TELA maize hybrids in Nigeria. It will also focus on building the framework for the intensive promotion of TELA maize in the target maizegrowing regions, thus building a demandpull of TELA maize from farmers and other stakeholders.

Stewardship messaging, seed availability referrals information flow, private seed sector engagement, farmer education, and grassroots outreach form the core priorities, with a sharper customer orientation to reach the last-mile players (extension workers, NGOs, aggregators, farmers, consumers, etc.). The regulatory journey to this point highlighted several lessons of interest to practitioners and for policy. Despite varying levels of regulatory complexity, consistent outreach work helped demonstrate compliance, which earned the support of the national regulators the -National Biotechnology Research and Development Agency (NABRDA). The team utilized diverse opportunities to showcase TELA maize during 'seeing is believing' at NPTs, town hall meetings, conferences, seminars, media briefings, farmer's days, and international events and fora. Overall, the team noted that consistency in information sharing with key regulators and decisionmakers during the product application dossier submission, CFTs, and NPTs paid off in terms of positive support for the TELA maize varieties.

In addition, the visibility of the TELA maize messages was strengthened throughout the testing phase and promotional activities by working closely with mainstream media, which paid off in terms of broader dissemination of the benefits of TELA maize, at the same time helping to counter anti-GM messages that could have affected the promotion. The significant milestones gained in visibility and public awareness translated into actual demand for seed from farmers early in the regulatory pathway. The entire experience of supporting the regulatory pathway highlighted vital lessons that can inform future practice.

Lessons learned

1. A functional regulatory framework is critical

A well-developed policy and practical and functional regulatory framework for biotechnology product deployment facilitated timely regulatory approval for TELA Bt maize Event MON8903410 insect-protected transgenic trait in Nigeria. The Nigerian regulatory landscape for biotechnology is governed by the National Biosafety Management Agency Act 2015, which established NABRDA. The policy provides a regulatory framework to adequately safeguard human health and the environment from potential adverse effects of modern biotechnology and its products such as genetically modified organisms, while harnessing the potentials of modern biotechnology and its derivatives, for the benefit of Nigerians. The NBMA Act 2015 was amended in 2019 to enlarge its scope and application by including new and emerging aspects of modern biotechnology. The Biosafety Protocol, which Nigeria signed, requires biosafety management and regulatory agency be separate from the biotechnology promoting agency for transparency and

to avoid biosafety being compromised and to also avoid the promoter being a judge in its own case. In this sense, NABRDA is the sole mandated agency to provide leadership and advice to the government on biotechnology and biosafety matters. This singular mandate ensures coherence in biotechnology oversight in the country.

2. External challenges can limit the scale of achievements

Still, there were some challenges in the regulatory context, including: i) poor understanding of the policy implementation by some regulatory staff, which led to delays in the decision-making process; ii) the adverse and unfavorable effects of COVID-19 (2020-2021); iii) delays in seed import into the country; iv) the inability to meet personalities concerned with proposed advocacies; v) insecurity in the country that unfavorably reduced areas where TELA project staff could access awareness and promotion campaigns; and vi) insufficient funding to conduct more promotional activities.

3. Compliance is a crucial ally in the regulatory pathway

The TELA team developed a complete, comprehensive, and informative application dossier for the biosafety approval of the transgenic TELA Bt maize Event MON89034 in Nigeria. Consistency in compliance with the regulator's conditions led to the realization of compelling field-testing data and results at the CFT, allowing for speedy biosafety approval and the environmental release of TELA maize Bt Event MON8903410 in Nigeria. Similarly, consistent compliance with the regulator's conditions at the NPT levels led to compelling field-testing data and results, allowing for the speedy release of Bt maize Event MON89034 hybrids in Nigeria. Critical stakeholder involvement during all the key steps of the process, including CFTs and NPTs, among others, was necessary, not only as a compliance requirement but also as a demonstration of strong stakeholder collaboration.

4. Continuous awareness creation is an invaluable investment

Continuous awareness creation and sensitization of various stakeholders ensured a shared understanding of the TELA products' attributes and expected benefits. Awareness campaigns also helped counter disinformation about TELA maize and GM crops. The team leveraged the media outreach and capacity-building strength of the Open Forum for Agricultural Biotechnology (OFAB), working through its journalism training programs and in-country networks to educate the public on TELA maize. OFAB networks helped increase the reach to various stakeholders. including journalists, judicial officers, farmers, and regulators. The team also recognized that the backing of commodity associations, farmer associations, and professional bodies was significant in promoting the TELA maize hybrid products.

