

## Lessons Learned on Scaling Aflasafe® through Commercialization in sub-Saharan Africa:

### *Contributions to Policy and Research Priorities for CGIAR*

Aflatoxin contamination of several crops is common in tropical and subtropical regions. Maize and groundnut, staples for billions of people, are among the most susceptible to contamination, primarily caused by the fungus *Aspergillus flavus*. Globally, an estimated 25 percent of aflatoxin-prone crops<sup>1</sup> are contaminated with aflatoxins and/or other mycotoxins<sup>2</sup>. Depending on the dose and exposure period, these toxins can cause severe health detriments in humans and animals. Farmers producing contaminated crops cannot sell to premium markets, including export markets.

Many practices can reduce aflatoxin contamination. The use of atoxigenic isolates of *A. flavus* as biocontrol agents is a highly efficient and practical technology that, when used as cornerstone of aflatoxin management programs, works best. After more than 15 years of research, the International Institute of Tropical Agriculture (IITA) successfully created a biocontrol solution to address aflatoxin contamination in maize, groundnut, and sorghum in Africa. IITA, along with the US Department of Agriculture–Agricultural Research Service (USDA-ARS), and national institutions and with support from A4NH and other donors, have developed several biocontrol products, with the tradename [Aflasafe](#), for use in maize (10 countries), groundnut (nine countries), and sorghum (in Ghana). Each product contains four atoxigenic isolates native to the target country.

These products were developed by identifying friendly fungi that are highly effective at reducing aflatoxin levels, then testing them in farmers' fields. This testing helps create the best composition of Aflasafe for each country, while also providing data needed for the product's registration and regulatory approval. The widespread application of Aflasafe in aflatoxin-affected areas can significantly increase quantities of aflatoxin-safe crops and reduce health

#### Key Scaling and Commercializing Messages

- *A public sector innovation in a new market segment must be championed by the public sector with initial support from development investors for uptake by the private sector.*
- *Scaling up challenges include low awareness, inadequate market incentives, and poorly enforced policies.*
- *Technology development and commercialization of Aflasafe required interventions by a team in a phased manner, with the initial product development phase led by science professionals whose involvement decreases but continues as leadership from business professionals in partnership with engineering and communication professionals grows.*
- *A well-planned commercialization strategy followed by careful investor selection and licensing agreements are crucial for successful technology transfer to the private sector.*
- *Technology developers require a few years to champion and steward the technology after licensing to the private sector, while licensees require a few years of technical, commercial, and communications backstopping before they independently manufacture and distribute Aflasafe.*
- *Private sector investors see an opportunity to grow their business with commercially viable products. They are interested in the business case, risks, opportunities, product quality, manufacturing requirements, market strategy, and projected return on investment.*
- *A marketing strategy for an entirely new product segment addressing a significant but little-known public health risk is more than a sales strategy – it requires a strategic, collaborative approach.*

effects, including liver cancer and potential stunting in children. Using Aflasafe, IITA and partners seek to contribute to improvements in food safety as well as increase incomes of smallholder farmers.

The aflatoxin biocontrol technology was initially developed in the US by USDA-ARS, where it is applied to maize, groundnut, pistachio, almond, and

<sup>1</sup> Susceptible crops apart from maize and groundnut include tree nuts, chili peppers, sorghum, sesame seed, figs, among others.

<sup>2</sup> Eskola, M., Kos, G., Elliott, C.T., Hajšlová, J., Mayar, S., Krška, R. 2019. Worldwide contamination of food-crops with mycotoxins: Validity of the widely cited 'FAO estimate' of 25%. *Critical Reviews in Food Science and Nutrition* 30: 1-17.

fig grown in several states. In Italy, a product is at final stages of registration, and several other European, South American, and Asian nations are developing products. However, the highest impact has been reached in the US and in African nations.

