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GUEST EDITORIAL

PROGRESS IN DEVELOPING AND DEPLOYING DROUGHT-TOLERANT AND INSECT-PEST RESISTANT CLIMATE-RESILIENT *DROUGHTTEGO*® AND *TELA*® MAIZE VARIETIES

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INTRODUCTION

Currently, drought stress and associated insect-pest damage pose a huge threat to food and nutrition security for over 300 million people in Africa who depend on maize as their main food source. Recurrent drought events cause an annual 17 to 25 percent yield loss of maize in Africa [1]. Compounding the impact of drought, is the ravaging effect of insect-pests infestation on maize production, especially for pests whose population pressure is highly triggered under dry conditions. The crop under weakened conditions created by drought stress and pest effect further becomes constrained biologically and physiologically, thus limiting the crop's ability to use already limited water and nutrients from the soil. The major insect pests of maize in Africa are fall armyworm (FAW, *Spodoptera frugiperda*) and various stem borer species (Spotted stem borer (*Chilo partellus*), African stem borer (*Busseola fusca*), and the pink stemborer (*Sesamia Calamistis*). For instance, in Kenya alone, an average of 13 percent or 400,000 tons of maize is lost to stem borer, which is equivalent to the annual maize imports, valued at USD 90 million [2]. The FAW, a transboundary pest, first observed in the continent in 2016, is a maize pandemic that if not controlled adequately, could potentially destroy up to 20 million metric tons of maize annually, enough to feed 100 million people in Africa [3].

In addition to maize yield loss, severe damage by both insect pests, through damage to the plant and the developing ears, predisposes the crop to the development of mycotoxins (aflatoxins) caused by fungal disease. This affects the quality of the grains for human and livestock consumption if not adequately controlled in the field.

The impacts of both drought and insect-pests on maize productivity can only be compounded by climate change if immediate measures are not in place to address these constraints. The Water Efficient Maize for Africa (WEMA) Programme was created in 2008 to address the threat by developing and deploying new drought-tolerant and insect-resistant (*climate-resilient)* maize varieties for smallholder farmers through an innovative public-private partnership (P-P-P) [4] that later evolved into TELA Maize Programme in 2018 which explores advanced technologies and objectives.

The WEMA/TELA Public-Private Partnership and Roles of Partners

The AATF, a foremost technology transfer organization, leads the partnership that includes Bayer CropScience (referred hereafter as Bayer), the International Maize and Wheat Improvement Center (CIMMYT), and the National Agricultural Research

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Systems (NARS) of Ethiopia, Kenya, Mozambique, Nigeria, South Africa, Tanzania, and Uganda. The key contributions of the partners to the P-P-P include:

AATF: Provides overall coordination of the P-P-P; brokerage of royalty-free licensing; leads product deployment and stewardship; communication, outreach, and advocacy; and in-country regulatory approvals and compliance with biosafety approval conditions; and monitoring and evaluation of the programme and products.

Bayer: Provision of the *traits Cry1Ab* and *Cry1A.105/Cry2Ab2* for insect resistance and *CspB* for drought tolerance, royalty free for use in product development; provision of over 700 global maize germplasm adapted to different maize growing regions of the world; conventional breeding exploring the use of marker-aided breeding and doubled haploids; genetic engineering for tolerance to biotic and abiotic stresses; trait testing and stewardship; seed production, deployment, and licensing; and free global regulatory data packages.

CIMMYT: Provision of global maize germplasm adapted to Africa; conventional breeding, including the use of MARS, Genomic selection, and doubled haploids, for tolerance to biotic and abiotic stresses; and field testing, including regional trials management.

NARS: Provision of locally adapted germplasm; conventional breeding for tolerance to biotic and abiotic stresses; field testing, including regional trials management; and coordination and management of knowledge of farmers' product needs and preferences.

Investors: The partnership has benefited from long-term investments by the Bill and Melinda Gates Foundation (BMGF); the United States Agency for International Development (USAID); and the Howard G. Buffett Foundation (HGBF; 2008–2017).

