PROJECT EXECUTIVE SUMMARY

GEF COUNCIL SUBMISSION

AGENCY'S PROJECT ID: P096058
GEFSEC PROJECT ID: 2911
COUNTRY: Regional (Benin, Burkina Faso, Mali, Senegal, Togo)
PROJECT TITLE: West Africa Regional Biosafety Project
GEF AGENCY: World Bank
OTHER EXECUTING AGENCY(IES):
DURATION: Four years (January 2007–December 2010)
GEF FOCAL AREA: Biodiversity
GEF OPERATIONAL PROGRAM: OP #1 (Arid and Semi-arid Zones), OP #2 (Coastal, Marine and Freshwater Ecosystems), OP #13 (Conservation and sustainable use of biological diversity important to agriculture)
GEF STRATEGIC PRIORITY: Biodiversity focal area Priority 3 (Capacity building for the implementation of the Cartagena Protocol on Biosafety)
ESTIMATED STARTING DATE: January 2007

FINANCING PLAN (US$)	
GEF PROJECT/COMPONENT	
Project	5,400,000
PDF A	
PDF B	700,000
PDF C	
Sub-Total GEF	6,100,000
CO-FINANCING*	
IBRD/IDA/IFC	2,400,000
Governments	1,340,000
WAEMU	750,000
Bilateral	5,425,000
NGOs	500,000
Others (private Sector)	5,000,000
Financial Gap *(to be confirmed)*	2,700,000
Sub-Total Co-financing:	18,115,000
Total Project Financing:	24,300,000
Financing for Associated Activities If Any:	
Leveraged Resources If Any: 6,250,000	

*Details provided under the Financial Modality and Cost Effectiveness section

CONTRIBUTION TO KEY INDICATORS OF THE BUSINESS PLAN:

Agreed joint management actions

- All five participating countries will have aligned national biosafety safeguards, regulations, and the like to regulate and monitor the use of specific modern biotechnologies (mainly cotton) and respond to gene/pollen flows and invasiveness by the end of the project.
- One or more countries will have aligned national policies, regulations, and the like to regulate the commercial release of transgenic cotton by the end of the project.

Regional cooperation

- Regional biosafety legal framework and regional risk assessment and management methods will be implemented by the end of the project with the strong coordination by a regional body (WAEMU).

Local technology development

- Three or more countries will have "regulatory" field trials on agricultural products using science-based risk assessment and management methods developed by the project. .

RECORD OF ENDORSEMENT ON BEHALF OF THE GOVERNMENT(S):

Name and position	Date
Benin	
Mr. Apolinaire Dah Dossounou (GEF Operational Focal Point), M. Raphael James Ogounchi (CPB Focal Point), Ministry of Environment, Housing and Urban Planning	September 28, 2005
Burkina Faso	
Mr. Alain Edouard Traoré (GEF Operational Focal Point), Permanent Secretary, National Council for Environment and Sustainable Development Mr. Soumayila Bancé (CPB Focal Point), General Director of Environment	August 31, 2005
Mali Mr. Alamir Sinna Touré (GEF Operational Focal Point), Mr. Bather Koné (CPB Focal Point), Ministry of Environment	August 26, 2005
Senegal Ms. Fatima Dia Touré (GEF Operational Focal Point), Mr. Ousmane Kane (CPB Focal point, acting), Ministry of Environment, Direction of National Parks	September 21, 2005
Togo Mr. Yao Djiwonu Folly (GEF Operational Focal point), Mr. Abdou-Kérim Moumouni (CPB Focal Point), Ministry of Environment	September 19, 2005
UPDATE with most recent endorsements	

Approved on behalf of the World Bank. This proposal has been prepared in accordance with GEF policies and procedures and meets the standards of the GEF Project Review Criteria for work program inclusion

Steve Gorman
GEF Executive Coordinator, The World Bank
Date: May 17, 2006

Project Contact Person
Christophe Crepin
Regional Coordinator

Tel. and email: 202-473-9727,
ccrepin@worldbank.org

1. PROJECT SUMMARY

a) Project rationale, objectives, outputs/outcomes, and activities

Rationale for Bank/GEF involvement

Mainly driven by insect resistance to chemical pesticides, Burkina Faso has engaged in "regulatory"[1] field testing of transgenic cotton for the last three years under private sector support. Scientists and government officials in Mali and Senegal, and to some extent in Benin and Togo, also wish to begin field trials of transgenic cotton as well as other crops, both food and cash. The plant science industry has already invested in Burkina Faso and is keen to move further in the cotton belt: first in Mali and Senegal, then in Benin and Togo at a later stage. All parties, including Burkina Faso, have expressed the need for biosafety regulatory and safeguard mechanisms to ensure the safe introduction of living modified organisms (LMOs) and their release into the environment. These mechanisms are not currently in place.

Without support from GEF, the five countries are not likely to coalesce in undertaking such activities. Designing a safeguard framework for the introduction of LMOs demands International expertise, but will provide regional and global benefits by protecting biodiversity from gene/pollen flow or invasiveness.

The establishment of a national biosafety framework has already started through UNEP/GEF-funded projects[2]. Moving beyond this stage into further design, adoption, and implementation is a challenging task. However, it is one that can be potentially rewarding in terms of protection of biodiversity while reducing the use of pesticides, and increasing agriculture productivity, food security, and competitiveness in international trade.

The World Bank, with its broad experience in bringing partners together to provide expertise and technical support related to pertinent policy issues (agriculture, environment, trade, intellectual property rights, science and technology, and international convention compliance), is the appropriate development institution for this undertaking. Its environmental and social safeguards and fiduciary frameworks make it the relevant institution that could support the stakeholders and assist in the sustainable arrangements, both ongoing dynamic and mainstream, for implementation of risk assessment and management.

Project development objective

The project's development objective is to assist the ongoing LMOs development dynamic in the agriculture sectors by implementing a biosafety regulatory framework that will ensure safe field trials and commercial release, if proven safe, of transgenic cotton and other crops in the beneficiary countries. This objective will be achieved by establishing an enabling regulatory environment, by capacity building, and by public outreach to meet not only the requirements of the Cartagena Protocol on Biosafety (CPB), which all five countries have ratified, but also other international obligations relevant to biosafety.

Project global environment objective

The global environment objective of the project is to protect regional biodiversity against the potential risks associated with introduction of LMOs that could eventually be released into the environment. This will be achieved through the development of common science–based, internationally accepted methods for risk assessment and management in the approval process of modern LMO biotechnologies. A particular attention will be given to gene transfer to related and unrelated organisms, pest resistances and effects on non target organisms. The project will initially benefit the West Africa Economic and Monetary Union (WAEMU) region (actually a smaller scale subregional entity), and offers a potential for scaling up to the level of the Economic Community of West African States (ECOWAS).

[1] As opposed to "showcase" trials, which are not for approval purposes.

Components, activities, outputs/outcomes

At this stage, the proposed project will include five of the eight member countries of WAEMU (Benin, Burkina Faso, Mali, Senegal and Togo). Most of these countries have already recognized the importance of the cotton sector (Benin, Burkina Faso, and Mali); some are ready to move ahead under the influence of an increasing public-private partnership, and are envisaging products trials or are encouraged about developing cotton production (Togo and Senegal). Senegal, Mali, and Burkina Faso already have a relatively advanced program on agricultural biotechnology in place and have indicated strong interest in the project, as they feel an appropriate safeguard framework is needed. They have also demonstrated a keen interest in moving forward with a harmonized biosafety framework at the regional level. All the beneficiary countries have participated in the National Biosafety Frameworks (NBF) projects, funded by GEF and implemented by the United Nations Environment Programme (UNEP).

Component A – Adapt and disseminate regional methodologies to assess and manage risks

This component will produce operational and regionally harmonized methodologies, such as guidelines, technical documents, forms, and checklists for risk assessment and management of LMOs, in order to safeguard biodiversity, including agro-biodiversity. At this initial stage the project will focus on risk assessment specific on transgenic cotton, but it could be extended to other crops according to the priorities of the biotechnology research institutions. The existing tools in the countries and in the subregion will be assessed and strengthened consistent with international standards on risk management developed by specialized organizations, such as the Organization for Economic Co-operation and Development (OECD) and UNEP. These tools will be disseminated at the national level through workshops and specific trainings. A web-based regional BCH will be established in partnership with the FAO and UNEP, and will allow governments and the main stakeholders to exchange information on LMOs. The regional BCH will therefore be an important tool to improve public awareness of biosafety issues and decision making process related to them.