#### FIVE STEPS TO SCALING

The scaling of Aflasafe involved five steps, beginning with product availability. IITA, with various partners, successfully adapted and improved an all-natural technology to develop the environmentally friendly product: Aflasafe. When properly applied, it consistently reduces aflatoxins in maize, groundnut, and sorghum by 80–100%. IITA has led the Aflasafe Technology Transfer and Commercialization (ATTC) initiative to partner with private companies to manufacture and distribute the product.

The second step of the process is product registration. After intensive laboratory and field tests, dossiers for registration are prepared and submitted to biopesticide regulatory agencies. Aflasafe™ was first registered in Nigeria. Aflasafe products have been registered with pesticide regulatory authorities for use in 10 African nations: Nigeria (Aflasafe™; 2014), Kenya (Aflasafe KE01™; 2015), Senegal and The Gambia (Aflasafe SN01™; 2016), Burkina Faso (Aflasafe BF01™; 2017), Ghana (Aflasafe GH01™ and Aflasafe GH02™; 2018), Zambia (Aflasafe ZM01 and Aflasafe ZM02; 2018), Tanzania (Aflasafe TZ01™ and Aflasafe TZ02™; 2018), Mozambique (Aflasafe MWMZ01™ and Aflasafe MZ02™; 2019); and Malawi (Aflasafe MWMZ01 and Aflasafe MW02; 2020). Products are being developed for another 10 nations. To overcome challenges for adoption of Aflasafe, the AgResults Nigeria Aflasafe project (2014-2019)<sup>3</sup> promoted large-scale Aflasafe adoption through an incentivization scheme in Nigeria<sup>4</sup>.

The third step of the process involves licensing and distribution. Kenya Agriculture and Livestock Research Organization (KALRO) is the registrant and manufacturer for Aflasafe KE01, while Koppert Biological Systems has the distribution rights of the same product. IITA has granted manufacturing and distribution licenses to HarvestField Industries Ltd

(HIL) (Aflasafe), BAMTAARE (Aflasafe SN01), A to Z Textiles Ltd (Aflasafe TZ01, Aflasafe TZ02). A distribution agreement has been signed with SAPHYTO (Aflasafe BF01). MacroFertil Ghana (Aflasafe GH02) has imported limited quantities to test the market. Discussions are underway in other countries for licensing agreements.

Fourth, for scaling to succeed one needs the hardware (factory) for mass-production of Aflasafe. Currently, there are three operational Aflasafe manufacturing plants: Ibadan, Nigeria; Katumani, Kenya; and Kahone, Senegal, while construction of a plant in Arusha, Tanzania, is nearly complete. The Ibadan plant will cease to produce Aflasafe for Nigeria when HIL builds its plant in Lagos in 2020.

The fifth step of the scaling process is commercialization, which begins once registration is granted. IITA, Chemonics International Inc., and Dalberg Advisors have designed, piloted, and adapted a unique approach to take Aflasafe to scale, ensuring products reach the people who need them most. Since 2016, these partners have been implementing the ATTC initiative, supported by the Bill & Melinda Gates Foundation and the US Agency for International Development, across East and West Africa. Working with the donor community and developing lasting partnerships with the private sector, ATTC has successfully transferred Aflasafe technology to manufacturers and distributors in Nigeria, Kenya, Senegal, Gambia, Burkina Faso, Ghana, and Tanzania, allowing local and regional exporters, buyers, and smallholder farmers to access the critical aflatoxin mitigation tool. Plans are underway to replicate the initiative in three southern African countries and in Rwanda.

