

## Developing a Subregional Approach to Regulating Agricultural Biotechnology in West Africa

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### SYNOPSIS OF PROJECT DATA

Country:	CILSS and ECOWAS member economies in West Africa
Project:	Rural Agricultural Income and Sustainable Environment Plus (RAISE Plus) Program: Short-Term Technical Assistance in Biotechnology (STTAB)
Implementing organizations:	Michigan State University (MSU), Agriculture and Biotechnology Strategies (AGBIOS), and the Donald Danforth Plant Science Center (DDPSC)
Budget:	US\$2 million
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### CONTEXT

In 2004, the Sahel Institute (INSAH, Institut du Sahel) completed a stock-taking exercise in the member countries of the Interstate Committee for Drought Control in the *Sahel* (CILSS, Comité Inter-états de lutte contre la sécheresse au Sahel) plus Ghana to gain a better understanding of the structure of the seed sector in each. During the country consultations, stakeholders provided the following justifications for establishing a subregional regulatory body for conventional and transgenic seed in the Sahel: (1) extending national seed markets that are considered limited; (2) formalizing an ancient transborder seed route; (3) ensuring the quality of the varieties released; and (4) monitoring the release of GE products in particular.

This insight led to the development of the “Framework Convention Introducing a Common Biosafety Regulation for the Prevention of Biotechnological Risks in the CILSS Countries” and the “Framework Convention Instituting

Common Regulations for Conventional and Transgenic Seeds in the CILSS Area.” The preambles to the conventions recognized both the benefits and potential risks of modern biotechnology. It stated that a subregional approach to biosafety regulation should be undertaken as “each country is neither able to individually take advantage of the known and potential benefits of genetically modified organisms (GMOs), nor cope with their known and potential risks.”

In 2005, the Economic Community of West African States (ECOWAS) published an action plan with three operational objectives for the development of biotechnology and biosafety in the subregion, one of which was to develop a subregional approach to biosafety regulation (ECOWAS 2005). The plan was critical of the slow progress in achieving a subregional biosafety framework in West Africa, which it attributed to “an absence of political support in the field of biotechnology and biosafety; lack of communication between stakeholders, even within the same country; lack of coordination between the concerned ministries in the member countries; and poor subregional cooperation on the subject.” The subregional approach to biosafety advocated by ECOWAS was to develop and implement a common regulatory framework that would be binding on all ECOWAS member countries.

### PROJECT OBJECTIVES AND DESCRIPTION

The primary objective of the Short-Term Technical Assistance in Biotechnology (STTAB) project was to work cooperatively with regulatory officials to develop practical, needs-driven policies, directives, guidance, and review procedures to address the regulation of confined field trials and eventual commercialization of GE crops in West Africa. The project’s components are described in the sections that follow.

### **Technical assistance to INSAH for the review and adoption of technical annexes to the CILSS biosafety convention**

The project worked in partnership with INSAH (the technical arm of CILSS) and the West and Central African Council for Agricultural Research and Development (WECARD, referred to more commonly by its French acronym, CORAF)<sup>1</sup> as well as representatives from national environment and agriculture ministries to improve the Framework Convention Instituting Common Regulations for Conventional and Transgenic Seeds in the CILSS Area. During a series of four subregional meetings and with additional bilateral inputs from CILSS country representatives, the CILSS Convention was substantively rewritten in an effort to address the activities of the subregional process consistently and without duplication. The contained, confined, and unconfined uses of GE organisms were clearly differentiated. The regulatory responsibilities for each of these activities were defined. The technical annexes, which describe the technical information required for applications to the regional scientific review panel, were more clearly aligned with the types of applications that will be received in the subregion and with international standards and guidance related to the regulation of GE organisms established by Codex Alimentarius, OECD, and the Cartagena Protocol.

### **Technical assistance to INSAH to develop and implement an ECOWAS regulation on biosafety**

In August 2008, the Experts Group Meeting on ECOWAS Biosafety Regulation, attended by environment and agriculture representatives from 14 ECOWAS countries, concluded with a request to INSAH-CILSS to extend the CILSS Framework Convention to all of the ECOWAS member countries. Building on the STTAB project's support to INSAH for the development of a regional biosafety framework within West Africa, this initiative aimed to extend the CILSS Biosafety Convention under the ECOWAS mandate.