The WEMA (TELA) Programme Structure and Operations

Due to the complexity of the partnership, a well-articulated implementation programme was efficiently structured to have an Executive Advisory Board (EAB), with members being either directors or director general of the national partner organisations, and representatives of the other partner and investor organisations. The EAB provides high-level policy oversight to the programme. The programme management office is supported by an Operations Committee (OPSCOM) with one representative each from AATF, CIMMYT, and Bayer; and a NARS representative. The OPSCOM serves as the primary and authoritative instrument for steering and coordinating the programme, and exercises leadership and overall responsibility for the programme strategies, policy, research quality and scientific excellence, and technical issues. It also serves as the clearinghouse for approvals of all the programme's activities and publications.

For the programme to be effectively managed to achieve set target milestones and outcomes, five functional teams with representation from each partner organisation were formed. They comprise (a) Trait Pipeline Testing; (b) Regulatory, Outreach, and Advocacy; (c) Seed Systems; (d) Stewardship; and (e) Legal and Licensing. The functional teams are repeated in each of the seven TELA partner countries.

The programme team members meet annually for a review of the progress of the previous year's activities and to plan for the next programme year. During the TELA Annual Review and Planning Meeting (TELA ARPM), the EAB also meets to review progress and provide recommendations to the functional teams.

To ensure that the implementations of the annual workplan are on track in all the countries, the functional teams meet either biweekly or monthly. Issues on the implementation of activities are brought to the attention of the programme management office and the OPSCOM for immediate resolution. When necessary, the issues are escalated to the EAB for its guidance.

Products Development and Testing Strategies

The partnership based on scientific evidence considers that the products of biotechnology can contribute to Africa food and nutrition security; and relies on global regulatory standards of evaluations to confirm their safety. At the beginning of the programme in 2008, the product concept was first defined to guide product development with focus on white varieties with 25 percent yield improvement over 2008 varieties under moderate-drought conditions; defined as drought stress that occurs two weeks before flowering until three weeks after flowering. The target was first to achieve a 15 percent yield advantage through conventional breeding over 10 years; followed by an additional 8–10 percent yield advantage through genetic engineering (GE).

To provide options for African farmers, the partnership used the following different approaches to develop climate-resilient varieties:

(a) *Non-transgenic, conventional breeding techniques:* These include the utilization of doubled haploids and molecular markers-assisted breeding (MAB). The doubled haploids technique involves the production of haploid

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seeds using haploid inducers followed by chromosome doubling of the haploid cells that are then used to develop homozygous parental lines in a single generation compared with up to six generations typical for a conventional selfing approach. The MAB techniques comprising marker-assisted recurrent selection (MARS) and genome-wide selection (GWS) that accumulates favorable alleles were used to further increase breeding efficiency and speed for the development of improved climate-resilient varieties [5]. The new drought-resilient varieties derived by conventional breeding were trademarked *DroughtTEGO*® (*TEGO* means 'shield' in Latin) and evaluated in the different maize-growing agroecologies through what is called WEMA-Wide Trials (WWTs) and national performance trials (NPTs) before being released for deployment and licensing for commercialisation by interested seed companies.

(b) *Transgenic techniques:* This involves the introduction of drought-tolerance and insect pest resistance transgenes via genetic engineering techniques into adapted conventionally bred drought-tolerant varieties developed using the conventional and MAB techniques described above, to further enhance their level of resilience to both drought and insect pests.

The drought tolerance (DT) gene known as cold shock protein (*CspB*; Event MON87460 or *DroughtGard*®) was sourced from *Bacillus subtilis*, a soil bacterium that has a long history of safe use in the fermentation industry to produce natto (fermented soybean) in Japan and to produce condiments such as *dadawa* (fermented African Locust Bean; *Parkia biglobosa*) in Nigeria. It was anticipated that the inclusion of CspB gene will further enhance the level of resilience of the conventional drought-tolerant maize varieties with an additional yield advantage of 10 percent under moderate-drought environments as previously reported in the USA [6, 7].

The yield gained was protected from the two-target insect-pests using insect resistance genes *Cry1Ab* (Bt Event MON810) or *Cry1A.105/Cry2Ab2* (Bt Event MON89034) derived from Bacillus thuringiensis (Bt), a globally known common soil bacterium that produces specific proteins which are effective in controlling some insect types but harmless to environmentally beneficial insects, livestock, and humans. Bt has a long history of application and is used as a biopesticide in the control of certain insect-pests, especially in the organic food industry globally. The use of maize varieties with Bt Event MON810 or Event MON89034 reduces the need for conventional chemical pesticide sprays for these insect pests; thus, improving the cost-effectiveness and sustainability of crop production including improved environmental safety from reduction in the use of hazardous chemical sprays. It therefore reduces the health hazards associated with the misuse of these chemicals by smallholder farmers. The Bt technology is safely used in different crops in various regions of the world, including Europe, Asia, Africa, Australia, the Middle East, and North and South America.