5. Reaching community leaders helped to amplify the messaging

A series of 'seeing is believing' tours were organized at the CFT and NPT sites, which helped to communicate the efficacy message of TELA maize technology. Grassroots outreach work included community-level town hall meetings with farmers, traditional leaders, and religious leaders. Community outreach forums allowed for spontaneous information dissemination on both benefits of the TELA maize technology, as well as addressing disinformation arising from media/societal discourse at the time. There was general advocacy

Key collaborators

Professional associations – Biotechnology Society of Nigeria (BSN), Genetic Society of Nigeria (GSN), Agricultural Society of Nigeria (ASN), Farmer groups – All Farmers Association of Nigeria (AFAN), Maize Association of Nigeria (MAAN), religious and traditional institutions, seed companies including National Seed Council (NASC) which is the supervisory body of all seed companies, relevant government agencies – MOAs, FMA&FS, NABRDA. The media – print, electronic, new media – were involved in the various steps of the process (CFTs and NPTs) toward the commercial release of TELA Bt maize MON89034 in Nigeria.

to influential persons as champions for TELA maize in Nigeria. These champions include the Catholic Bishop of Sokoto H.E Matthew Hassan Kukah, and Farouk Rabiu Mudi , the AFAN president who were vocal in promoting the technology. Former President Goodluck Jonathan, whose administration laid the enabling environment for promoting biotechnology in the country, is also a champion for biotechnology and he played a significant role in amplifying key messages on TELA maize to the broader public in Nigeria.

6. Private seed companies must accept the product for a successful pathway

Seed companies will provide the lastmile link with farmers. As part of the preparation for commercialization, meetings with more than 16 seed companies were organized to provide updates on the progress of TELA maize to build support and potential partnerships in seed production. This interaction with seed companies was sustained throughout the CFTs and NPTs rollout to ensure that private seed companies are key partners in the regulatory pathway. This was done with a clear understanding that the strength of the values proposition for TELA maize depended on seed companies' buy-in right from the outset.

7. Vigilance is key to counter opposing voices

A significant external challenge was the frequent attacks on the policy provision by anti-GM activists throughout the process, affecting outreach work for TELA maize alongside other biotech crops in Nigeria. A notable case was the proposed amendment of the National Biosafety Management Agency (NBMA) Act. Anti-GM groups in Nigeria sought the proposed amendments to thwart and limit the function of the regulatory agency in Nigeria. The aim was to curtail the progress and activities of biotechnology research and use of biotechnology products in Nigeria. As part of joint advocacy efforts, the TELA team actively participated in the public hearing on the proposed amendment of the NBMA Act. As key stakeholders, the TELA Principle Investigator (PI) and the Executive Director of the IAR attended public hearing sessions held by the National Assembly of Nigeria (Senate) in August 2022. The final submission by a panel of experts and stakeholders to the parliament was that the provisions of the NBMA Act were sufficient to guide and regulate biotechnology activities in Nigeria, and there was, therefore, no need for its amendment.

8. Successful demand-creation raises expectations that must be fulfilled

Vigorous outreach activities to create awareness resulted in an unprecedented demand for TELA maize seeds from farmers nationwide. This presented a dilemma because the robust pre-release variety promotion resulted in demand for the TELA maize varieties that had not yet been released by the National Variety Release Committee (NVRC). The risk of farmers losing interest before the varieties became available was confirmed, along with the potential of losing the credibility of the TELA partnership. There was also the risk of losing the political buy-in that farmer demand had created at the grassroots level if there is no crop on farmers' fields. This dilemma was at its peak after the completion of the second round of NPTs in 2023 and would have become a real setback if TELA maize varieties were not approved and released in time.

2.5: Five years of supporting commercialization and uptake of TELA maize in South Africa and beyond: Lessons learned

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Overview

Maize is a major staple food crop in the Republic of South Africa (RSA), with an annual production of over 15 million tons and annual consumption of over 12 million tons. At least 85% of maize produced in South Africa is GM maize. The South African farmer profile is about 95% large-scale commercial farmers. with approximately 5% smallholder farmers. The proportion of yellow and white maize is 55% and 45%, respectively, and 85% of white maize is GM against 90% of yellow GM maize. Since 1998, the Bt trait (insect resistance alone) accounted for 24%. Herbicide tolerance (HT) alone accounted for 15% since 2002. However, since 2007, up to 61% of GM maize contained the stacked Bt + RR (Roundup Ready) traits.

