



RAISE PLUS Task Order: Short-Term Technical Assistance in Biotechnology (TORFP No. M/OAA/EGAT/EMD-05-1263) Semi-Annual Progress Report: October 2005 – February 2006

Introduction

Under the “Rural and Agricultural Incomes with a Sustainable Environment (RAISE PLUS)” IQC, EGAT has launched a three year \$2 million Task Order entitled “Short-Term Technical Assistance in Biotechnology. RAISE PLUS services are provided by a consortium of partners consisting of Development Alternatives Inc. (DAI), Michigan State University (MSU), Agriculture and Biotechnology Strategies (AGBIOS) and Donald Danforth Plant Science Center. The purpose of this task order is to complement the longer-term development efforts with short-term technical assistance in service of EGAT/ESP/IRB, USAID field missions and USAID client countries. The scope of activities covered by this task order reflect the need for rapid and targeted technical assistance to address the requests of client countries, as well as providing a mechanism for EGAT/ESP/IRB to provide technical leadership and support to other USAID units and US government agencies.

This report encompasses activities conducted under the RAISE PLUS Task Order: Short-Term Technical Assistance in Biotechnology (TORFP No. M/OAA/EGAT/EMD-05-1263) during the first 5 months of Year I of the project (October 2005 – February 2006). The majority of activities have focused on start-up, technical conferences, planning and implementing training programs, translations of appropriate documents and organizing activities for the next quarter.

Specific Activities: October 2005 – February 2006

Technical Conferences (A.3.6)

Activity 1: APEC Conference on Biosafety Policy Options, Manila, Philippines, January 16 – 18, 2006.

APEC, in collaboration with the Department of Agriculture of the Republic of the Philippines and the U.S. Agency for International Development held the APEC Conference on Biosafety Policy Options in Manila on January 16-18, 2006. The primary target audience of the conference, which was co-sponsored by the economies of the USA, Philippines, Vietnam, Peru and Canada, included regulators, government policy makers and experts in the areas of agriculture, trade, environment, economics and foreign affairs. The conference focused on exploring policy options for biosafety regulation in the APEC region. The theme of the conference reflected one of the priorities identified in the APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB). Among the topics that were covered are, i) comparison of economies obligations under the WTO and the Cartagena Protocol, ii) impact of regulation on trade flow in the APEC region, iii) differing impacts and implications for importing and exporting countries, iv) biosafety regulation and socioeconomic considerations, v) regional initiatives for biosafety compliance, vi) impact of biosafety regulation on public/private research in agricultural biotechnology, and vii) economy experiences of biosafety policy development and implementation. The specific aims of the conference were to give participants a clearer understanding of the breadth of sectoral considerations embedded in biosafety policy, and to increase their understanding of the implications and options for agricultural biotechnology regulation in different sectors of government. In the longer term, it is hoped that, based on this increased understanding and sharing of experiences, APEC economies will be able to successfully meet the requirements of international agreements, thus strengthening their agricultural biotechnology sectors.

Summary of support:

DAI contracted Jeff Bowyer to provide support and be responsible for local conference logistics in Manila. DAI was also responsible for budget development and provided logistical support in arranging air tickets for speakers and sponsored participants. Through Jeff Bowyer DAI was responsible for developing an extensive invitation package and sending formal invitations to participants; identifying the hotel and conference venue; local transport; preparation of conference materials; on-site coordination; managing local conference expenses; and developing media information.

MSU was responsible for developing the participant database; sending out initial e-mail invitations; inviting speakers and participants; providing support with conference agenda development; communication with Conference Overseers (Julian Adams & Alicia Ilaga); supporting budget development; and liaison and communication with Jeff Bowyer

For more information see Jeff Bowyer's report (Annex 1)

Bio-engineered Cotton (Bt Cotton) in Africa (A.3.2)

Activity 2: Entomology Training in Bamako, Mali, December 2005

Training in Entomology was conducted in Bamako, Mali in December 2005. A total of 4 participants from Benin, Burkina Faso, Tchad and Mali participated along with 1 participant from Tuskegee University, USA. DAI provided logistical support by purchasing and providing air tickets for the 5 participants (See Annex 2).