Component B – Implement national biosafety regulatory frameworks

This component will focus on strengthening the existing NBFs in the five beneficiary countries, all of which have benefited from the UNEP/GEF NBF development projects. As none of the countries has started NBF implementation, the project will first review and update the existing legislation, then support the process for adoption. This component will also raise public awareness and participation and support the involvement of civil institutions in decision making. A particular effort will be made to build the human, institutional, and material capacity of relevant stakeholders: risk assessment for scientists, national laboratories (small equipments), and regional centers of excellence; risk management for farmers and their associations; and regulatory functions for national regulatory and enforcement agencies. Finally, the component will strengthen the capacities of National Agricultural Research Institutes (NARIs) and regional centers of excellence in developing strategies for managing and negotiating intellectual property rights (IPRs) and in assessing the impact of IPRs on the plant breeding and seed sector. Producer organizations, private seed companies, and other stakeholders will be informed of and trained in their rights, options, and obligations under plant variety protection and patenting regimes so that they are better equipped to engage in a policy dialogue on the evaluation and refinement of the IPR systems and their enforcement.

Component C – Set up biosafety and IPR legal frameworks among beneficiary (WAEMU) countries

This regional component will contribute to WAEMU's effort to integrate an economical and political area and harmonize sector policies related to biosafety. Given the interdependence of the economies of the five beneficiaries, the project will help national policymakers coordinate and harmonize their biosafety and IPR legal frameworks and guidelines and make them binding, according to the mandate of this regional organization. The regional strategy will be based on WAEMU key principles of subsidiarity (WAEMU

only acts where member states agree that the action of individual countries is insufficient) and progressiveness (if some countries need more time before the regional framework becomes effective). For instance, the component will build on the experience of countries such as Burkina Faso and Senegal, which are keen to progress rapidly in their NBF implementation, and will establish a regional biosafety framework in which the member countries would fit. The goal is to develop a harmonized regulatory framework on biosafety and IPRs for plant varieties.

A regional observatory on environment, food and feed safety and the socioeconomic impact of agricultural biotechnology will be established, and will monitor a set of key indicators in accordance with a framework of regional results developed by WAEMU and all its stakeholders. Particular attention will be dedicated to potential contamination of local plants by genes originating from LMOs and/or the potential annihilation of agro-biodiversity and replacing it with a single variety. According to the progress made in the foreseen regional harmonization, the observatory could gradually become responsible for LMO approvals, first planned to be handled at the national level. During the midterm review of the project, an assessment will be undertaken to determine whether resources of Component C should be increased.

b) Key indicators, assumptions, and risks (from log frame)

Development objective key performance indicators include:

Percentage of field trials using science-based risk assessment and management methods prior to implementation.

Global environmental objective key performance indicators include:

Satisfactory annual impact monitoring results showing that regional ecosystems are adequately protected especially on risks related to gene transfer to related and unrelated organisms, pest resistance and effect on non target organisms,. A scorecard will be used.

Table 1: *Critical Risks*

	Risks	Risk Mitigation Measures	Risk rating with mitigation
	The participation of five countries with different interests and capacities to implement the CPB and the participation of multiple institutions involved within each country may make project implementation difficult.	The initial focus on one commodity, cotton, among countries with a common interest (cotton is important to their economy) should facilitate regional coordination and project implementation tailored to the readiness of each country.	M
	Regional harmonization efforts are hampered by national resistance or resistance of regional stakeholders.	The proposed implementation agency, WAEMU, possesses political will and experience in regional integration and harmonization of policies. It also has a good reputation in the five countries.	M
	Reputational risk for the Bank when dealing with the sensitive issue of agricultural biotechnology.	Project preparation will involve all stakeholders, including those opposed to LMOs. The project will recruit a communication specialist and prepare a strategic communication plan.	S
	Possible economic gains from the production of Bt cotton or other transgenic plants may be offset by the fact that the countries have not been able to negotiate issues related to intellectual property rights (IPRs).	Through other co-financing, support will be provided for both legal and technical advisory services to assist countries with IPR negotiations and with the setting up of a regional IPR legal framework.	M

	Countries fail to provide agreed counterpart resources on time.	Written commitments from the beneficiary governments to provide the necessary resources are a condition of Board presentation.	M
Overal l risk rating			M

S: Substantial; M: Moderate.

2. COUNTRY OWNERSHIP

a) COUNTRY ELIGIBILITY

At the national level, out of the eight WAEMU countries[3], the five beneficiary countries in the project have ratified the CPB: Burkina Faso (November 2003), Mali (September 2003), Benin (May 2005), Togo (September 2004) and Senegal (January 2004). WAEMU has expressed its interest to see the three other WAEMU countries (Côte d'Ivoire, Guinea-Bissau, and Niger) participating in preparatory and/or implementation activities of the project (under WAEMU financing).

b) COUNTRY DRIVENNESS

All five countries have indicated strong ownership of the project and are providing co-financing during preparation (PDF B stage) and during project implementation. The project fits within the priorities identified in relevant areas by all five countries in their national reports to the Convention on Biological Diversity (CBD).

Benin, Burkina Faso, and Mali were included on the basis of the importance of cotton in the rural economies and as a foreign exchange generator. Togo was retained because it is actively pursuing policies that encourage the development of cotton production. Senegal is part of the project because of its relatively advanced program of agricultural biotechnology and its keen interest in moving forward with a biosafety program at the regional level while pursuing its policy of increasing cotton production.

All WAEMU countries have participated in projects funded by GEF and implemented by UNEP to develop National Biosafety Frameworks.[4] Toward this end, interministerial biosafety committees have been created by the UNEP-GEF projects for policy decision making and preparation of NBFs.

For the implementation phase, the National Competent Authorities (NCAs) will be key players in the establishment and consolidation of functional national biosafety systems. Burkina Faso established its National Biosafety Agency (NBA) within its Ministry of Environment in February 2005. As stipulated in the law prepared by the government with the support of the UNEP/GEF project, the mandate of this agency is to coordinate biosafety activities among government agencies and private organizations and to ensure safety in the use of LMO products (production, imports and exports, and commercialization). The same kind of regulatory and institutional mechanisms are expected in the other countries, especially in Mali and Senegal where the process has already been started. The project will identify and involve relevant government agencies and committees for the implementation of the NBFs. In particular, the project will strengthen, when and if needed, the capacities of the NCAs and enable them to ensure in-country coordination between different stakeholders as stated in the GEF biosafety strategy.

Through WAEMU, within the francophone countries subregion, many efforts on the development and promotion of a common regulatory framework in the agricultural and environmental sectors have begun. WAEMU recognized the strategic place of agriculture in the economy of its member countries and adopted a common agricultural policy in December 2001; it aims primarily at achieving food security,

[3] The eight WAEMU countries are: Benin, Burkina Faso, Côte d'Ivoire, Guinea-Bissau, Mali, Niger, Senegal, and Togo.

[4] See http://www.unep.ch/biosafety/ for more detailed information.

strengthening the common market of agricultural products, and improving the livelihood of producers. In fact, as part of this sector policy, WAEMU has embarked on developing a common approach and harmonization of integrated policy on the production of agricultural and industrial goods and services. Other related areas are fostering cooperation among national agencies on agricultural research, seed certification, industrial norms and testing, phytosanitary measures, and food and feed safety standards. Initiatives have also been undertaken to improve the competitiveness of major agricultural supply chains such as cotton, rice, and maize with a view to harmonizing and carving out a common position for the subregion, particularly on cotton. On the environmental side, a common policy is being prepared and will be examined by the Head of State Council at the end of 2006. As a part of this process, WAEMU intends to launch an initiative on regional biosafety frameworks and has created a budgetary line for 2006.

3. PROGRAM AND POLICY CONFORMITY

a) FIT TO GEF OPERATIONAL PROGRAM AND STRATEGIC PRIORITY

This project aims to improve the participating countries' capacities to handle issues concerning the safe and sustainable use of transgenic crops and derivatives of agricultural importance, and to contribute to the quality and health of the global environment. Thus, the project fits within the GEF focal area on Biodiversity and the GEF Operational Program (OP) on Conservation and Sustainable Use of Biological Diversity Important to Agriculture (OP 13). Because of the cross-cutting nature of the biosafety issue, the project also fits under the Arid and Semi-Arid Ecosystems Operational Program (OP 1), and the Coastal, Marine and Freshwater Ecosystems Operational Program (OP 2).

The project fits within the GEF Biodiversity Strategic Priority No. 3 on capacity building for the implementation of the CPB. It will build capacity on biosafety by supporting: the development of a regional program for risk assessment and management; development at the regional level of the Biosafety Clearing House (BCH) mechanism; biosafety knowledge generation; training, and capacity building; promotion of public awareness; institutional strengthening; and coordination related to biosafety. The end of the project may also contribute to Priority No. 4 on the generation and dissemination of best practices for addressing current and emerging biodiversity issues by identifying innovative approaches and tools in risk assessment, as well as database tools for knowledge generation and sharing in biosafety, and by developing models for capacity building and institutional strengthening.