GM maize production has recorded remarkable benefits including increased yields of 2.4 t/ha to 5.0 t/ha in dryland maize and between 12 to 20 t/ha in irrigated maize. Farmer income benefits for maize production for 1998 to 2016 were US\$2.3 billion with up to 97% attributable to GM maize production. Other benefits include efficient weed control with herbicide tolerance (HT) technology, yield protection with Bt technology, decreased pesticide and labor costs, Lower risk of fungal infection and associated mycotoxins (fumonisins and aflatoxin), strengthening national Food security and making RSA a net exporter of maize. Production and consumption of GM maize in South Africa has been ongoing for over 20 years without substantiated incidents of damage to human or animal health or the environment.

TELA maize promotion work began in 2018 mainly in Mpumalanga and Limpopo provinces in South Africa to support farmers in tackling fall armyworm which had proved very difficult to control with insecticides. Preventative spraying was not viable and pest presence prediction was not possible. For instance, in Matibidi village in Mpumalanga province, farmers abandoned their maize crop in 2018 due to severe infestation of fall armyworm after failing to control the pest with chemicals.

The RAO team implemented a series of outreach activities including farmer information days in the TELA target provinces of Mpumalanga and Limpopo in close collaboration with the Department of Agriculture. Farmer testimonies of adopters for MON810 TELA maize varieties were documented and used as promotional material for local and external audiences. In addition to farmer outreach, the TELA team utilized media interviews, speaking opportunities, and other channels to communicate TELA messages to various audiences. The RAO South Africa team is also mandated to support advocacy in other TELA countries, utilizing 'seeing is believing' tours for visiting scientists and regulators for the region including Mozambique, Ethiopia, Kenya, and Nigeria from 2019-2022. These bench-marking tours served to persuade visiting teams of the efficiency to the technology and helped inform decision-making in the respective countries on regulatory approvals for TELA maize varieties.

The TELA Maize Project is coordinated by AATF, with technical support from Bayer and the International Mize and Wheat Improvement Center (CIMMYT) and funded by the Bill and Melinda Gates Foundation and USAID.

Why a Regulatory, Advocacy and Outreach team?

The TELA RAO South Africa team was set up to support commercialization and seed company engagement for the wide-scale adoption of TELA Bt maize Event MON810 hybrids by smallholder farmers in South Africa. In South Africa, biosafety approval and environmental release of Bt maize Event MON810 had already been achieved before the WEMA and TELA projects. Likewise, the variety release of TELA Bt maize MON810 hybrids had already been completed by 2016. The team's experience in supporting the commercialization of MON810 in South Africa generated useful lessons that can inform similar initiatives.

Lessons learned

1. Reaching smallholder farmers in a mature transgenic maize seed market required targeting small, micro, and

medium enterprises (SMME) as an entry strategy

The South African transgenic maize seed market has matured for over two decades. The TELA team held stakeholder meetings with seed companies to create awareness and demand for TELA products so that companies could make them part of their product profile. This was considered a critical step in mainstreaming TELA maize varieties within the more comprehensive and very vibrant maize seed value chain in South Africa. The team mobilized six SMMEs certified seed companies to apply for licenses to produce and market TELA seeds. The process of mobilization and outreach to seed companies highlighted some unique contexts that had implications for the promotion of TELA maize seed varieties. For instance, several certified seed companies approached for partnership either had similar products to TELA (Bt MON810) or superior products (either BT MON89034 or stack of BTMON89034 + Roundup ready, i.e. BT + RR) which they were already selling to farmers.

This meant that only small companies with breeding programs came on board leaving out the more prominent companies with products on the market that they considered superior to TELA. This would have implications on the amount of TELA seed sold. However, considering the original target beneficiaries for TELA maize varieties (smallholder farmers). this outcome was not surprising and, therefore, was not necessarily a failure on the part of the TELA promotion. Nonetheless, the timely availability of RR to the TELA portfolio of royalty-free traits would have greatly upped the number of seed companies marketing TELA maize hybrids and the farmers demanding the same.

2. Perceived liability caused hesitance and low engagement by some private sector actors

Many companies approached were not interested in or involved in GM maize seed production. For this group, the value proposition was not strong enough and the TELA team recognized this reality. Other companies that had experience working with smallholder farmers were concerned about their preparedness for the intellectual property (IP) and the trade implications of signing up for the TELA maize technology, with some expressing apprehension about potential litigation if stewardship commitments for the TELA maize were not adhered to. These concerns also affected the final number of companies that agreed to promote TELA maize in the target locations.

On a positive note, the TELA team's continuous engagement with farmers and provincial departments of agriculture to create awareness and demand for TELA products, particularly in Mpumalanga province, resulted in TELA maize being part of the input support system for the department of agriculture. This was a critical achievement that helped fill up the gap left by the low participation of the mainstream seed companies.