In each country, ATTC refines and adapts the commercialization approach based on lessons learned from each experience, resulting in the proven **five-phase “Science to Scale” process** (Exhibit 1). Each phase of this process includes various steps required to bring Aflasafe to market.<sup>5</sup>

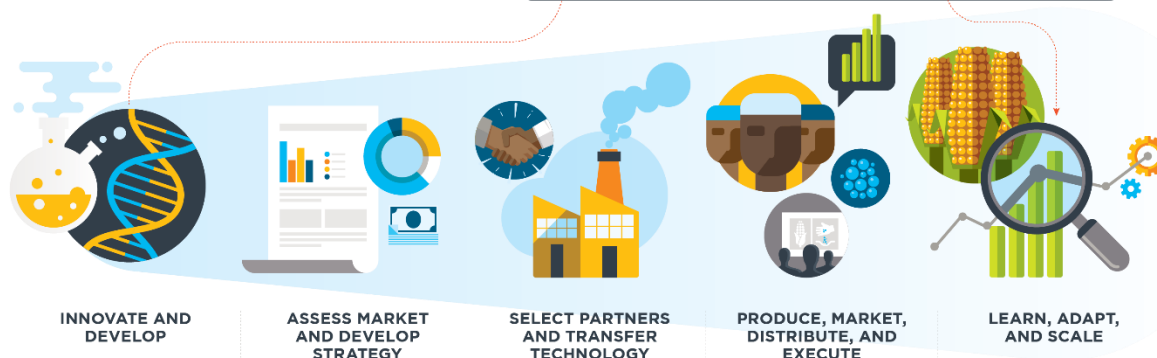
**Phase 1: Innovate and Develop**, as described above as a pre-requisite for scaling.

<sup>3</sup> <https://agresults.org/projects/nigeria>

<sup>4</sup> Bandyopadhyay, R., Atehnkeng, J., Ortega-Beltran, A., Akande, A., Falade, T.D.O., Cotty, P.J. 2019. *Frontiers in Microbiology* 10:2528

<sup>5</sup> For more details, see [https://aflasafe.com/wp-content/uploads/pdf/Status\\_of\\_Aflasafe\\_Commercialisation\\_in\\_Africa.pdf](https://aflasafe.com/wp-content/uploads/pdf/Status_of_Aflasafe_Commercialisation_in_Africa.pdf)

# HOW DO WE GO FROM SCIENCE TO **SCALE?** COMMERCIALIZATION



**Phase 2: Assess Market and Develop Strategy:** A commercialization strategy<sup>6</sup> is the start of a private sector approach to disseminate Aflasafe to farmers. It is the roadmap ATTC uses to understand demand drivers and supply practicalities, with the overall goal of maximizing uptake of Aflasafe. At this stage, the research, development, proof of concept, and registration/patent work has already been reasonably completed, so the focus turns to understanding market dynamics and economics potential private sector manufacturing and/or distribution partners will want to know prior to investing in a factory and marketing efforts. The commercialization strategy seeks to answer:

1. What is the rationale for private sector actors to invest in an innovation like Aflasafe?
2. What does this rationale suggest for which market segments will drive demand?
3. Based on expected demand, what are the manufacturing and distribution options?

The strategy development process focuses on answering these questions through a combination of hypothesis generation, desk research, field interviews, and financial modeling. The findings are then synthesized into a professional document for use as a roadmap during the commercialization process and to persuade potential partners to invest in Aflasafe. Once the commercialization strategy is in place, there is a clear understanding of how to commercialize Aflasafe in the target country by prioritizing core market segments sensitive to aflatoxin and likely to adopt Aflasafe. The strategy

also identifies capacities and expertise required for an investor to undertake major investments in manufacturing and distribution.

**Phase 3: Select Investor and Structure the Business Relationship:** ATTC develops a recommended process for sourcing, analyzing, and ultimately selecting the investor(s) with the best potential to successfully manufacture, market, and distribute Aflasafe in a specific country. Investor selection involves an iterative solicitation and review process to identify the most qualified manufacturing and/or distribution firms in the target market. Based on outreach and research during market assessment and strategy development, ATTC solicits initial expressions of interest from potential investors and requests more detailed applications, including a business plan, from those most likely to qualify. A shortlist of investors is compiled based on pre-determined evaluation criteria. ATTC determines top recommendations after in-person due diligence site visits and presents with those investors to a board made up of IITA and key stakeholders, who make the final investor selection.