The proposed project will be developed taking into full account recent conclusions and recommendations from the November 2005 GEF Council meeting, "Elements for a Biosafety Strategy." The emphasis will be on: *in-country coordination and stakeholder involvement* in strengthening NBAs to ensure NBF implementation and coordination between different stakeholders; *the regional approach* with WAEMU, which will complement the national approach; the *use of regional centers of excellence*, such as the West and Central African Council for Agricultural Research and Development (WECARD) in risk assessment and the Sahel Institute (INSAH) in biosafety regulations; and *collaboration with existing bilateral and multilateral projects*, such as USAID's PBS, the French Development Agency's (AFD's), cotton producer organizations, and UNEP's forthcoming *Building Capacity for the Effective Participation of Countries in the Biosafety Clearing House (BCH)*.

b) SUSTAINABILITY (INCLUDING FINANCIAL SUSTAINABILITY)

The project will build on existing national and regional institutions. At the national level, NCAs already exist within environment, health, and agriculture ministries and at the regional level; the coordination unit will be mainstreamed into the existing environment department of WAEMU. Moreover, participating governments are required to commit at negotiations to identifying a source of funding to maintain and operate the institutional set-up, the regional observatory, and the regular updating of the regional risk assessment and management guidelines and other project investments to ensure that the benefits of the project are sustained. Agreement by the countries to identify a regional body and a source of funding for its coordination activities is a condition of Board presentation. The cotton industry and biotechnology industries are expected to contribute significantly to the costs. The PDF Block B grant will finance a

study of options for institutional and financial sustainability, which will be carried out in May/June 2006. The study will include an evaluation of the existing institutional capacities for the proposed biosafety framework implementation at the national and regional levels, identification of specific weaknesses that would require capacity building and technical assistance, and an evaluation of the various financing mechanisms required for the biosafety framework implementation. The main recommendations will be included in the project design

c) REPLICABILITY

The project's subregional approach will lay the groundwork for other countries in West Africa to establish similar biosafety regulatory frameworks. The other WAEMU countries are expected to show interest first; following them, the ECOWAS countries that do not belong to WAEMU. Indeed, the strategy of developing and strengthening the capacity of both subregional institutions and national-level entities in the participating countries can serve as a potential model for other subregions in Africa based on their agro-ecological (i.e., maize and wheat) and social characteristics.

By the end of the project, knowledge-sharing mechanisms (through the Biosafety Clearing House-BCH) are expected to be well tested and fine-tuned; in other words, other countries or subregions can have easy access to knowledge about the project's successes or shortcomings and replicate project strategies according to their needs. In addition, as a result of the project, trained technical personnel will be available to other countries within the larger region.

d) STAKEHOLDER INVOLVEMENT

The main stakeholders and beneficiaries of this project are regional- and national-level policymakers, especially the environment department of WAEMU and NCAs in the five beneficiary countries. Through participation in the project training programs and the activities at the subregional level, government officials from WAEMU and the Ministries of Environment, Agriculture, and Research will gain valuable knowledge and experience in biosafety. Through activities supported under Component 3, a broad range of stakeholders will participate and benefit from the project, including: (i) environmental conservation organizations and other NGOs; (ii) cotton producer organizations and farmer groups; (iii) scientists; and (iv) consumers groups. The centers of excellence that will participate in the implementation of the project, WECARD and INSAH, are both stakeholders and beneficiaries.

The technical capacity developed by the project will help participating countries establish a transparent and predictable regulatory environment that will benefit all agricultural biotechnology stakeholders, including farmers, product developers, others in the supply chain, and civil institutions. The project will aid the establishment of an information-based decision process with key subregional institutions that already give support to the NCAs of each corresponding country. Fostering subregional cooperation and coordination for capacity building and information sharing during the project would set the basis for an effective mode of collaboration between countries facilitating the implementation of the Cartagena Protocol on Biosafety at the regional level. A detailed stakeholder participation action plan will be prepared no later than project appraisal in order to involve all stakeholders, including those sharing a different vision.

e) MONITORING AND EVALUATION

To track progress toward the desired outcomes, the coordination unit within WAEMU will regularly monitor a set of intermediate result indicators in accordance with the result framework specified in Annex B. This result framework names the key results and outcome indicators, annual targets, baseline situation, source of data, frequency of data collection, and entity responsible for collecting and reporting the data. The coordination unit will produce monthly reports describing progress in implementing the components for which they are responsible, and noting trends in key performance indicators where information is available. In addition, six months after project effectiveness, they will produce semiannual reports summarizing the progress achieved during the previous period, and submit them to the Bank one month thereafter. Project managers will pay close attention to the information contained in the progress reports

so that they can quickly identify and address challenges to implementation. Monitoring reports will also be shared with all project stakeholders, including government officials. These reports will also serve as key inputs to project planning and strategic exercises and to steering committee meetings. The coordination unit will monitor implementation of the overall project through quarterly financial management reports and annual technical audits (Project Appraisal Document, Annex 7).

Under Component C, the project will support development of the project monitoring system and creation of the capacity for monitoring as needed within the coordination unit ($150,000) as well as the creation of an observatory on environment, food and feed safety and the socioeconomic impact of agricultural biotechnologies ($US 2million, mainly under IDA financing)

Midterm review and implementation completion report. A midterm review will be carried out no later than December 2008 by the Bank, together with the coordination unit and the other involved parties. In addition to covering all areas included in annual reviews, the midterm review will focus on the project's institutional and financial arrangements, the monitoring and evaluation system, and progress with implementation of all aspects of the project. The midterm review is also expected to thoroughly review and assess the institutional and financial sustainability action plans of each beneficiary country and to lay out the options for institutional and financial sustainability of the project's regional aspects. Finally, it will recommend measures to reorient the project if needed to ensure that it achieves its objectives. Prior to the midterm review, the coordination unit will contract a consultant (under GEF finance) to review and assess the progress of project implementation and prepare the necessary documentation for the review. No later than four months after the project closing date, the coordination unit with input from the other involved agencies will prepare and provide to the Bank a report on the execution of the project, its costs and the current and future benefits to be derived from it to be used in the preparation of the Bank's implementation completion report.

4. FINANCIAL MODALITY AND COST-EFFECTIVENESS

Table 2. *Co-financing Sources*

Name of Co-financier (source)	Classification	Type	Amount (in US$ million)	Status
Beneficiaries' governments	Government	In-kind	1.3	In discussions
WAEMU	Regional governmental institution	In-Kind	0.8	In discussions
USAID	Bilateral donor	Grant	3.3	In discussions
France	Bilateral donor	In-kind	0.7	In discussions
AFD	Bilateral donor	In-kind	0.5	In discussions
International industry	Private Sector	In-kind	5.5	In discussions
Swiss Development Corporation	Bilateral donor	In-kind	1.0	In discussions
IDA	multilateral donor	Loans	2.4	In discussions
Sub-Total Co-financing[5]			**18.2**	

The governments of all participating countries have submitted letters endorsing the project and committing their support to work closely with the Bank/GEF team. The bilateral donors and the private sector named in the table above have all expressed their support for the project. Letters clarifying the nature and value of donor and private sector support will be obtained prior to the CEO endorsement.

[5] A financial gap of US$2.7 million needs to be added *(to be confirmed)*

In countries where the Bank is financing Agricultural Services Projects or other planned IDA operations (see Annex 2 of the GEF brief), IDA co-financing could tentatively be made available for US$2.4 million to support project implementation, mainly components B and C. Some activities are indeed not eligible for GEF funding, such as the setting up of the regional observatory for modern agricultural biotechnology to monitor the impact of modern biotechnology and the adoption and the creation of a regional IPRs framework to mitigate the commercial risk associated with LMOs. The link between the project and the West Africa Agricultural Productivity Program (WAAP) will be further discussed during project preparation, when WAAP preparation results become evident.

5. INSTITUTIONAL COORDINATION AND SUPPORT

a) CONSULTATION, COORDINATION AND COLLABORATION BETWEEN (IAS), AND IAS AND (EXAS), IF APPROPRIATE.

At the subregional level, biosafety is entering the policy arena through the larger subregional economical organizations such as ECOWAS and the Permanent Inter-State Committee for Drought Control (CILSS). Initiatives have commenced in the research and technical sector, in particular through WECARD and INSAH, a specialized arm of the CILSS. WECARD has published a biotechnology and biosafety action plan, while INSAH is working on a regional biosafety regulatory system.