3. An opportunity to persuade audiences and influence decision-making through cross-border learning

The TELA RAO team also undertook various activities to support advocacy in other TELA countries. This included generating communication products such as farmer testimonials, organizing 'seeing is believing', 'eating is believing', and benchmarking tours for scientists, policymakers, and regulators from other TELA-participating countries and showcasing the story of TELA maize in international fora including the annual World Science Forum. To further leverage the partnership, the team worked with OFAB to conduct outreach and capacity building for judicial officers and legal teams from different countries on biotechnology awareness. These information-sharing opportunities contributed to increased awareness and strengthened conviction about TELA maize technology by the visiting teams and had a positive effect on the regulatory pathway for TELA maize where regulatory and policy maker teams had visited South Africa's TELA maize growing areas between 2019 and 2023. While direct attribution is not possible, there is evidence that 'seeing is believing' events helped persuade audiences about the efficacy of the technology, and 'eating is believing' events helped overcome preexisting doubts and prejudices among participating audiences ultimately affecting final decisions in TELA maize technology in other countries.

4. Structured partnerships are critical for last-mile outreach to farmers

Maintaining communication and good relationships with provincial departments of agriculture was essential for effectively promoting TELA maize hybrids among smallholder farmers. It was instructive that where the Agricultural Research Council (ARC) - the TELA focal point and the Department of Agriculture had a formal memorandum of understanding (MOU). there was less restricted access to the farmers, emphasizing the need for formal institutional engagement to maximize the benefits of last-mile outreach work to smallholder farmers. The partnership with Mpumalanga Department of Agriculture, Environment and Rural Development, worked well because of this existing MOU.

Chapter 3 Global Learnings

Synthesis of the learnings from countries (similarities, differences, and global learnings)

Why synthesize the lessons?

TELA is pioneering the deregulation of transgenic traits and commercialization of transgenic maize in four African countries. Any lessons learned will help develop more technologies for food and nutrition security in Africa. Such lessons will optimize resource use by avoiding duplication of activities. They would also help grow national institutions in technology development, deployment, regulation, and stewardship.

The five country case studies detailed here have provided invaluable lessons on what worked or did not work towards the deregulation and commercialization of transgenic droughttolerant and insect-protected (TELA®) maize varieties in the specific countries. A look at these shows a number of those that are common across three or more countries and a number specific to a particular country. There were also differences in the way a lesson in a country was experienced or expressed in a different country. An analysis of these lessons will help the TELA and other projects design future projects to ensure the timely and costeffective process of trait deregulation and transgenic product commercialization. This will also help national technology developers and regulators improve their institutions for

effective and efficient delivery of muchneeded transgenic products for national food and nutrition security.

The areas where common lessons or first-level lessons were observed were: 1) compliance with regulatory conditions, 2) biotechnology policy frameworks, 2) outreach efforts, and 4) political goodwill. Countries had varied experiences in the second-level lessons, including: 1) partnerships, 2) seed company contributions, and 3) external influences. There were significant and varied numbers of unique lessons (third-level lessons) in every country, ranging from one to three lessons per country.

First-level lessons common among the TELA partner countries

1. Compliance with regulatory conditions during trait and product testing

Compliance is the state of being in accordance with established guidelines or specifications or the process. The universally highly regulated GM technology undergoes tests and observations, each preceded by an application to a regulatory agency. The first application is usually for testing the transgene or trait under confinement in laboratories and greenhouses or confined field trials. Each of the five countries conducted confined field trials where material and genetic confinement were observed by keeping the transgenic maize plants and products away from the food and feed chains and isolated to prevent it from crossing with non-transgenic maize. Strict compliance is essential at this stage, which involves record keeping by the applicant and regular inspections by the regulators. The results of CFT testing are a decision on trait deregulation or approval for environmental release that paves the way for the next step of testing, NPT/VCU, and DUS observations.

The next application is for a national performance trial (NPT) in eastern African countries, also known as value for cultivation and use (VCU) trials in southern African countries. The NPT testing usually comes along with distinctiveness, uniformity, and stability (DUS) observations and is conducted by the regulator. DUS is generally performed at one location, while NPT/VCU tests are conducted across locations in the variety's target growing environment. These tests end with a recommendation for variety release, gazettement, and addition of the varieties to the national variety list.

Initially, the implementers, supporters, and critics were apprehensive about the success of WEMA and even the TELA Project, as regulatory processes were viewed as the weak points in the proposed implementation process. However, all TELA partner countries have proven this view wrong, as there has been hardly any breach of compliance at any step in any of the numerous CFTs and NPTs during the last 15 years.