Solidifying the business relationship between IITA and the investor who will become the manufacturing and distribution (M&D) partner, which in some cases may be two separate firms, then requires navigating CGIAR policies, practices, and private sector motivations. The goal is to successfully craft a legal document known as a Technology Transfer Licensing Agreement (TTLA) to transfer the Aflasafe technology to the investor. A

<sup>6</sup> Dalberg Advisors were instrumental in developing the initial commercialization strategy.

TTLA is used because it grants limited non-transferable and non-sublicensable rights for manufacturing, distribution, and sale of the product in line with CGIAR Principles on the Management of Intellectual Assets.

#### **Phase 4: Implement the Business Development**

**Strategy:** Once a TTLA is signed, ATTC works with the partner(s) to transfer the know-how of the technology and provide technical assistance to implement a business plan for Aflasafe. The know-how transfer takes various forms depending on partner capacities and needs. ATTC's support package includes training the technical and sales staff on the integrity of the technology, supporting preparation of the factory and its staff, and transferring of consumer profiles for sales and marketing purposes. ATTC also provides technical assistance for structured awareness-raising and demonstration of the economic and social value of the product to different market segments using business cases and awareness/marketing tools. Supporting business knowledge and planning through an extended handover process with M&D partners is critical to ensure partners understand the product and how to manufacture it to quality standards, market and sell it, and promote greater uptake of Aflasafe in target markets.

**Phase 5: Learn, Adapt, and Scale:** ATTC's science-to-scale commercialization process is a new solution to the challenge of getting public sector scientific breakthroughs into public hands at scale. The initiative has been tested and refined across seven countries, but further adaptation of the methodology will continue as Aflasafe is rolled-out in other African countries. ATTC takes a deliberate learning and adapting approach to Aflasafe commercialization, ensuring each roll-out improves upon the last by reviewing the process, identifying strengths and weaknesses, and analyzing results in terms of uptake in each country. For example, based on government engagement in previous rollouts, in Tanzania, ATTC created a communications group of strategic partners who were informed of all decision points to increase their buy-in to the overall process.

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<sup>7</sup> Ramsay, D. 2019. Private sector development and international trade in The Gambia. Rural 21, International Journal for Rural Development. <https://trade4devnews.enhancedif.org/en/impact-story/detoxifying-crops-gambia-ground>

Similarly, in Ghana, government efforts were enabled for developing policies, creating awareness and forming coalitions to make food safe and increase trade.

#### **SUCCESS STORIES**

The re-launch of Gambia's groundnut export sector from using Aflasafe SN01<sup>7</sup>; the Galana Irrigation Scheme, a 2,000 ha food security project implemented by the government of Kenya to produce maize for food insecure populations, where 99 percent of the maize contained less than 4 parts per billion (ppb) total aflatoxin (the limit in Kenya is 10 ppb), compared to more than 1,000 ppb in neighboring areas<sup>8</sup>; and large-scale adoption of Aflasafe in Nigeria by around 100,000 farmers who were able to commercialize aflatoxin-safe maize in premium markets and received a combined US\$ 5 million as a result of premium prices from the market have all been successes. As of 2019, Aflasafe products have been applied in 315,000 ha, and more than 95 percent of treated crops contain aflatoxin below regulatory limit. The treated area is likely to be more than 500,000 ha by the end of 2020.

#### **WHAT'S NEXT?**

There are many difficulties in scaling any aflatoxin control technology because aflatoxin cannot be seen or smelled, does not reduce yield, and markets typically do not discriminate it. ATTC's five-phase approach was developed specifically to address the challenges of getting Aflasafe to smallholders across Africa, but also has the potential to be adapted for new innovations. ATTC has developed guides outlining details of the process that IITA or others can potentially tailor to new commercialization efforts. As ATTC learns from and builds on the last five years of work, private sector commercialization will continue to evolve as an innovative, sustainable method to bring Science to Scale.

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<sup>8</sup> <https://aflasafe.com/2017/06/14/successfully-combatting-aflatoxin-in-kenyas-food-with-aflasafe-on-a-large-scale/>