The project will complement the biotechnology-biosafety initiative undertaken by ECOWAS, a larger regional organization that includes all WAEMU member countries, as well as Cape Verde, The Gambia, Ghana, Guinea, Liberia, Nigeria, and Sierra Leone, a total of 15 member countries. Following ministerial conferences in June 2004 in Ouagadougou and in June 2005 in Bamako, WECARD, at the request of ECOWAS, has developed an action plan on agricultural biotechnology and biosafety with support from USAID. Although WAEMU, a monetary union of the eight francophone member states, has the mandate on regulatory harmonization and is well known for its fast track adoption of compulsory harmonized regulation and sector policies, ECOWAS decisions are only propositions. However, the project will favor a common approach between WAEMU and ECOWAS. Thus, it is expected that the project will have positive externalities across the ECOWAS region.

b) PROJECT IMPLEMENTATION ARRANGEMENT

*Project implementation period***.** The project will be implemented during fiscal 2007–11, completed by June 30, 2010, and closed by December 31, 2010.

Executing agencies. Experience from various regional projects has demonstrated that the choice of executing agency and project coordinator is key to the successful implementation of a complex project that involves several countries and partners. WAEMU, an established regional body based in Burkina Faso, was able to successfully coordinate several regional activities because of its understanding of the issues facing the participating countries and the region as a whole, and its long experience coordinating activities of its member states.

From this experience, several options are being considered for management of the proposed project. One is to appoint a regional coordination unit whose head will be responsible for overall coordination of project implementation. The unit will also be accountable for ensuring that financial reporting and auditing requirements are met and that procurement, disbursement, and financial management policies and procedures are complied with. WAEMU is being considered as a suitable organization to serve as the regional unit. National project coordinators from each country's ministry of environment, agriculture or research will coordinate implementation of the national-level activities and all beneficiary agencies. The project will help build the capacity of the unit, the specific national entities involved in the project, and the National project coordinators for project management and project monitoring.

Project oversight. A steering committee—proposed to be headed by WAEMU, and comprising senior officials responsible for agriculture, the environment, or both of each beneficiary country—will be

responsible for the overall monitoring of project implementation. The steering committee will be responsible for coordination of the WAEMU coordination unit, WECARD, and INSAH; the regional coordination unit will oversee coordination of all donors.

Procurement. Works, consultants, and equipment to be financed under the GEF grant will be procured according to World Bank procurement guidelines dated May 2004.

*Accounting, financial reporting and auditing arrangements***.** Before January 1, 2007, the regional coordination unit within WAEMU will establish project accounting systems tracking the cost of the various goods and services provided under the project, according to the most recently published World Bank Financial Management Guidelines. They will keep separate project accounts together with their statutory financial statements. Terms of reference for annual audits of project accounts and semiannual audits of the statement of expenditures will be agreed upon at negotiations. Auditing will be carried out by independent auditors acceptable to the Bank, and the reports of these audits will be submitted to the Bank no later than six months after the end of the fiscal years of the regional coordination unit.

Supervision. The Bank will devote some 120 staff weeks to supervise progress under the GEF grant through fiscal 2011. Supervision will focus on progress in achieving specific objectives, such as establishing the appropriate safeguards, ratification of conventions, development of the national and regional frameworks, development of capacity for the national regulatory entity, procurement, financial management, and overall project implementation. During supervision and project reviews, particular attention will be paid to implementation of the mechanisms designed to promote institutional and financial sustainability.

ANNEX A: INCREMENTAL COST ANALYSIS

1. Broad Development Goals and Baseline

The development goal of the project's beneficiary countries is to introduce modern biotechnologies in their agricultural sector, both to improve competitiveness of cash crops such as cotton and to improve food security in subsistence sectors. The countries have chosen to reach this development goal by implementing field trials to test the agronomic performance of the transgenic crops and their impact on the environment.

Under the baseline scenario, it is anticipated that the WAEMU region will progressively adopt transgenic cotton and mostly likely other transgenic crops. This adoption will follow the financing of the capacity building of the involved countries' scientists, and public awareness activities geared toward LMO acceptance by the end-users. However, this approach will not be harmonized between countries and will not guarantee that adequate risk assessment and management safeguards—those that meet international standards—will be applied to field trials prior to commercial release.

Thus, under the baseline scenario, the lack of adequate safeguard guidelines, lack of commitment and coordination in adopting a regional biosafety legal framework, and the absence of monitoring and evaluation tools at different stages of LMO development might result in potentially high risks of contamination for local biodiversity from genes originating from the LMOs and potentially higher costs in setting up the regulatory framework. In the baseline scenario, the socioeconomic impacts on farmers of LMO introduction are not anticipated to be monitored.

Total costs under the baseline scenario are estimated at some US$7 million, dominated by already invested and forthcoming investments from the private sector in field trials in Burkina Faso and LMO acceptance campaigns, from bilateral donors such as USAID in capacity building in the general field of biotechnology and biosafety, at the national level in Mali and at the ECOWAS regional level with WECARD and INSAH.

2. Global environmental objective

The global environment objective of the project is to protect regional biodiversity against potential risks associated with introduction of LMOs that could be released into the environment. This will be achieved through risk assessment and management methods for modern LMO biotechnologies that are based on common science and are in compliance with international standards.

At this initial stage the project will focus on risk assessment specific on transgenic cotton, but it could be extended to other crops according to the priorities of the biotechnology research institutions. The existing tools in the countries and in the subregion will be assessed and strengthened consistent with international standards on risk management developed by specialized organizations, such as the Organization for Economic Co-operation and Development (OECD) and UNEP. These tools will be disseminated at the national level through workshops and specific trainings. A web-based regional BCH will be established in partnership with the FAO and UNEP, and will allow governments and the main stakeholders to exchange information on LMOs. The regional BCH will therefore be an important tool to improve public awareness of biosafety issues and decision making process related to them.

The methods will initially benefit the West Africa Economic and Monetary Union (WAEMU) region (actually a smaller scale subregional entity), and offers a potential for scaling up to the level of the Economic Community of West African States (ECOWAS).

3. GEF Alternative

Under the GEF alternative scenario, the five beneficiary countries (Benin, Burkina Faso, Mali, Senegal, and Togo) will be able to (i) define common risk assessment and management procedures of international standards in order to mitigate environmental and food/feed safety risks associated with transgenic crops

and eventually other crops such as maize, tomatoes, cassava, and cow pea; (ii) undertake application review using these procedures under a harmonized legal biosafety framework; and (iii) monitor the impact of LMO introduction on biodiversity, and its socioeconomic impact.

Under the alternative, the countries will be able to reach their development objectives (that is to introduce modern biotechnologies in their agricultural sector) at a lower economic cost compared to the baseline scenario because they will build and use a regional legal framework and also to reach the global environmental objective because they will have developed and adapted risk assessment and management methods for modern LMO biotechnologies that are based on common science and are in compliance with international standards

The domestic benefits of the proposed alternative and the baseline will differ: They will be more important in the first option. Under the alternative, farmers' organizations will be better informed and also more closely associated to commercial negotiations between the cotton industry and the plant science industry regarding the level of the technology fee that is going to be paid each year for the transgenic seeds. As a result of capacity building activities, the technology fee would probably be lower in the alternative scenario than in the baseline scenario and thus, the introduction of LMOs in the cotton sector will benefit farmers more in the alternative scenario that in the baseline scenario. From a distribution point of view, it will imply a gain in income for the farmers compared to the baseline scenario that is likely to be neutral from the farmer's point of view (he will pay as much for the transgenic seed than what he would have paid for the conventional seed plus the pesticide).

Total costs under the GEF alternative scenario are estimated at US$24.4 million.

4. Scope of the analysis

The activities related to the development of common science-based risk assessment and management methods in the approval process of modern biotechnologies of LMOs and the setting up of an enabling regulatory environment to meet the requirements of the Cartagena Protocol on Biosafety (CPB), and building the regional observatory would not take place without the GEF alternative. The capacity building and public outreach activities are largely baseline activities and the GEF will allocate limited funding for these, focusing on activities designed (i) to create the regional risk assessment and management methods and the regional legal framework and (ii) to strengthen regional collaboration.

Domestic benefits in addition to those in the baseline include reductions in risks of damage to agro-biodiversity that provide employment, foreign exchange, and food for country nationals, through the export and subsistence agricultural sectors. Additional domestic benefits will also arise from the increased efficiency of national review processes faced by the science plant industry that want to invest in the region. Countries will also benefit from the reduced cost of adoption of risk assessment and management procedures that will not anymore be designed at national levels but at the regional level avoiding thus the financing of the same activities in the five beneficiary countries.