Specifically, the objective was to develop an ECOWAS Regulation governing the importation, development, manufacture, and use of GE organisms and products derived thereof within ECOWAS Member States and to facilitate a consultative process leading to the adoption of the Regulation. The ECOWAS Biosafety Regulation was to be consistent with the spirit of the CILSS Biosafety Convention, incorporating the best elements of that framework, including its technical guidance on risk assessment procedures. The resulting document was "Regulation C/Reg.1/12/08

Establishing a Procedure for the Review and Authorisation of Products of Modern Biotechnology within the ECOWAS."

### **Technical assistance to enhance the environmental risk assessment capacity of the national biosecurity agency, Burkina Faso**

The STTAB project also endeavored to work with national agencies and authorities to build institutional and human resource capacity in risk assessment, risk management, and decision making at the national level. When the project began, Burkina Faso was the only country in West Africa to have approved confined field trials of a GE crop, insect-resistant (Bt) cotton. To approve these trials, Burkina Faso had promulgated biosafety regulations and established ANB, its national biosafety agency reporting to the environment ministry (Ministère de l'Environnement et du Cadre de Vie). While the ANB, which has a legal mandate for the coordination and monitoring of all activities pertaining to the implementation of biosafety in Burkina Faso, was already active in the field, budgetary and technical capacity constraints limited its effectiveness. Preserving and building on the advances in Burkina Faso required building significant and sustainable capacity within the ANB.

## **INNOVATIVE ELEMENTS**

The innovative elements of STTAB were its regional approach to what was initially perceived as a national priority. The approach proved flexible enough to be developed into a novel model for subregional harmonization of biosafety regulations.

### **Identifying and responding to a national priority with positive regional spillovers**

Initially, the STTAB project focused most of its technical capacity-building in Burkina Faso. This strategic decision was based on the fact that: (1) Burkina Faso's government had clearly indicated its support for the commercialization of Bt cotton and, to that end, had made significant steps toward establishing a biosafety regulatory system (see box 6.28 in TN 4 in this module) and (2) farmers expressed significant interest in cultivating Bt cotton, generated by promising results from field trials conducted from 2003 to 2006. Environmental risk assessment training was provided to ANB personnel and other scientists so that a premarket environmental risk assessment of Bt cotton could be

undertaken. The assessment was a prerequisite for the decision to approve Bt cotton.

### **A novel but feasible model for subregional harmonization**

Given the ease of transboundary movement of seed between countries in West Africa, the impending commercial authorization of Bt cotton in Burkina Faso was an important catalyst for countries to work toward implementing a subregional approach to biosafety regulation. From prior stock-taking exercises and subregional consultations, it was apparent that the project should direct regional harmonization to the development of a mechanism whereby the science-based risk assessment would be undertaken by a subregional body but all decision-making would remain at the national level. A subregional body responsible for undertaking risk assessments for specific types of applications (such as confined field trials, food safety assessments for GE food, environmental risk assessment of GE plants) and providing scientific opinions to the member countries was considered the most achievable form of harmonization. This model differed from the only other examples of subregional harmonization that have been implemented internationally. In the EU, national decisions about cultivating GE crops are delegated to a subregional body, but this model has been ineffective. In Canada and the United States, harmonization of technical requirements for risk assessment has not resulted in appreciable gains in the efficiency or effectiveness of their representative regulatory systems.

The revised CILSS Convention and follow-on ECOWAS Regulation provide a practical and achievable approach to biosafety regulation in a subregion where national governments have limited scientific resources (human, financial, and institutional) to draw upon. An essential element of this project was to build capacity among the country representatives involved in drafting these documents so that the implications of specific policy choices and regulatory approaches could be considered.

### **BENEFITS, IMPACT, AND EXPERIENCE**

This STTAB project has resulted in both direct and indirect benefits in the subregion. Building the capacity of Burkina Faso risk assessors and regulators to undertake the environmental risk assessment of GE cotton was one of the factors contributing to its eventual approval. This effort has strengthened the ANB nationally, promoted its visibility within West Africa as a regional resource for risk assessment

training, and serves as a potential model for other countries in the subregion (or elsewhere in sub-Saharan Africa).