Biosafety and Regulatory Assistance (A.3.5)

Activity 3. INSAH/CILSS Technical Support: Regional Biosafety Framework Development, January 17-19, 2006

USAID is supporting work by INSAH to initiate a project to create a regional biosafety framework for West Africa. INSAH requested further support specifically related to an INSAH/CILSS meeting to validate the “Framework Convention Introducing a Common Biosafety Regulation in the CILS countries” and the “Framework Convention Instituting Common Regulations for Conventional and Transgenic seeds in the CILS area” in Niamey, Niger January 17-19, 2006. This request was specifically to support the translation from French into English of three draft documents (two draft conventions and an elaboration of a proposed implementing committee structure), review of the same draft documents, and participation in the January workshop of a technical resource person. The following deliverables were expected:

- Accurate translations of three INSAH documents:
 - Project de Convention Cadre instituant une réglementation commune en biosécurité dans l’espace CILSS
 - Convention Cadre instituant une réglementation commune en matière de semences conventionnelles et transgéniques dans l’espace CILSS
 - Structure et Fonctionnement du Comité Sahélien des Semences et Biosécurité (CSBS)
- Written review of same draft documents
- Participation in January workshop

Dr. Donald MacKenzie, Vice President, AGBIOS attended these two meetings (see Annex 3). Significant progress was made during this meeting on amending both framework conventions and in confirming the desire for a regional approach to biosafety and seeds regulation. Pending further revisions by the drafting team, both of these conventions will be presented for signature at the upcoming CILSS Council of Ministers meeting to be held in March 2006.

The amended biosafety convention has included new articles dealing with foods derived from genetically modified organisms (GMOs), public access to information, and has made clearer distinctions between “contained”, “confined” and “unconfined” activities involving GMOs. The revised convention also better describes the role of the Regional Consultative Committee and the division of decision-making responsibility between national competent authorities and the regional body. Once adopted by the Council of Ministers, there will need to be additional work on developing specific protocols under the convention to deal with risk assessment criteria and administrative requirements for different levels of activity (e.g., confined field trials vs. unconfined, or general, release) and with food safety.

Activity 4. Translation of ECOWAS action plan for biotechnology and biosafety strategy development, January, 2006

USAID supported the development of a regional strategy for biotechnology and biosafety in West Africa through a series of workshops and meetings led by CORAF that culminated in the ECOWAS Ministerial Conference on Agricultural Biotechnology, held in Bamako, Mali in June, 2005. The ministers endorsed several overarching recommendations that provided general direction for such a strategy, and recommended that an action plan be prepared to detail the way forward. ECOWAS convened a meeting in October 2005 in Abuja, Nigeria to discuss the elements of the action plan, and assigned the further development of the action plan to two consultants, who recently completed a draft which is partially in English and partially in French. This activity translated the draft “Action Plan for the Development of Biotechnology and Biosafety in Countries of the ECOWAS 2006-2010” into two complete versions in English and French. AGBIOS completed the assignment and the required deliverable before January 16, 2006.

New Activities (to be initiated during the period March to August 2006)

Regional Development Mission for Asia (RDMA) – Biotechnology dialogue with ASEAN

RDMA (Regional Development Mission for Asia) has transferred funds to USAID/Washington for this activity. An illustrative scope of work was provided by USAID. This activity falls under the Environment SO, and will focus on regulatory aspects of biotech and on trade.

The RDMA wants to work with the Association of South East Asian Nations (ASEAN) to hold a biotechnology conference. For the last few years USDA has endeavored to establish a biotechnology dialog with ASEAN. The US is not a member of ASEAN but approval for this dialog was finally received from ASEAN during late fall of 2005. A workshop/conference will be held on **April 4-5th** in Bangkok, Thailand. The meeting will be hosted by Thailand, and organized and sponsored by the USDA

AGBIOS will take the lead on the ASEAN biotech program. Ms. Muffy Koch of AGBIOS is currently planning to attend the ASEAN biotechnology conference. It will be a good opportunity for AGBIOS to gauge interest and opportunity for further work with ASEAN. Ms Koch will also plan to visit RDMA during the trip, as well as go on to visit the ASEAN Secretariat to start planning for the RDMA-funded program.

CORAF Priority Setting Workshop(s) in Dakar, Senegal: Training Workshop (March 2006) and Follow-up Workshop (June/July 2006)

USAID would like to support an activity with CORAF, a series of two workshops to build capacity for impact assessment. The concept for the activity was developed by Will Masters of Purdue University, who will serve as the technical resource person. CORAF is in agreement to the value of the activity and was willing to take care of logistics, including inviting the

appropriate participants. The first workshop was scheduled for March 2006. The sub-contracting process between DAI and CORAF was not workable and it was proposed that MSU take responsibility for logistics such as purchasing airtickets, per diem pay-outs and lodging payments. MSU will help identify a CORAF Staff member for the establishment of a Personal Services Contract (PSC). The CORAF staff member will be responsible for identifying the hotel and workshop venue and for local transport. USAID decided to postpone the first workshop until the summer of 2006 to allow more time for nomination and selection of participants from CORAF countries.