5. Incremental costs

The difference between the cost of the baseline scenario (US$7.1 million) and the cost of the GEF alternative (US$24.3 million) is estimated at US$17.2 million. This represents the incremental cost for achieving global environmental objectives. Of this, about 32 percent, or US$5.4 million, is requested from GEF. The remaining support will come from beneficiary countries governments and WAEMU primarily in form of in-kind ($1.8 million), IDA, bilateral donors such as USAID, SDC, French cooperation, and AFD, primarily in the form of grants and from the international industry and nongovernmental organizations representing the science plant industry.

Table A: Incremental Cost Summary

	Costs (US$M)	Domestic Benefit	Global Environment Benefit
Baseline			
A. Adapt and disseminate Regional Guidelines to assess and manage risks.	0.4	Limited coordination among Burkina Faso, Mali, and Senegal.	Imperfect "regulatory" field trial procedures.
B. Implement national biosafety regulatory framework.	3.8	Slow adoption of Bt cotton in Burkina Faso and Mali.	Trials are imperfectly monitored and could result in environmental contamination.
C. Set up a Regional biosafety and IPR legal framework among WAEMU countries.	2.9	No harmonization of legal frameworks, low protection of local varieties and farmers benefits.	Impact of LMOs on biodiversity is not well monitored and evaluated.
SUBTOTAL	*7.1*		
Alternative			
A. Adapt and disseminate Regional Guidelines to assess and manage risks.	3.5	Lower the cost of adoption of a common risk assessment framework.	Science-based risks assessment procedures established.
B. Implement national biosafety regulatory framework.	11.4	Speed up the review process for adoption and commercialization of modern biotechnologies in Mali, Burkina Faso and Senegal	Trials are properly monitored and evaluated and risk of contamination is reduced.
C. Set up a Regional biosafety and IPR legal framework among WAEMU countries.	9.4	Scale up the safe adoption of modern biotechnologies in the region including for farmers' benefits	Impact of LMOs on biodiversity is properly monitored and evaluated.
SUBTOTAL	*24.3*		
Increment			
A. Adapt and disseminate Regional Guidelines to assess and manage risks.	3.1		
B. Implement national biosafety regulatory framework.	7.6		
C. Set up a Regional biosafety and IPR legal framework among WAEMU countries.	6.7		
SUBTOTAL	*17.2*		

GEF Grant	**5.4**		

ANNEX B: PROJECT LOGICAL FRAMEWORK

Results Framework

Project Global Environment Objective (GEO)/ Development Objective (PDO)	Outcome Indicators	Use of Outcome Information
GEO: Regional biodiversity protected against the risks associated with introduction of LMOs that could be released into the environment.	Satisfactory annual impact monitoring results showing that regional ecosystems are adequately protected especially on risks related to gene transfer to related and unrelated organisms, pest resistance and effect on non target organisms,. A scorecard will be used.	YR1-YR2: Gauge compliance of countries with regional risk assessment and management guidelines. YR3: Determination of whether guidelines need to be strengthened. YR4: Feeds into broader regional program (ECOWAS).
PDO: Biosafety regulatory frameworks, which will ensure safe field trials and commercial release, if proven safe, of transgenic cotton and other crops in the beneficiary countries, implemented to accompany ongoing GMOs development dynamic in agricultural sectors.	% of field trials using science-based risk assessment and management methods prior to implementation.	YR1-YR3: Low level of safely conducted field trials may flag either poor capacity or lack of regulator commitment to adopt science-based guidelines; information used to guide project focus. YR4: Will inform development of regional regulations.
Intermediate Results by Component	**Results Indicators for Each Component**	**Use of Results Monitoring**
Component One: Regional risk assessment and management methodologies designed and disseminated in the WAEMU region.	**Component One:** % of application reviews using the new regional risk assessment and management handbook.	**Component One:** YR2: Handbook finalized and accepted by GEF. YR3-YR4: Low level of proper methodologies may flag poor training programs or lack of research institutes and regulator capacity.
Component Two: Functioning national biosafety regulatory systems in the five beneficiary countries.	**Component Two:** Number of completed reports describing full application reviews. % of field trials conducted in compliance with the approval requirements. Number of written comments submitted by the public before regulatory decisions (law and regulations, guidance and LMO applications).	**Component Two:** YR3: Biosafety systems in place and accepted by GEF. YR4: Low level of properly completed reports may flag governance issues. YR1-YR4: High number of public complaints may flag acceptance problems.
Component Three: IPR and Biosafety frameworks are harmonized at WAEMU level Functioning regional observatory.	**Component Three:** Regional biosafety and IPR frameworks ratified by WAEMU Council of Ministers and implemented Number and quality of environmental and socioeconomic impact monitoring. reports.	**Component Three:** YR2: Regional framework in place and acceptable for GEF. YR1-YR3: Slow progress may flag effectiveness problems. YR4: Feed into a regional program (ECOWAS). YR1-YR4: Low level of reports with adequate may flag information gaps.

Tentative arrangements for results monitoring

		Target Values [6]				Data Collection and Reporting		
Project Outcome Indicators	**Baseline**	**YR1**	**YR2**	**YR3**	**YR4**	**Frequency and Reports**	**Data Collection Instruments**	**Responsibility for Data Collection**
Project Development Objectives								
Percentage of cotton field trials using the new regional science-based risk assessment and management methods prior to implementation	0	While regional tools are not yet designed, ongoing field trials will be assessed case by case, and appropriate action taken	80	90	100	Quarterly	M&E system + Project implementation reports	WAEMU/Regional coordination NCAs/ National coordination
Global Environmental Objectives								
Satisfactory annual impact monitoring results showing that regional ecosystems especially against gene transfer to related and unrelated organisms, pest resistance and effect on non target organisms, are adequately protected. A scorecard will be used.	Baseline data to be gathered during preparation	Scorecard rate: satisfactory	Scorecard rate: satisfactory	Scorecard rate: Assessment highly satisfactory	Scorecard rate: Assessment highly satisfactory	Annually	Annual assessment	WAEMU/Regional coordination NCAs/ National coordination
Result Indicators for each component								
A1: % of application reviews using the new regional risk assessment and management handbook	0	While regional tools are not yet designed, ongoing field trials will be assessed case by case, and appropriate action taken	80	90	100	Quaterly	M&E system + Project implementation reports	WAEMU/Regional coordination NCAs/ National coordination
B1: % of application timely[7] processed	to be assessed during preparation (baseline data)	20	50	75	100	Quaterly	M&E system + Project implementation reports	WAEMU/Regional coordination NCAs/ National coordination
B3: % of field trials	0	While regional tools are	80	90	100	Quaterly	M&E system +	WAEMU/Regional

[6] Target values are indicative at preparation and may be revised during appraisal following discussions with the client countries.
[7] Timely means that the applicant will receive a response (approval or not, request of additional information) within [to be determined by regional and national rules] months

		Target Values [6]				Data Collection and Reporting		
Project Outcome Indicators	**Baseline**	**YR1**	**YR2**	**YR3**	**YR4**	**Frequency and Reports**	**Data Collection Instruments**	**Responsibility for Data Collection**
conducted in compliance with the approval requirements		not yet designed, ongoing field trials will be assessed case by case, and appropriate action taken					Project implementation reports	coordination NCAs/ National coordination
B4: Annual increase of written comments submitted by the public before regulatory decisions	to be assessed during preparation (baseline data)	+30%	+50%	+100%	+100%	Annually	M&E system + Project implementation reports	WAEMU/Regional coordination NCAs/ National coordination
C1: Regional biosafety and IPR frameworks ratified by WAEMU Council of Ministers	0 (feasibility study during preparation)	In countries studies + stakeholders workshops	Regional workshops	Common regulation prepared	Common regulation adopted	Quarterly	WAEMU annual report, and Project implementation reports	WAEMU Regional coordination
C2: Number of annual environmental and socio-economic impact monitoring reports	0	Burkina (1) Others (0)	Burkina (1) Mali (1) Senegal (1) Togo (0) Benin (0)	Burkina (1) Mali (1) Senegal (1) Togo (1) Benin (1)	Burkina (1) Mali (1) Senegal (1) Togo (1) Benin (1)	Annually	WAEMU annual report, and Project implementation reports	WAEMU Regional coordination