The programme carries out its traits integration process in Bayer facilities in Mexico as part of this partner's contribution to the programme. The GE process involved using select well-adapted *DroughtTEGO®* hybrid parent materials that had been introgressed with Bt or Bt and DT genes in crosses to form single-cross or three-way hybrids which are known as *TELA®* (derived from the Latin word, *TUTELA*, meaning 'protection'). They either have Bt only or Bt stacked with DT. They were then evaluated for their efficacy in confined field trials in the countries participating in the programme in collaboration with the respective NARS and other programme partners.

The data collected from the confined field trials and biosafety data on the safety to humans, livestock, and environment were used to develop a dossier to seek deregulation of the insect-resistant (Bt) and drought-tolerant (DT) traits (genes) from the various national biosafety authorities to allow for open-field cultivation. Such approvals have allowed the programme to commence the evaluation of several test *TELA®* hybrid varieties in participatory collaboration with farmers for adaptation to the different maize growing agroecologies in five of the seven programme countries. The programme initially included Tanzania and Uganda, but activities have been temporarily paused in both countries in 2020 awaiting the institution of the necessary biosafety regulations for the commercialisation of GE crops.

Products Deployment and Commercialisation Strategies

To deploy and commercialise the climate-resilient maize hybrid varieties to smallholder farmers, AATF developed and utilised a robust business model that delivers these seed-based technologies starting with Kenya in 2013. The model includes, among other components: the establishment of demonstration plots for farmer participatory variety selection in collaboration with community-based organizations; for example, Rural Outreach Africa (formally known as Rural Outreach Program - ROP) in Kenya; issuing royalty-free (without payment of technology fee) humanitarian-use licenses to small- and medium-enterprise (SME) seed companies; establishment of linkages with early-generation seed enterprises QualiBasic and ECOBasic seed companies, which are AATF subsidiaries, for the production of foundation seeds. The business model also includes developing an

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account management system, involving technical backstopping on seed production and business support for licensed SME seed companies.

For *TELA*® varieties, the business model was expanded further to include additional components such as the provision of stewardship support and related capacity enhancement of SME seed companies and farmers. This includes insect resistance management to delay the potential development of resistance by the target pests, the preservation of product integrity by adopting standard operating procedures, and quality control and quality assurance.

Progress in Climate-resilient DroughtTEGO® Maize Varieties

After a decade of excellent breeding in the WEMA phase of the programme, 124 DroughtTEGO® (TEGO®) hybrid varieties were developed and approved for commercialisation to farmers in different countries in Africa. The programme achieved for the first time in the history of maize variety improvement in Africa, a mean genetic gain of 70.5 kg per hectare per year, for DroughtTEGO® hybrids developed through the GWS breeding strategy. This was 2 to 4 times higher than those ever reported from conventional or non-GE breeding in Africa [8], an attestation to the highly resilient nature of the products.

DroughtTEGO® hybrids are being grown in all TELA partner countries. Using the AATF business model outlined above. Within a five-growing season period, in less than three years, the programme working with smallholder farmers successfully established over 4,860 demonstration plots across 17 counties in Kenya. The yields obtained with the DroughtTEGO® varieties ranged from 5.5 to 6.3 tons per hectare; 33 to 54 percent higher than those of the commercial check varieties [9].

Based on the experience and lessons learned from the programme and because of the high resilient nature of the DroughtTEGO® varieties in adapting to different maize growing agroecologies in Africa, the varieties have been released and are making impact among farmers in six non-programme countries including Benin, Cameroon, Ghana, Rwanda, Zambia, and Zimbabwe through the Technologies for African Agricultural Transformation (TAAT) programme funded by the African Development Bank.

Progress in Climate-resilient *TELA*® Maize Varieties

From the confined field trials (CFTs) conducted to demonstrate the efficacy of the *TELA*® traits, (Bt MON810; Bt MON89034; DT MON87460), under natural FAW and artificial stem borer infestation, *TELA*® hybrids with Bt MON810 trait gave an average of 43 percent yield advantage compared with the isogenic hybrids from 12

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CFTs across six locations in five countries from 2016–2020 (unpublished). Similar trials on Bt MON89034 carried out in Nigeria for two years, showed that the *TELA®* hybrids gave 19 percent higher yield than their non-transformed isogenic versions, and 40 percent higher yield than the commercial checks under the target pests infestation [10].