INSAH/CILLS Technical Support: Regional Biosafety Framework Development : Follow up to Activity 3

USAID has supported work by INSAH to initiate a project to create a regional biosafety framework for West Africa (see Activity 3). INSAH has requested further support to: review and provide comments on biosafety and seed conventions; support translation from French into English of revised biosafety and seed conventions; provide technical assistance to develop a workplan for the six-month period from April through September 2006; assist with candidate interviews to staff regional biosafety office. In addition, support will be provided for participation of a technical resource person in an upcoming meeting to finalize the ECOWAS biotechnology and biosafety strategy in Cotonou, Benin.

Dr. Donald MacKenzie (AGBIOS) is planning to work with INSAH staff in Bamako, Mali, between 20-31 March 2006 to implement these activities, and to attend the ECOWAS meeting in Cotonou.

Pending Activities

WARP Bt Cotton Conference for C4 Countries in Cotonou, Benin

USAID requested that the DAI Consortium work with the National Cotton Council on a West Africa conference being organized in Cotonou by the WARP mission for the end of November. The purpose was to bring together governments from the C4 countries (Burkina Faso, Mali, Chad, and Benin), the National Cotton Council, research organizations, ECOWAS, and others to discuss the cotton strategy for West Africa. The DAI Consortium was requested to provide an expert to attend the conference and incorporate the discussions and Bt Cotton into the strategy. The strategy will inform the US Assistance plan in this area. The WARP contact is Robert Kagbo and the USAID Africa Bureau contact is Tom Hobgood. The target date for completion of this activity was initially set for January 2006 but has been postponed. The way forward for implementation will be discussed during a meeting with Drs. Larry Beach and Tom Hopgood to be scheduled during March 2006 in Washington DC.

Burkina Faso Bt Cotton gene flow and refugia study

Burkina Faso has submitted a request to support ongoing cotton trials by conducting a pollen flow (gene flow) study on Bollgard 2 cotton. The DAI Consortium will work with Monsanto who is providing technical assistance. The implementation of this activity needs to be discussed with USAID during the next few months

ANNEX 1: Biosafety Policy Options for APEC Economies - Summary Report of Conference Logistics

The conference on “Biosafety Policy Options for APEC Economies” was held in Manila, Philippines on January 16-18, 2006. It was sponsored by the U.S. Agency for International Development, APEC, and the Philippines’ Department of Agriculture. The target audience of the conference was regulators, government policy makers and experts in the areas of agriculture, trade, environment, economics and foreign affairs. The aim of the conference was to give participants a clearer understanding of the breadth of sectoral considerations embedded in biosafety policy and to increase their understanding of the implications and options for agricultural biotechnology regulation in different sectors of government. In the longer term, it is hoped that, based on this increased understanding and sharing of experiences, APEC economies will be able to successfully meet the requirements of international agreements, thus strengthening their agricultural biotechnology sectors.

This report provides a summary of the conference logistics. It is roughly organized by the responsibilities that were laid out in the scope of work.

Participant database: The organizers were aiming for around 100 participants, and, after many last second subtractions and additions, they managed to attract – participants. The task of maintaining a participant database (see attached) proved more challenging than expected because there were many changes after the original list was provided to me. First, a number of the people who were offered sponsorship were unable to attend. Second, the conference was joined with another group – the Philippine Rice Research Institute (PRRI) – which added an additional 21 participants. And third, the Department of Agriculture decided to invite a number of Filipino participants the week before the conference.

Conference invitation package: I sent out two rounds of this invitation package, the first about four weeks before the conference and an updated version five days before the conference. Also, I sent out a number of different versions – one to sponsored participants who purchased their own airline tickets, one to sponsored participants whose ticket was purchased for them, one to unsponsored participants, and another to Filipino participants. An example of this package is provided in Attachment 1. Because this information was clear and comprehensive, I did not have to respond to a lot of requests for additional information.

Formal invitations: The invitation package mostly served as the invitation, but some participants needed more formal invitations to obtain a visa. I passed such requests to Alicia Illaga of the Department of Agriculture.