ANNEX C: RESPONSE TO PROJECT REVIEWS

a) Convention Secretariat comments response

Issues raised by GEF Secretariat concept agreement review (12-05-2005)	*Replies of the World Bank Team*
At WPI a clear description of project's fit within the six countries' National Reports to the CBD should be included.	All five countries have submitted their national reports to the CBD for several rounds. This project fits within the priorities identified in relevant areas by the participating countries in their NBFs reports.
A good description of sector issues in each country as well as explanation on how the project will build on the UNEP/GEF implemented projects in countries of the region should be provided at WPI.	Sector issues in each country are described in annex 1 of the GEF brief. The brief explains also that the project will build on UNEP/GEF implemented projects by working this time at the regional level with WAEMU that is going to set up a binding regional biosafety legal framework that will be enforced at national level by NCAs that were designed by the UNEP/GEF implemented projects
Issues raised by the GEF Secretariat concept agreement review(04-24-2006)	
Consultation, Coordination, Collaboration between IAs,: Please explain coordination activities foreseen with UNEP and FAO, as crucial partners in the countries.	UNEP and FAO :Coordination activities were discussed during a face to face meeting with UNEP on 04-12-2006. The project will build on the existing NBFs which have been prepared with UNEP-GEF support. The NBFs will be evaluated during the stocktaking assessment, strengthened and harmonized nationally and regionally. The project will also work closely with national and regional stakeholders, in cooperation with UN agencies regional representative.
Institutionnal and financial sustainability: please update this section of the proposal taking into account the studies carried out during the PDFB phase.	The study financed under PDF Block B, will be carried out in May/June 2006. It will include an evaluation of the existing institutional capacities for the proposed biosafety framework implementation at the national and regional levels, identification of specific weaknesses that would require capacity building and technical assistance, and an evaluation of the various financing mechanisms required for the biosafety framework implementation. The main recommendations will be included in the project design in view of further strengthen the project sustainability.

b) Other IA and relevant ExA response

Issues raised by other IA	*Replies of the World Bank Team*
UNEP sent comment to the World Bank on 04-11-2006	The comments were addressed during a face to face meeting with UNEP on 04-12-2006

c) STAP expert review and IA/ExA response

Professor Lynn Frewer
University of Wageningen,
MCB group, Hollandseweg 1
6706KN, Wageningen, The Netherlands

General comments

Overview of project.

The proposed activities focus on developing an approach to regional capacity building and participatory process regarding risk assessment and risk management (and to some extent communication) linked to introducing an LMO (in this case transgenic cotton) into cotton-producing countries (or potentially cotton-producing countries) in West Africa. The approach is presented as a future model for subsequent introduction of LMOs into this region.

Introducing any LMO into a new region is associated with potential controversies (e.g., relating to environmental or human and animal health impacts, or effects on the rural economy). Given the potential controversies associated with LMO introduction and different views being presented by a broad range of stakeholders and end-users, the process demands systematic and unbiased analysis of credible data relating to potential benefits and risks (environmental, health, and impact on regional economic factors). The data (and their interpretation) must be addressed in the process of risk/cost benefit assessment and management, and must be included as part of the process of stakeholder and end-user participation and communication in introducing LMOs to the broader community. For these reasons it is essential that a *credible* and *unbiased* approach to introduction is in place prior to introduction—one that takes into account existing data regarding risk assessments and the potential for local differences in environmental impact and risk management. Systematic, transparent, and independent evaluation of decision-making and participatory processes is essential if this credibility is to be developed and maintained.

A primary objective of the proposed activities is to build local capacity for the development of regulatory activities that are designed to optimize both environmental protection and food safety, and socioeconomic impact factors on regional rural economics (including those related to the potential effects of IPR and novel transgenics).Introducing LMOs into a new region with the potential controversies repeated above is also addressed within this framework.

In terms of the potential problems associated with introducing any LMO into the environment, it is important to consider risk assessments related to health (human and animal) and the potential for negative environmental impact. Socioeconomic risks relate to the potential impact on local and national economies (including compromised export capacities) and, increasingly, bioethical issues. Implementing an effective risk assessment process locally is contingent upon identification of local expertise in key areas and knowledge of local ecology (e.g., the vulnerability of the local ecology to the toxic effects of increased pesticide use). Capacity building is contingent on both training of such expertise, and discussion of what local issues need to be addressed.

The major issues for community discussion relate to potential transboundary issues associated with LMO release, potential impacts on biodiversity and the environment, and the possible socioeconomic or societally transformative consequences of its introduction (IPR and rural farming practices, or adoption of novel farming practices to include effective risk management of LMOs). Human health effects may be related to the introduction of novel food allergens into the human food chain, or potentially allergenic pollens into the environment. The inclusion of antibiotic resistance marker genes in transgenic cotton plants is also the focus of international debate over potential development of microbial resistance.

The benefits of adoption relate to implementation of more effective farming practices in the cotton-producing countries (or potential cotton-producing countries) involved in the project, which, according to the proposal, should ultimately lead to reduction in poverty in these countries. The literature is somewhat equivocal regarding potential environmental impacts of transgenic cotton. A systematic evaluation of potential positive impacts (e.g., reduced use of pesticide ensembles) needs to be made, and evaluated against potential negative effects (increased total usage of pesticides). Due consideration of these data should be made as part of the stakeholder consultation. I am not able to comment on potential impact on local biodiversity in this area, but I assume this information would be supplied by regional research institutes with the relevant expertise in this field as a consequence of capacity-building activities.

There is a reasonable set of data available regarding the introduction of LMO cotton in other regions that can contribute to the local development of a risk assessment and management strategy. However, regional factors may be influential (e.g., variations in local biodiversity and/or farming practices). I assume that these factors will be systematically analyzed as part of the proposed activities. Potential transfer to other crops (in particular nontransgenic cotton) should be considered with due regard to local farming practices.

The expertise needed to contribute to the risk assessment process itself is generally drawn from natural science. Local capacity building in the area of economics is needed if a cost-benefit analysis is to be made. Further comments regarding implementation and evaluation of the social science activities are made later in this review. Risk assessment of potentially hazardous events must be done in the context of local farming practices. For example, the potential impact of pesticide application on local biodiversity will depend on methods of application, as well as on local weather conditions. Thus risk assessment must consider the interaction of both farming practices and the prevailing weather as variables to be considered.

The proposed activities include improving public knowledge and communication. I assume social science expertise will be included in the steering group in order to optimize best practice in this area.

This is contingent on implementation of an effective risk assessment strategy, which also needs to take into account local capacity in the area. I assume this will be a consequence of the proposed activities, and needs to be evaluated as part of the monitoring process.

In particular, the following need to be considered:

- Potential for gene transfer to local plants.
- Potential for increased use of pesticides (or a specific broad-range pesticide) in ecosystems (e.g., insect or fish populations).
- Development of effective assessment methodologies given that some eco-toxicological effects may be difficult to measure (e.g., insect or populations with a habitat at a physically high level in the ecosystem).

Because of the controversy associated with (in particular) different methodological approaches to ecological risk assessment (e.g., probabilistic *versus* deterministic approaches), discussion of methodology should be included in the stakeholder consultation. Training local experts in emerging eco-risk assessment methodologies may need to be considered as part of the capacity-building activities.

The type of ecosystem management proposed and whether it requires further research are outside my area of expertise; this is contingent upon specialist knowledge regarding regional biodiversity. I have been assured that this will be provided by World Bank personnel as well as local research institutes and local knowledge.

A need exists for development of indicators to achieve the objectives. Key performance indicators primarily relate to the documentation associated with risk assessments. Risk management monitoring implicitly involves some assessment of regional harmonization of the activities of the national competent authorities. The effectiveness of the participatory processes themselves, and effectiveness of

communication practices, are not included explicitly in terms of evaluative activities (please see comments regarding participatory processes below).

The evaluation of the impact on biodiversity and human health will be a consequence of regional harmonization of risk assessment activities, and implementation of effective risk management systems. Appropriate monitoring therefore needs to be put into place.

Whether the approach taken in the project proposal achieves the objectives of conserving biodiversity is contingent upon the success of the proposed activities, and depends on the development of appropriate risk assessment methodologies, capacity building in risk assessment and risk management practices, and local adoption of risk management strategies. Effective communication between the authorities and local farmers is key to successful implementation.

Successful operationalization is contingent on the development of a successful regional strategy to assess and manage risks, and, of course, potential benefits. One issue that needs to be considered is the credibility of the participatory process itself, particularly in a potentially controversial area, which is why independent evaluation is required.

Weakness or gap in the project

A systematic and structured approach to the participatory approaches discussed below needs to be identified. Specific comments are raised below. While capacity building, particularly in the risk assessment area, requires considerable investment in terms of training and other knowledge transfer activities, the proposed approach appears satisfactory in this respect. I am, however, less certain that the budget is adequate to cover all of the proposed activities, and reassessment may be required. However, I am not an expert at research costing regarding activities in this region.