Under moderate drought stress, on average, *TELA®* hybrids with DT MON87460 trait gave about 17 percent yield advantage relative to the non-transformed isogenic hybrids from four CFTs in three partner countries (Mozambique, Tanzania, and Uganda) from 2016–2020 (unpublished). Similarly, under moderate drought stress in Nigeria, the pairwise comparison showed two *TELA®* hybrids with DT MON87460 had 12.4–20.4 percent higher ($P < 0.01$) yield than their isogenic versions [10].

But under optimum-moisture conditions with chemical control of the target pests as required for regulatory trials, the *TELA®* hybrids gave a similar yield as the conventional isogenic hybrids, indicating that the inclusion of the *TELA®* traits did not in any way alter non-target traits based on 12 CFTs conducted across six locations in five partner countries from 2016–2020.

These CFT results were used to support the applications for environmental release of the *TELA®* traits confirming that the varieties with the traits are safe for human and animal consumption, and the environment, having passed the rigorous environmental, health, and biosafety assessments in the partner countries. Currently, approvals have been received from the biosafety authorities in Ethiopia, Kenya, Nigeria, and South Africa; but pending in Mozambique. With these approvals, the programme commenced multilocation national performance trials (NPTs) or value-for-cultivation and use (VCU) trials with 38 potential *TELA®* ([21 Bt MON810 and 12 Bt MON89034]; or Bt stacked with DT [5]) hybrids across the maize growing agroecologies with farmers. These trials are necessary to identify the most adapted and farmer-preferred varieties to be released and certified by the national seed regulatory agency for commercialisation to farmers through licensed SME seed companies. These companies will sell the *TELA®* seed to farmers at the prevailing market price for hybrid seed without charging an extra fee for the *TELA®* traits, which are royalty-free.

The trials had been concluded in South Africa with five *TELA®* Bt (MON9034) hybrids commercialised for access and availability to farmers since 2016. An evaluation of the hybrids under moderate drought stress condition with a high infestation of FAW and stem borer pests in Makhathini showed that *TELA®* Bt

WE6208B hybrid had over six times more yield than the non-Bt (TEGO® WE3128) hybrids.

In Kenya, independent NPTs were conducted in 2020/2021 cropping season by the seed certification agency, Kenya Plant Health Inspectorate Service (KEPHIS) with natural infestation of FAW and artificial infestation with stem borer. Three *TELA*® Bt (MON810) hybrids (WE1259B, WE3205B, and WE5206B) with grain yield of 15–62 percent higher than commercial hybrids were recommended for commercial release pending government final decision. Over 10 tons of certified *TELA*® seeds have been produced and are ready to be used to initiate commercialisation when the programme receives final approval.

Similar trials are ongoing in Ethiopia, Mozambique, and Nigeria with promising results and anticipating variety releases for commercialisation as from 2024.

Impacts of *DroughtTEGO* and *TELA* Maize Varieties

One of the main success factors for impact, unique to the programme was the issuance of humanitarian-use licenses to over 40 SME seed companies to commercialise *DroughtTEGO*® and *TELA*® varieties. Through the account management system implemented by the programme, the volumes of certified seeds that were produced by licensed SME seed companies were tracked annually. It was estimated that between 2013 and 2020, over one million hectares were sown with over 29,000 tons of certified seeds of these resilient maize varieties in 13 countries, Benin, Cameroon, Ethiopia, Ghana, Kenya, Mozambique, Nigeria, Rwanda, South Africa, the United Republic of Tanzania, Uganda, Zambia, and Zimbabwe.

An external impact evaluation of the WEMA programme was commissioned by AATF in Kenya, the United Republic of Tanzania, and Uganda in 2021. The productivity of maize and the consequent income generation by farmers were shown to increase with the adoption of these new varieties. In Kenya and Uganda, for instance, the cultivation of *DroughtTEGO*® led to a significant increase in the average yield by 69 percent, while income generation was significantly enhanced by 75 percent among the adopting- farmers relative to non-adopters [11]. Previously reported ex-post economic impact study in Kenya had indicated that the adoption of *DroughtTEGO*® varieties will generate economic benefits to farmers with a net present value of US$ 2.1 billion over a 20-year period [12]. These benefits are sustainable when adoption levels remain above 32 percent with yield advantage of at least 21 percent over commercial hybrids. The adoption level in Kenya in the 2021 impact study was estimated at 39 percent [10].