Coordination with Shangri-La: The first step in my consultancy was to identify a suitable hotel for the conference, since Alicia Illaga was not happy with the first choice of the Intercontinental. I checked with five hotels and concluded, with input from the organizers, that the Shangri-La offered the best choice considering quality and price. Based on original estimates of participants, I told the Shangri-La to expect 70 guests. As more sponsored participants cancelled (and more Filipino participants were added), this number dropped to 50 and finally dropped to about 30. Thankfully, the Shangri-La based their cancellation charges on the final rooming list I provided to them and not on the earlier estimates we gave them. This is something I negotiated with them. The rooming list instructed the Shangri-La which of the participants were sponsored and which were not.

Conference Logistics: I was in frequent contact with Julian Adams and Josette Lewis of USAID and Johan Brink of MSU regarding the logistics for the conference. As the conference approached, I was providing daily update emails. Arranging for the meeting rooms was a bit of a challenge. A week before the conference, it appeared that as few as 55 people might be attending, but then the DA invited an additional 15+ Filipino participants plus 20 members of the media. Therefore, I had to change my plans at the last moment with the hotel. Again, the hotel was flexible and provided the extra space with no extra charge. For the media, we rented a small room with internet access, which did come at a charge. I also arranged for a group photograph of the participants, which was printed up and passed out on the last day. Last, I rented buses for the field trip on the second day and selected and coordinated with a restaurant for a sponsored dinner that evening.

Conference materials: With help from the EcoGov staff in Manila, I put together 75 binders that included the conference agenda, copies of the Powerpoint presentations, and speaker CVs. Lume Inamac designed a nice cover for these binders. This design was also used for two large placards, which were displayed outside the conference venue.

One-site coordination: There was quite a lot of coordination that needed doing on-site, largely because the hotel made numerous mistakes in the setup of the conference. Thankfully, these mistakes were largely unseen by the participants. I was assisted by two EcoGov staff, one to offer computer support and the other to help in conference registration and errands. I gave announcements during the breaks.

Conference expenses: This proved to be perhaps the most challenging part of organizing the conference, largely because APEC's contribution was changing up until the very last moment. We expected that they would contribute \$15,000 (\$10,000 for airline tickets and \$5,000 for per diems). In the end, they covered only one person's airline ticket for around \$6,000. Therefore, I was forced to put more of the costs under the DAI contract at the last moment. I communicated closely with staff from EMERGE, who provided me with the M&IE for the sponsored participants (I handed it out to the participants) and also with DAI staff in Washington, DC, who purchased a number of airline tickets and provided guidance on budget matters.

Media information: I wrote the first draft of a media release, which was distributed to different media outlets three days prior to the conference (see Attachment 2). I also put together a media packet for the media.

ANNEX 2 – Entomology Training in Mali

TRAINING PROGRAM FOR WEST & CENTRAL AFRICAN C4 COUNTRIES:

Integrated pest management for sustainable cotton production in West & Central Africa

December 11-19, 2005

List of participants

Country	Name	Position	Background/ training	Contact
BENIN	NOUDOFININ, Maurice Comlan	Chief of phytosanitary & plant protection service, Ministry of agriculture, livestock & fisheries	Undergraduate in Agronomy with special training at IITA	(229) 30-0500 Ex 1103(229) 30-0500 Ex 1103 Service de la PV, B.P.: 58 Porto-Novo, Rép. du Bénin; Tél. (229) 21-32-90/93; cel.: (229) 28-71-81 E-mail: mnoudofinin@yahoo.fr
BURKINA FASO	Dr. OTOIDOBIGA, Lenli Claude	Research Entomologist	Research entomologist, Office of research laboratory for crop protection. Ph.D. Mcgill University	Laboratoire de Recherche de la PV, 01 B. P. 2868, Bobo- Dioulasso (Burkina Faso). Tel. (226) 20 97 01 44 (Office) ; (226) 20 98 16 72 (Home). E-mail : pognoa@yahoo.com
TCHAD	BEDINGAM, Le Diambo	Research Entomologist	IRCT, Bébédjia (Chad) Undergraduate in plant protection and entomology for food crops. TRCT & Leitzig Germany	Ministry of Agriculture ITRAD Station Bebedjia B.P. 31 Moundou, Tchad Tel : 235-36-03-19 e-mail lediambo@yahoo.fr
MALI	DIARRA, Sylvestre Lassana	Crops Protection Officer	M.Sc. Entomology, Oklahoma State University	Direction Nationale D'Appui Au Monde Rural, Bamako, Mali, 223-222-2404, Cell: 223 679 1713 e-mail lassidiar@yahoo.fr

ANNEX 3: Niamey Trip Report (12-20 January 2006)

Prepared by:

Dr. Donald MacKenzie (AGBIOS)

Purpose:

To participate in the INSAH/CILSS meeting on validation of the "Framework Convention Introducing a Common Biosafety Regulation in the CILSS Countries" and the "Framework Convention Instituting Common Regulations for Conventional and Transgenic Seeds in the CILSS Area."