Compliance did not come easily as the project devoted significant resources to training team leads, national implementers and all staff on trial management and keeping excellent records. This enabled the generation of compelling and convincing data on the hybrids evaluated in the well-managed CFTs and NPTs in each of the five countries. In CFTs, effective control of stem borer and, to some extent, fall armyworm without chemical pesticides was demonstrated. Similarly, consistent compliance with the regulator's conditions at the NPT/VCU levels led to compelling field-testing data and results, allowing for the recommendation to release Bt maize Event MON810 and MON89034 hybrids by the regulators in the respective countries.

Each of the respective TELA teams in the various countries developed a complete, comprehensive, and informative application dossier for the biosafety approval of the respective transgenic TELA Bt and DT traits, allowing speedy review and decision-making by the respective regulator. Critical stakeholder involvement during all the key steps of the process, including CFTs and NPTs among others, was necessary, not only as a compliance requirement but also as a demonstration of strong stakeholder collaboration.

Maintaining compliance with regulatory conditions is critical for acceptance of TELA, as compliance with regulatory conditions is the starting point for a favorable review of the application for environmental release of highly regulated technologies such as TELA GM maize.

Global lesson No. 1

It is important to ensure compliance with all regulatory requirements as this helps build trust with regulators that stewardship and other guidelines will be followed. This is crucial for a positive consideration of applications for trait deregulation and the commercialization of highly regulated technologies such as GM Maize.

2. Biotechnology policy frameworks

A biosafety policy framework is a prerequisite for most institutions and countries that plan to adopt novel technologies such as genetic modification. Biosafety frameworks usually consist of policies, laws, and regulations. Biosafety policy broadly states that the country would like to use biotechnology for food security. It further spells out the perceived benefits and risks of the technology and broadly considers how the technology will be used. Biosafetv law either creates or identifies the institutions responsible for various activities and spells out the precautions to be implemented to mitigate the risks of its use. Biosafety regulation helps to operationalize the biosafety laws at the different institutions that regulate technologies with potential biosafety issues.

Depending on the number and maturity of the institutions assigned the various aspects of biosafety regulations, the chains through which an application for biotech activity passes can be either short, long, simple, or complex. The relationship between the staff of the different institutions plays a role in the efficiency of the inter-institutional processing of applications. Even more important is the clarity of the distinct roles among the institutions in the biosafety regulation process. Clear mandates of each institution add to the efficiency, while mandate overlaps can grossly reduce the functionality and efficiency of the regulation process.

All the TELA countries, except South Africa, developed their biosafety policies, laws, and regulations during or later than 1990. This means that TELA maize is one of the products used to assess and run the developing biosafety framework, and there were important lessons to be learned from that process. The countries have recognized that a functional and supportive biotech policy framework is essential. This includes the necessity for clear and non-overlapping mandates of the various regulatory institutions. Clear regulations for each regulator are also crucial, enabling consistent interpretation and application by regulating staff. This, in turn, can lead to improved reviews and decisions on biotech applications.

A well-developed policy and practical and functional regulatory framework for biotechnology products deployment have been instrumental in promptly approving TELA traits and products. This underscores the practical benefits of a supportive biotech policy environment, which is crucial for the successful employment of modern biotech research in addressing food and nutrition security.

Lack of clarity in regulations and their interpretation by various stakeholders and lack of consistency in decision-making led to considerable delays in approvals for the deregulation of biotech traits and the commercialization of their products in a country.

Global lesson No. 2

The timely deregulation and commercialization of drought-tolerant and insect-protected transgenic TELA maize traits and products is facilitated in countries with practical and functional regulatory frameworks. These frameworks should include a well-developed biosafety policy, supportive biosafety laws, and practical regulations. Regulatory institutions must have clear and distinct roles and responsibilities without overlapping mandates.

3. Outreach efforts

Accountability has become a significant focus for most issues that touch the public, and science and its products are essential for society. GM technologies have been attracting much public attention, and their use in research and development, as well as in production and commercialization, has attracted much attention. Therefore, its regulation is often accompanied by public participation to obtain support and buy-in through assurances that the technology is safe for human, livestock, and environmental health and that its use is not impeded by ownership and other legal issues.

The TELA project emphasized outreach, extending services or assistance beyond current or usual limits. Outreach activities are, therefore, meant to engage a large audience and bring knowledge and expertise on a particular topic to the public. Outreach aims to establish beneficial connections between people and organizations. It is oneway communication that tells community members about an issue, problem, opportunity, or decision. A successful outreach program's benefits include increased brand recognition, improved customer service, and better public relations.