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The hybrids were recently described as 'magic seeds' [13] because they were already significantly enhancing the livelihoods of farmers in both Kenya and Uganda. However, these significant improvements were not observed for these two indicators in the United Republic of Tanzania, possibly because the deployment of the *DroughtTEGO*® varieties started very late, a couple of years before the closure of the WEMA phase of the programme in 2018.

The *TELA*® varieties are already making impacts among smallholder farmers in South Africa [16]. Socio-economic studies are ongoing to document the perceptions of adopting farmers and the level of impacts among farmers.

Major Challenges Experienced

There has been sustained anti-biotech activism in Africa aimed at preventing African farmers from adopting transgenic crop varieties such as the *TELA*® maize varieties. The impact of the dis-information from these activists created unnecessary bureaucratic processes and constraints that added cost and delayed decisions on biosafety and variety release approvals.

In developing the climate-resilient *TELA*® varieties, the programme encountered challenges with drought stress assays in confined field trials across countries which were planned in formats that were suitable for data transferability. In addition, the programme encountered challenges with demonstrating drought tolerance efficacy due to the small number of CFTs approved by national regulators.

In some of the programme countries, there were also prolonged delays in getting government approvals for the environmental release of the transgenic *TELA*® traits. These approvals were needed for the conduct of variety certification trials, that are part of the processes to obtain approval for the commercialise release of Bt and DT traited varieties for cultivation by farmers and access to markets.

Key Lessons Learned in Programme Implementation

The public-private partnership (P-P-P) model of the programme was built on trust among partners and governed by agreements with well-defined roles and responsibilities; and with top executive-level commitments from all partner organizations to make the partnership work. The key success factor was the willingness of partner organizations to participate and share responsibilities and risks to achieve a common goal of enhancing food security and rural livelihoods among smallholder maize farmers in Africa.

The use of the P-P-P model along with the collaborative team spirit created in the programme to support product development and deployment enabled access to critically important proprietary conventional and GE traits, tools, expertise, as well as adapted and diverse African and exotic elite germplasm sourced from both public and private partners, which otherwise would not have been available to any single partner organization working alone.

The humanitarian-use licensing model introduced for the first time in SSA by the programme has provided a unique opportunity to incorporate a product branding strategy (i.e., *DroughtTEGO*® and TELA®) and to facilitate communicating promotional and marketing information to farmers of the unique benefits they stand to derive from the programme's climate-resilient maize products.

Under the programme, all licensee SME seed companies engaged were responsible and accountable for meeting high seed quality production standards through the adoption of the humanitarian-use licenses and account management systems offered along with other measures that includes detailed stewardship management procedures stressing on strong regular compliance audits among farmers, as effective ways to enhance the efficiency of product deployment long term sustainability, post-programme.

Securing approvals for the general releases of transgenic crops such as *TELA*® maize in Africa may appear difficult and complicated, but it is not impossible if the requisite legal and regulatory frameworks at country levels are accompanied by consistent and supportive political goodwill.

CONCLUSIONS

The adoption of transgenic insect-resistant maize varieties in the USA has been linked to improvement in maize grain quality and reduction of aflatoxin risks that translated to high economic and health benefits to farmers in the USA [15]. Similarly, the adoption of the 124 climate-resilient *DroughtTEGO*® and 38 TELA®, developed in the programme, by smallholder farmers will enhance maize productivity and grain quality. The products have demonstrated the potential to contribute to food and nutrition security in Africa. These varieties will certainly reflect a significant step change in maize production in Africa when widely adopted. WEMA/TELA programme has demonstrated a successful P-P-P for the development and deployment of climate-resilient *DroughtTEGO*® and *TELA*® varieties, and this was largely due to several factors such as institutional commitments; mutual partner respects; a functional governance structure; and realistic targets, benefits, and distinct roles undertaken by the respective partners. Sustained investments are, therefore, needed to develop more of these climate-resilient *DroughtTEGO*® and *TELA*® hybrid varieties and to deploy them widely in Africa to address climate change impact.

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