In my opinion, there are clearly controversial aspects associated with the introduction of any LMO into a new environment where there is potential for impact on health, biodiversity, and socioeconomic changes. The proposed activities do not, however, focus on environmental introduction of transgenic cotton *per se*, but rather the process of capacity building and stakeholder and end-user consultation regarding the introduction of an LMO.

I am somewhat concerned that the text is ambiguous about issues associated with conducting the regionalized risk assessment itself, and developing the capacity to so do. The proposed activities appear to be adequate regarding the development and implementation of the framework (e.g., regional policy harmonization), but are not explicit regarding what inputs from which areas are required in order to obtain a satisfactory risk assessment in the broader sense of the term. This includes technical risk assessments (e.g., introduction of allergens into the human food chain, potential for local populations to develop pollen allergies, ecotoxicity), socioeconomic impact potential, and systematic analysis of bioethical issues. In particular, issues such as genetic differentiation in the human potential for allergic response to pollen may be prone to regional differences; clearly, the possible impact of horizontal gene transfer or increased use of a specific pesticide is contingent on local ecological systems.

Specific issues include the following:

1. Health impacts
    - The food chain (human and animal) including allergic responses
    - Respiratory effects (transgenic pollen)
    - Long-term and transgenerational effects
    - Antibiotic resistance in micro-organisms resulting from inclusion of marker genes in transgenics.
2. Economic effects

- Impact of using monocultures and single varieties that are potentially vulnerable to localized changes in the environment
- Increased cost of specific pesticides
- Impact of IPR associated with seed repurchases on rural economy
- Negative impact on export markets resulting from the introduction of LMOs into a particular region.

The issue of reduction of genetic diversity should be discussed as part of the risk assessment process, particularly in the context of potential gene flow (e.g., to nontransgenic cotton) or the impact of increased pesticides on the local biodiversity. Overharvesting is not an issue relating to this specific introduction.

Legal aspects are reflected, in particular, in harmonization of the biosafety/IPR in the WEAMU framework, which will be a deliverable of the proposed activities. The model of sustainable use outlined in the project will be developed as a consequence of the approach adopted, which emphasizes capacity building and localization of risk management

The proposed activities appear to be highly effective for the region targeted. It is important that, as part of the participatory process and communication activities, viable alternatives for genetically modified organisms (GMOs) that are the result of traditional breeding are also considered, in particular if there are also benefits to the regional economy or to local biodiversity. Any initiative designed to facilitate localized risk assessment practice, harmonized regulation, and risk management will provide the optimal solution for long-term development in this area, providing initial activities are supported by sustainable risk analysis practices that are also amenable to any future changes in global regulation. The interdependence of the five economies that will benefit from the proposed activities implies that the process will only work if regulatory regional harmonization is achieved.

Identification of global environmental benefits

Potentially problematic issues regarding the introduction of transgenic cotton are also discussed under controversial aspects of introduction.

Very generally, an assessment of the social, environmental, and health risks and benefits of potential introduction of any transgenic crop into a new region needs to be considered. The potential effects on local biodiversity (positive or negative) need to be addressed, and, although extrapolation can be made from other regions where genetically modified (GM) cotton has been introduced, the impact on the local case must be considered in detail.

Environmental issues must include systematic assessment of increased pesticide use as a consequence of horizontal gene transfer to weeds, and subsequent pesticide resistance; impacts on biodiversity (gene transfer and increased pesticide use); and impact of pollen on local insect (and human) populations. Capacity training and knowledge transfer activities must also address these factors. The credibility and independence of data sources and their interpretation are an important part of this process. As a general rule, it is useful to consider both significant and nonsignificant effects, providing methodologies have been scrutinized as part of the process of peer review. The World Bank itself has suggested that the development of an Environmental and Social Risk Assessment (ESRA) would be helpful, from the perspective of identifying what should be included in a risk assessment, and of setting the stage for capacity building and knowledge transfer.

How does the project fit within the context of the goals of GEF?

The proposed activities are broadly in line with the recommendations of the Cartagena Protocol on Biosafety, specifically aiming at assessment and management of potential risks associated with the environmental introduction of an LMO (transgenic cotton) into five West African countries, either those currently cotton producers, or those being encouraged by international bodies to be cotton producers. The

issue of risk-benefit communication is also addressed, although this is not operationalized in a formal way in the proposal.

The project aims to build on specific CPB recommendations for the implementation of localized national regulatory frameworks, stakeholder (and implicitly end-user) involvement in decision-making processes regarding risk assessment and management activities, and (less formally) promotion of public awareness and participation. The focus of the project is not to conduct a formalized risk assessment per se, nor to make specific recommendations regarding risk management activities, but rather to operationalize regional activities directed toward effective risk assessment and risk management.

Regional context

The project extends over five WAEMU countries, specifically taking steps to establish the implementation of a regional observatory regarding "environmental, food and feed safety and socioeconomic impact of agricultural biotechnology." Assuming the appropriate risk assessment measures with respect to local biodiversity are implemented, the issue of transboundary risks in this specific regional context should be well addressed.

Replicability of the project

The proposed activities focus on developing best practice regarding regional introduction of transgenic crops. If successful, there is good potential for subsequent replication, potentially adjusted according to the outcomes of the present proposal (but see comments regarding sustainability below). However, replication is dependent, for example, on successful "auditing" and "benchmarking" of participatory activities.

Sustainability of the project

The proposed activities aim to improve best practice in biosafety through greater stakeholder involvement in risk assessment and management in the introduction of an LMO into a new environment, as well as capacity-building activities that are relevant to harmonization of local regulations on risk assessment and risk management activities. As I understand the presentation of issues in the proposal, successful stakeholder participation in introducing transgenic cotton may form the basis for future stakeholder consultation in the introduction of other transgenic crops in the region under consideration. In other words, the procedures adopted in the proposed activities, if successful, may constitute a "model" for best practice, or provide information regarding improvements on existing practices. I assume that successful implementation of such an activity would also provide the basis for public consultation regarding other activities in the area.

Secondary issues

Linkage to other focal areas

Linkage is contingent upon the extent to which the proposed activities successfully implement regulatory harmonization outside of the WAEMU countries, which, in turn, will be dependent on the successful implementation of the project itself.

Other beneficial or damaging environmental effects

The potential impacts on the local economy and environment of the countries are discussed elsewhere in this review. In particular, the potentially controversial aspects of LMO introduction need to be considered. Ecotourism or bio-harvesting are not an issue in this particular proposal.

Degree of involvement of stakeholders in the project

From the information provided, the establishment of appropriate lines of communication is an integral part of the proposed activities. More transparency regarding how these are to be operationalized would be helpful.

A plan exists for facilitating the flow and exchange of technical information between communities and stakeholders. Clarification regarding the communication process is needed, particularly in those WAEMU countries with a low capacity in risk assessment and management. For example, it would be necessary to identify who are the relevant stakeholders under these circumstances.

In general, the structure of the participatory activities in *any* area of consultation examining potentially controversial agrifood activity should systematically include issues of potential risks and benefits in all countries affected. Local variation (e.g., in the context of biodiversity and local economic conditions) may need to be systematically analyzed as part of the national consultation process. Discussion of risks and benefits should be included in communication with local stakeholders.

I do have some concerns about the participatory process, which could usefully be addressed in the project proposal. This relates primarily to the evaluation of the process and outcome of the stakeholder consultation (see, e.g., "Evaluating Public Participation in Policy Making" [Paris: OECD Publishing, 2005]). An important goal of the stakeholder activities will be to identify local concerns regarding potential risk management activities, particularly at the level of farm management.

The issues to be included on the agenda for the consultative exercises have not been systematically addressed in the proposed activities. I assume that the agenda for participatory activities will be developed by the steering committee, and localized according to community needs. The four main issues are summarized below:

1. Promoting public awareness and participation is presented as an important element of the proposal. However, it is not clear how this will be operationalized outside of the stakeholder *fora*. Presumably other entities, such as community networks, would be useful in this context. An expert in communication, who has specific expertise in any local factors that may have influence on the effectiveness of the process, might usefully be added to the steering group.
2. The key performance indicators include "multi-stakeholders for contributing to biosafety policy development." How would this actually be measured? Against what criteria will stakeholder participation be assessed (e.g., it may be useful to apply a set of criteria relating to the process itself, features of the activity that ensure it takes place in an effective way) and acceptance criteria determined (features of the method that make it acceptable to those involved, and to a broader public)? This would also facilitate the comparison of the outputs of stakeholder consultation in different countries, where some cross-cultural variation on process and acceptance might occur.
3. Independent evaluation of the stakeholder consultation process itself, as well as the acceptability of the process to stakeholders, would increase not only the credibility of the results of the activity but also resulting communications with the broader public. Such independent evaluation is particularly important in a potentially controversial area (which, at present, is likely to include any introduction of LMOs into the environment).
4. Further clarity regarding the procedures and goals of stakeholder participation would be useful. For example, is it information dissemination and outreach activities to end-users, or are the proposers seeking input from stakeholders regarding effective biosafety assessment and management? If risk management on the part of farmers is required, how is best practice spread through the relevant communities who are not involved with the stakeholders themselves? Will this again be conducted through community networks? If so, what mechanisms will be put in place to facilitate this?