TELA country teams engaged the political class to gain buy-in and support favorable policies, the media to disseminate correct scientific and commercial information, farmers and consumers to raise awareness of the new technology and products, and the public to create demand for the products.

Countries noted that consistent outreach to regulators and other stakeholders was important in this process. Sustained outreach or continuous awareness creation and information flow is an effective tool and a prerequisite for positive regulatory support. This outreach process provided an opportunity to persuade audiences and influence decisionmaking through cross-border learning.

Key strategies to reach the different stakeholder groups included symposia, use of champions, 'seeing is believing', 'eating is believing' and benchmarking tours for policymakers to countries where the GM maize technology was already working, such as South Africa. These diversified outreach methods helped sustain the intensified interactions, information flow which supported the process of applications in visiting countries.

Continuous awareness creation and sensitization of various stakeholders ensured a shared understanding of the TELA product's attributes and expected benefits. Awareness campaigns also helped counter disinformation about TELA maize and GM crops. The team leveraged the media outreach and capacitybuilding strength of the Open Forum for Agricultural Biotechnology (OFAB), working through its journalism training programs and in-country networks to educate the public on TELA maize.

Global lesson No. 3

Consistent outreach to regulators, influencers, users, and other stakeholders is crucial in obtaining trait approval, deregulation, and approval for commercializing and placing TELA transgenic maize products on the market.

4. Political goodwill

Political goodwill is the willingness to do favors or act constructively on the side of politicians. It is the determination of an individual political actor to do and say things that will produce a desired outcome. Political leaders are vital influencers in public policies and opinions. In matters such as GMOs that attract public debate, policies are often made not just based on scientific facts and evidence but often on the opinion of the highest level of community leaders.

These case studies demonstrate that all the TELA countries benefited from political goodwill. TELA Ethiopia leveraged political goodwill and support for TELA maize. The team recognized that policy-level support and political goodwill were critical to the regulatory pathway for the environmental release of Bt MON810 and DT MON87460 and submitting the dossier for Bt MON89034 maize transgenes. To fully utilize the existing policy support and political goodwill, the TELA team deployed various information-sharing and awareness-creation strategies, targeting policymakers and high-level leadership as champions for the technology.

Kenya reported that political goodwill could mean everything in the regulatory journey. For example, the ban on importing, producing, and consuming GMOs had widereaching implications for product approvals and promotion, requiring high-level political support that regulatory agencies alone could not mobilize effectively.

Mozambique noted that political goodwill is essential for the uptake of biotech-derived food crops. The influences of the Minister for Science, Technology, and High Education and all provincial governments where the multi-location trials were grown enhanced the approval for commercialization.

Global lesson No. 4

Policy-level support and political goodwill is crucial for the regulatory pathway of the environmental release of TELA transgenic traits and the commercial release and placement of the same in the market.

Second Level Lessons that were common among only some TELA partner countries

Partnerships

A partnership is the association of two or more people as partners. There are at least two people in a relationship that is more than transactional—one person cares about, supports, and provides value to the other and vice versa. Being in a partnership is not about one person 'being in charge' or always getting their way; it is about two people listening to each other and working together to accomplish a common goal. In a true partnership, respect is present, and power is shared.

The benefits of a partnership include getting more people for the work and additional resources, skills, and knowledge. The partners can divide up tasks, meaning tasks will get done faster, and the partners might be able to tackle more than if they worked alone. The disadvantages of the partnership include limited solo decision-making and the possibility of disagreements. You cannot act independently when you're in a partnership. It would help if you worked with your partner to make decisions or at least run all decisions by your partner.

The TELA partnership is coordinated by AATF, with technical support from Bayer and the International Mize and Wheat Improvement Center (CIMMYT). It includes the NARS of Ethiopia, Kenya, Mozambique, Nigeria, and South Africa. It is funded by the Bill and Melinda Gates Foundation and USAID. Only Kenya and South Africa highlighted partnerships as lessons. On project internal partnerships, Kenya observed that 'effective partnership agreements can energize product promotion'. The emphasis was that TELA country NARS partners obtain an all-inclusive agreement covering R&D and commercialization. All partners must be familiar with the agreements and contracts before the projects are executed to ensure all parties' concerns are well captured, ultimately saving valuable time during implementation. On TELA Project beneficiary partnerships, South Africa observed that 'structured partnerships are critical for last-mile outreach to farmers. It was instructive that where the ARC (TELA focal point) and the Department of Agriculture had a formal MOU, there was less restricted access to the farmers, emphasizing the need for formal institutional engagement to maximize the benefits of last-mile outreach work to smallholder farmers.