The commercial cultivation of Bt cotton in Burkina Faso contributed to an increase of about 16 percent of overall production in 2009/10. It is anticipated that 95 percent of harvested area (442,900 hectares) in 2010 will be planted to Bt cotton compared to the 2009/10 season (106,000 hectares). This expansion is expected to contribute significantly to national cotton production.

The ECOWAS regulation has not been submitted for approval, so it remains to be seen how implementation will proceed. The West Africa Regional Biosafety Project, launched in June 2009 by the West African Economic and Monetary Union (WAEMU) with funding from UNEP-GEF and the World Bank, has a component to strengthen institutional capacity for preparing regional laws and regulations on biosafety and creating an institutional framework to accompany the dissemination and implementation of the regional biosafety framework in WAEMU countries. A joint CILSS-ECOWAS-WAEMU committee is currently reviewing the ECOWAS Regulation to determine how it may be best incorporated into the WAEMU project. The end result may be that the ECOWAS Regulation will become a joint ECOWAS-WAEMU Regulation.

### **LESSONS LEARNED AND ISSUES FOR WIDER APPLICATION**

The lessons from this experience are summarized in the sections that follow. They focus on the factors that contribute to successful collaboration, including a clear appreciation of the stakeholders involved, the potential incentives for collaboration, and the capacity-building requirements that must be fulfilled if collaboration is to yield useful results.

#### **Understand who the key players are and engage them early in the process**

The INSAH-CILSS process that led to the development of the first draft of the Framework Convention was criticized because the Convention was developed by Ministries of Agriculture without representation or input from national biosafety focal points or Ministries of Environment. The process to revise the Convention under the STTAB project deliberately included representation from a broader range of ministries. This more inclusive approach was an important step in correcting the apparent absence of prior inter-ministerial engagement.

**Collaboration with like projects should begin early and continue through the life of the project**

Deficiencies in cooperation and coordination between the CILSS-ECOWAS initiative to develop a subregional approach to biosafety risk assessment and the West Africa Regional Biosafety Project under WAEMU led to early concerns that two competing approaches to regional biosafety regulation would develop. This concern may have been resolved with the CILSS-ECOWAS-WAEMU committee mentioned previously. Other capacity-building initiatives have also been launched in West Africa since the STTAB project began, notably the African Network of Biosafety Expertise, established by the African Union/New Partnership for Africa's Development (NEPAD) Office of Science and Technology, with a specific mandate to improve technical capacity in biosafety regulation and risk assessment. Collaboration between all of these projects will be essential if subregional harmonization is to be achieved.

**Subregional harmonization is unlikely unless there is an imperative for countries to engage meaningfully in the process**

In the case of West Africa, the commercial release of Bt cotton in Burkina Faso was a pivotal event. While there had been efforts to promote a subregional approach to biosafety regulation prior to the impending approval of Bt cotton, the expectation that Bt cotton seed would move to other countries within the subregion provided a real-world example of why a subregional approach to risk assessment was desirable and even necessary. Given that most West African countries have very limited capacity in biosafety risk assessment and risk management, a subregional risk assessment of Bt cotton under the process described in the

ECOWAS Regulation would be more efficient and cost-effective than if each country performed its own assessment. It might also help mitigate potential trade disruptions that can occur when trading partners have asynchronous product approvals.

**Building national biosafety capacity is necessary for subregional harmonization**

It is difficult for policy makers to support efforts to develop subregional approaches to biosafety regulation, let alone determine the appropriate model to advance, unless some national capacity in this area has been achieved. A national government does not need to have established and operationalized a biosafety regulatory system before engaging in such discussions, but it requires at least some expertise in biosafety (or related) regulation and/or risk assessment to ensure that national interests can be met.

**Identify how project outcomes can be sustained**

Neither the CILSS Convention nor the ECOWAS Regulation identifies provisions for funding the subregional activities described in each (such as convening the subregional scientific panel). Funding for biosafety capacity building in West Africa, including support for the development of national and subregional biosafety regulatory approaches, has come from the EU, United States, and Japanese donor agencies, as well as foundations and international financial institutions such as the Bill and Melinda Gates Foundation, the McKnight Foundation, the Rockefeller Foundation, and the World Bank. Mechanisms for sustainable funding of a subregional biosafety regulatory system by West African governments have not been established.