How conflict issues are being dealt with?

Resolution of conflict in participatory processes

Resolution of majority and minority consensus conflicts, which might arise as a consequence of participatory processes in implementing a specific strategy such as introduction of LMOs into a specific environment, will always be potentially problematic. The current recommendation is to provide information to interested stakeholders, end-users, and the broader community regarding *why* a particular decision has been made, as well as what the outcome of the decision was.

Resolution of conflict regarding introduction of transgenic cotton into international commodity chains

This issue is not specifically addressed in the proposal, and in my opinion is "out of scope" of the proposed activities. However, I suspect those most likely to be affected by the introduction of transgenic crops in these regions will be small farmers. These are the producers who may be vulnerable to even small changes in demands for their crops, as well as increased dependence on large multinational companies. The introduction of GM cotton into the global commodity chain has not resulted in the same level of consumer negativity as, for example, has been the case with genetically modified foods and ingredients in Europe and some other countries. Yet European consumers have not generally recognized that cottonseed oil is used as a foodstuff (particularly in the international fast food industry), which may have a negative impact on consumer acceptance of transgenic food oils at a later date.

Capacity-building aspects

One of the activities GEF is funding is supporting capacity-building efforts that promote the preservation and maintenance of indigenous and local communities, along with knowledge, innovation, and practices relevant to conservation of biodiversity with their prior informed consent and participation.

Examination of Table 1 indicates that, with the exception of Burkina Faso, risk assessment expertise is low. Thus capacity building in risk assessment for LMOs is a critical part of the proposed activities.

One of the outputs of GEF projects should be stronger institutions and well-trained staff to address these issues. Capacity building represents the core of the proposed activities.

Community inputs into the conservation of biodiversity

A specific framework for incorporating community inputs is not presented. Generic methodologies (stakeholder participation) are discussed but not formalized.

Training needs

It is useful to distinguish stakeholder consultation (what are the local demands for risk assessment?) and knowledge transfer (what are the training needs if effective risk assessment is to be applied within local regulatory frameworks?). I assume similar arguments apply to the risk management aspects. As far as I can tell form my reading of the proposed activities, communication and informed choice are developed from the consultation exercises, but the issue of local expertise in this area has not been explicitly addressed. Perhaps clarification would facilitate the success of the proposed activities.

Is there sufficient human capacity to tackle the issues addressed in the project?

Human capacity is not explicitly addressed in the proposal. The identification of local research institutions has been made, although core competencies need further explanation, particularly with respect to risk assessment activities. The local community networks (e.g., farmers' organizations) required for risk management of LMOs have not been explicitly listed.

c) World Bank Team response to STAP Review

1. The World Bank West African Biosafety Team consulted the STAP Reviewer, Dr. Lynn Frewer, to evaluate the proposed project as required by the GEF funding requirements.

2. On the whole, Dr. Frewer supports the World Bank initiative on the West African Biosafety Project. She particularly emphasized that the proposed project is not primarily focusing on the introduction of transgenic cotton per se, but took a larger initiative to provide and strengthen the capacities of various stakeholders (policymakers, enforcement officials, scientists) and end-users (farmers) in risk assessment and management of LMOs with the initial focus on transgenic cotton. This is, in her view, consistent with objectives embodied in Article 22 of the Cartagena Biosafety Protocol and also the GEF goals.

3. On the proposed regional effort through the WAEMU framework, Dr Frewer is supportive of such an approach, particularly on the establishment of the regional observatory that could serve to operationalize the harmonized risk assessment and management that addresses transboundary movement of LMOs within the specific regional context.

4. All the comments made in the STAP review are addressed in the executive summary as well as in the GEF brief. However, some important concerns highlighted by Dr. Frewer have been picked up and summarized in the table below with replies by the team :

Issues raised by STAP Reviewer, Dr. Frewer	Replies of the World Bank Team
1. The introduction of transgenic cotton may pose environmental (gene transfer, pesticide resistance, impact to local biodiversity), economic (cost benefit analysis, rural economy), human (allergy), and animal health (cotton oil in animal feed) issues in the West African countries.	The first component of the project is to help the participating countries build capacity to assess and manage potential risks relating to environment, human, and animal health. In addition, the Team, with guidance from the Safeguard Specialist in the Africa region, has developed an Environmental and Social Impact Framework in Annex 12 to address the issues raised by the Dr. Frewer.
2. Indicators for measuring the outcome of the project should not be measured by the development of tools for risk assessment. The effective assessment and management of risks by the national competent authorities and other stakeholders must also be measured and tested. The output must take cognition of the local African context.	The Team, with support from the AFTQK team, has developed a revised set of outcome indicators in Annex 4 of the Project Brief for each activity under the three components. The proposed project is not primarily concern with the development of tools but also the capability of the NCA and various stakeholders, including end-users at the national and regional level, in handling and managing risks posed by transgenic cotton. For instance, an outcome indicator will measure the percentage of field trials and commercial release using science-based risk assessment and management methods prior to implementation.
3. Training of various stakeholders including end-users was raised. The concerns expressed were related to the proposed methods to include eco-risk assessment methodologies by the NCA and various stakeholders, the lack of information on the capacity of local stakeholders except for Burkina Faso, and also the capacity of local research institutions including farmers' organizations.	A list of various stakeholders has been developed in Annex 8 to the Project Brief; further deliberations on their level of needs and the type of training required for each category of stakeholders are called for. A detailed training needs assessment will be undertaken in the preparatory phase of the project; it will identify the needs of the local experts and design a training program on risk assessment methodologies and management that is tailored to their needs.
4. There is a need to operationalize the risk-benefit	The Team will engage a Communication Specialist to

communication aspect of the proposed project.	assist the team in developing a communication strategy to address issues relating to the line of communication from the regional level (WAEMU) to the national competent authorities, including interagency communication strategy. The specialist will also to act as a liaison between the project and the external stakeholders like NGOs, civil societies, and farmer organizations.
5. A need to address issues relating to the degree of involvement of stakeholders exists.	The stakeholder participation is essential in a biosafety regulatory system and is the key element for project success. The project has further improved to reflect stakeholder participation and a stakeholder participation plan is scheduled to be prepared with the countries involved. The plan will identify all major stakeholders, assess their needs in information and training, and propose actions to improve their participation in decision making. In addition, the project Team has used two special missions to the participating countries, other WB-related missions, and participation in the regional meetings to consult with stakeholders during the project preparation. The stakeholders that met the Team so far include: government officials from different ministries/agencies, academics, cotton producers, farmers, bilateral agencies working in these countries, NGOs, regional organizations, and UNEP.

Response to comments :

Page 8, Please update this section of the proposal taking into account the studies carried out during the PDFB phase.

- See revision page 8 and 18 of the Executive Summary, and 13 of the project brief. The institutional and financial sustainability assessment of the proposed biosafety framework will be undertaken in May/June 2006 and the major conclusions presented at CEO endorsement. The Expression of Interest (EOI) of the study have been published, and the firm with the most appropriate EOI has been invited to submit a combined technical and financial proposal. The study will include an evaluation of the existing institutional capacities for the biosafety framework implementation at the national and regional level, identification of specific weaknesses that would require capacity building and technical assistance, and an evaluation of the various financing mechanisms required for the biosafety framework implementation. It is expected that a biosafety framework harmonized regionally, and implemented with common risk assessment methods will be more cost effective and sustainable than National Biosafety Frameworks implemented independently in each of the beneficiary country.

Page 12, Please explain coordination activities foreseen with UNEP and FAO, as crucial partners in the countries.

- See the addendum page 18 of the Executive Summary. Comments were sent by UNEP on April 11 and were addressed during a face to face meeting with UNEP on April 12. UNEP will be a crucial partner, as the former implementation agency for the development of the NBFs in the beneficiary countries. The project will work closely with national and regional stakeholders, in cooperation with UN agencies regional representatives (UNEP and FAO)