Observations and Outcomes:

Significant progress was made during this meeting on amending both framework conventions and in confirming the desire for a regional approach to biosafety and seeds regulation. Pending further revisions by the drafting team, both of these conventions will be presented for signature at the upcoming CILSS Council of Ministers meeting to be held during the latter part of February 2006.

Regarding the biosafety convention, there was agreement on some significant amendments, including:

- Differentiating between contained use and "confined" and "unconfined" releases of genetically modified organisms (GMOs). Confined release referring to release under conditions intended to minimize the establishment and spread, in the environment, of GMOs or of genetic material from GMOs, and the interaction of the GMO or genetic material with the environment, and unconfined release referring to release on an unrestricted basis. These distinctions, which are significant as they imply different approaches to risk assessment and risk management, were only poorly elaborated within the original draft.
- Limiting the scope of regulation. The intent of the convention was to regulate GMOs and "derived products" without fully specifying the scope of such products. It was agreed that in this instance, derived products would include anything extracted or produced from a GMO and intended for use in, or as, food or livestock feed, or for use in human or animal health. So this could include such items as derived food or feed products, recombinant vaccines, veterinary biologics, and food or feed enzymes produced using GMOs. It would not include, for example, cotton fibre derived from genetically modified cotton plants or the industrial (non-food/feed) use of any derived product.
- Limiting liability. In its original form, the convention held users generally accountable for any damage resulting from the release of GMOs. It was important to qualify this, such that in the case of "accidental or unauthorized" releases the user was fully liable, however, in the case of authorized unconfined release there is a sharing of responsibility between the user and the regulator.
- Providing additional text around public access to information (i.e., transparency) and participation. The existing article on confidential business information (CBI), while providing adequate protection for applicants, did not go far enough in defining the nature of CBI nor the types of information that would be ineligible for protection as CBI

(some good guidance in this area is contained within the Aarhus Convention, which grants the public rights and imposes on authorities obligations regarding access to information and public participation and access to justice).

- Removing specific risk assessment criteria from the body of the convention. Within the original draft, this information was poorly organized, oftentimes duplicative, and in some cases not consistent with international practice. Although it has yet to be finalized, a possible approach would be to include these types of administrative and risk assessment information requirements within discrete "protocols" or "schedules" under the convention.
- Further elaborating the role of the regional authority and in particular the division of responsibilities between regional and national authorities. The original draft discussed the role of National Competent Authorities but did not make reference to the Regional Consultative Committee proposed by INSAH.
- Rearranging the organization structure of the document to improve the logic and flow.

Proposed amendments to the seeds convention were more minor. However, a significant weakness of this document was that it did not deal with regional variety registration requirements (e.g., numbers of registration trials, locations, etc required to generate data for variety registration). This point was highlighted at the end of the workshop and was not discussed at length.

The respective consultants retained to develop the biosafety and seeds conventions will be working with their drafting teams over the next 2-3 weeks to finalize each of these documents.

Considerations for the Work Plan:

1. Providing inputs to the final editing of the biosafety and seeds conventions in preparation for the upcoming meeting of CILSS Council of Ministers.
2. Working with INSAH on the selection of a suitable candidate to staff the regional biosafety office. This office could act as a secretariat to the Regional Consultative Committee (RCC). Related to this, is additional work with INSAH on clarifying the role of the RCC and national vs. regional decision-making. Although there is general consensus that regional decision-making would be required in the case of commercial applications or situations of unconfined release, the same may not hold for field trial (e.g., confined release) applications.
3. Working with INSAH (and CILSS member country representatives) to develop specific "protocols" or "schedules" to handle specific uses/releases of GMOs within the CILSS area. For example, specific protocols dealing with the application, review and authorization process for confined and unconfined releases of GMOs, GMOs destined for direct use in food, feed or processing, etc. This would involve the formation of small task-oriented working groups to elaborate the: administrative process; risk assessment criteria; risk management considerations; decision-making process; monitoring and inspection

requirements; and other considerations relevant to a particular use of specific types of GMOs and derived products.

4. Working with INSAH to develop specific biotechnology and regulatory communications materials and further supporting their role in public outreach activities.

A follow up trip is proposed for 20-31 March 2006 to work with INSAH representatives at their office in Bamako to lay the groundwork for these activities. This would also be the appropriate opportunity to review candidates for the biosafety office.