Global lesson No. 5

Effective partnership agreements can boost product development and deployment. To capture all parties' concerns, it is crucial for agreements to be comprehensive and well negotiated and for all partners to be familiar with them before commencing activities.

Seed companies for impactful TELA maize seeds

Only South Africa and Nigeria, which have commercialized TELA maize products, have learned valuable lessons on the role of seed companies in commercializing and placing the same on the market TELA maize droughttolerant and insect-protected seeds and grain.

Nigeria learned that 'private seed companies must accept the product for a successful pathway'. Seed companies are critical in deploying seed-based technologies as they link the last mile with farmers. To prepare for the commercialization of the Bt maize event MON89034 hybrid, TELA needs to meet with seed companies to interest them in licensing the technology, train them on how to handle it and build support and potential partnerships in seed production. This was done with a clear understanding that the strength of the value proposition for TELA maize depended on seed companies' buy-in right from the outset.

South Africa had a valuable lesson: 'reaching smallholder farmers in a mature transgenic maize seed market required an entry strategy that targeted small, micro, and medium enterprises (SMME)'. The South African transgenic maize seed market has matured for over two decades, but the large seed suppliers do not serve smallholder farmers well. The TELA team mobilized six SMME certified seed companies to apply for licenses to produce and market TELA seeds. This aligned with the original target beneficiaries for TELA maize varieties – smallholder farmers.

Global lesson No. 6

Seed companies must be involved early in technology development and testing. The appropriate seed company fit for purpose must be identified and empowered to provide value to farmers.

Third-level lessons that were unique to various TELA partner countries

Since every country has different political, economic, and social setups, the five TELA countries had lessons unique to the respective countries. Ethiopia learned that 'normal institutional changes can present real risks and challenges. A technology that generates much debate often takes many resources to create awareness by regulators, influencers, and users. Hence, when those staff who have benefited from outreach change positions, the technology developers must start bringing up a new set-up date. This is worse for influencers, especially the political class since they are often from non-science backgrounds. Ethiopia learned that to sustain momentum, it was necessary to repeat onboarding and sensitization of new teams, an activity that consumes more resources than planned. Although this lesson was highlighted in Ethiopia, it was common in all the countries, and a global lesson has been drawn below.

Global lesson No. 7

In African countries, it is crucial to consider the impact of frequent staff turnover among project implementers, regulators, and influencers. It is important to factor in the potential costs of outreach to onboard new staff and get them up to date with project activities.

The Kenya TELA team learned the lesson that 'a thorough review of all applicable laws and regulations is important for expedited review and approval of biotech products. When Kenya obtained biosafety approval for the insect-protected Bt maize event MON810 trait from the NBA in 2016, the TELA team was unaware of what the Environmental Management and Coordination Act (EMCA) spelled out on the environmental requirements for NPT testing of the TELA hybrids. Some compliance challenges arose from the interpretation of the guidelines, emphasizing the need to thoroughly review all applicable laws and regulations before submitting applications for environmental release. For instance, the requirement to implement NPTs under confinement proved to be a challenging, expensive, and timeconsuming exercise.

Global lesson No. 8

Applicants for environmental release and commercialization must review and be familiar with all relevant laws and regulations in the country. This will help ensure that national regulators promptly review and approve biotech products. Overlooking any regulation can slow down or delay the approval process.

Mozambique learned a valuable lesson: 'when appropriately handled, mainstream media can be a crucial ally in introducing new products and technology.' Mainstream media is very effective in raising awareness and support, especially on issues that have the potential to stir differing opinions in society. Obtaining regulatory support for TELA MON810 maize hybrids in Mozambique took a long time, and it required a deliberate focus on engaging high-level authorities, regulatory agencies, and other critical stakeholders through demonstrating good performance, raising awareness, and building buy-in. A crucial ally in this process was the mainstream media. Close working partnerships with journalists, especially science journalists, where capacity building, feature stories, field interviews, and approaches were deployed, ensured that critical messages on the technology were communicated consistently during the CFTs and MLTs establishment and harvesting, and additional capacity-building events for the media organized in partnership with initiatives such as the Open Forum for Agricultural Biotechnology (OFAB).

Global lesson No. 9

Applicants for transgenic agricultural technology can significantly benefit by collaborating with the media, particularly mainstream media, to engage with high-level influencers, regulatory agencies, and other key stakeholders. Main media can facilitate showcasing the technology's efficacy and performance, raising awareness, and gaining support for the new technology and products.

Nigeria had three unique lessons. The first lesson was that 'reaching community leaders helped to amplify the messaging'. Nigeria has a unique societal aspect where community leaders, including kingdoms, are respected. They are often opinion leaders, and their word is taken very well. TELA Nigeria, therefore, organized a series of 'seeing is believing' tours at the CFT and NPT sites, which helped to communicate the efficacy message of TELA maize technology. Grassroots outreach work included community-level town hall meetings with farmers, and traditional and religious leaders. Community outreach forums allowed for spontaneous information dissemination on the benefits of the TELA maize technology, as well as addressing disinformation arising from media/societal discourse at the time.

Global lesson No. 10

To obtain timely approval for a new technology and product in a specific country, reaching out and advocating to influential community, social, or religious groups and institutions is essential. This will help gain acceptance for the project among the target users.

The second unique lesson in Nigeria was that 'vigilance is key to countering opposing voices'. As expected, Nigeria encountered heightened anti-GMO activism as it neared the commercialization of TELA maize. A notable case was the proposed amendment of the National Biosafety Management Agency (NBMA) Act. Anti-GM groups in Nigeria sought the proposed amendments to thwart and limit the function of the regulatory agency in Nigeria. The TELA team actively participated in the public hearing on the proposed amendment of the NBMA Act. Parliament ruled that the provisions of the NBMA Act were sufficient to guide and regulate biotechnology activities in Nigeria, and there was, therefore, no need for its amendment.

Global lesson No. 11

It is wise to proactively address the growing concern of anti-GMO activists by providing accurate information to stakeholders. Failing to do so will result in reactive measures that are often too late and may not effectively improve the situation.

The third unique lesson in Nigeria was that 'successful demand-creation raises expectations that must be fulfilled'. Vigorous outreach activities to create awareness can result in high demand for the product long before it is approved and released. The risk of farmers losing interest before the varieties become available is real, along with the potential of losing the project's credibility. Nigeria was lucky that TELA maize Bt MON89034 was released before the crisis hit. Other countries are facing this dilemma now.

Global lesson No. 12

The promotion of transgenic products builds up expectations that need to be met. It's essential to time the marketing efforts, considering that approval for commercializing these products often takes a while. This minimizes the risk of farmers losing interest before the products are available and maintains the project's credibility.

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Global lessons learned in TELA Project

No	Issue	Ethiopia	Kenya	Mozambique	Nigeria	South Africa
1	Compliance	Maintaining compliance with regulatory conditions is critical for accepting TELA maize in Ethiopia.	Compliance with regulatory conditions is the starting point for a favorable review of the application for the environmental release of TELA maize.	In highly regulated technologies such as GM maize, strict compliance is an essential ally in the regulatory pathway.	Compliance is a crucial ally in the regulatory pathway.	
2	Biotech policy	A supportive biotech policy environment and proven collaboration among key institutions are important.	Clear institutional mandates are essential to the regulatory pathway.	Clarity in regulations and consistency in following criteria in reviewing applications can enhance decision- making among regulators.	A functional regulatory framework is critical.	
3	Outreach	Consistent outreach to regulators and other stakeholders was important in this process.	Consistent outreach to regulators and other stakeholders was important in this process.	Sustained outreach and information flow are crucial prerequisites for positive regulatory support.	Continuous awareness creation is an invaluable investment.	An opportunity to persuade audiences and influence decision-making through cross- border learning
4	Political goodwill	Leveraging political goodwill and support for harnessing TELA maize in Ethiopia was important.	Political goodwill can mean everything in the regulatory journey.	Political goodwill is essential for the uptake of biotech-derived food crops.		

No	Issue	Ethiopia	Kenya	Mozambique	Nigeria	South Africa
5	Partnerships		Effective partnership agreements can energize product promotion.			Structured partnerships are critical for last-mile outreach to farmers.
6	Seed companies			Private seed companies must accept the product for a successful pathway.		Reaching smallholder farmers in a mature transgenic maize seed market required an entry strategy targeting small, micro, and medium enterprises (SMME).
7	Unique feature	Normal institutional changes can present real risks and challenges.	A thorough review of all applicable laws and regulations is essential for expedited review and approval of biotech products.	When appropriately handled, mainstream media can be a crucial ally in introducing new products and technology.	Reaching community leaders helped to amplify the messaging.	Perceived liability caused hesitance and low engagement by some private sector actors
8	Unique feature			Natural calamities and other unforeseen occurrences can affect even the best plans.	Vigilance is key to countering opposing voices.	
9					Successful demand- creation raises expectations that must be fulfilled.	

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