INITIAL ENVIRONMENTAL EXAMINATION

PROGRAM/ACTIVITY DATA:

Bureau/Office: Bureau for Food Security / Agricultural Research & Policy
Program/Activity Title: Abiotic Stress Tolerant Bioengineered Cereals
Country/Region: Australia and India, South Asia

Functional Objective 4: Economic Growth
Program Area: 4.5 Agriculture
Program Elements: 4.5.2 Ag Sector Productivity

Funding Begin: Jan 2013 Funding End: Jan 2018 LOP Amount: Approx. $4 million

Specific Activity: 1) Design DNA transformation vectors conferring traits for temporally sensitive and tissue specific responses to abiotic stress response. 2) Transform rice and wheat varieties with new constructs. 3) Test lines containing drought and salinity genes in the greenhouse. 4) Conduct confined field tests of transgenic varieties at multiple locations in Australia and India. 5) Transfer successful transgenic traits into local adapted varieties and elite lines through breeding. 6) Conduct biosafety testing to collect data necessary for regulatory approvals.

IEE Expires: January 31, 2018

IEE Prepared by: Saharah Moon Chapotin, BFS/ARP and Walter Knausenberger, AFR/SD

Current Date: Dec 13, 2012

Is this an IEE/CE Amendment? NO
If “Yes,” Filename & Date of Original IEE: N/A

ENVIRONMENTAL ACTION RECOMMENDED:

Categorical Exclusion: □ Negative Determination with Conditions: ☑
Positive Determination: □ Deferral: □

ADDITIONAL ELEMENTS:

CONDITIONS: X Biosafety: X EMMP: N/A PVO/NGO: N/A

RELEVANT DOCUMENTATION:

Tab 1: USAID Confined Field Trial IEE Amendment Submission Guidelines
SUMMARY OF FINDINGS

The Australian Centre for Plant Functional Genomics (ACPFG), in partnership with Vibha Agrotech Limited and DuPont Agricultural Biotechnology, is proposing to conduct research activities to develop and deploy transgenic rice and wheat varieties for improved tolerance to drought and salinity. This IEE covers the scope of this soon to be awarded project by USAID under the Climate Resilient Cereals Addendum to the Global Development Alliance FY11 APS. The proposed activities include development of transgenic rice and wheat plants with genetic elements designed to confer discrete temporal expression patterns or stress induction features that improve abiotic stress tolerance. The main technical objectives of the program are:

1) Design DNA transformation vectors conferring traits for temporally sensitive and tissue specific responses to abiotic stress response.
2) Transform rice and wheat varieties with new constructs.
3) Test lines containing drought and salinity genes in the greenhouse.
4) Conduct confined field tests of transgenic varieties at multiple locations in Australia and India.
5) Transfer successful transgenic traits into local adapted varieties and elite lines through breeding.
6) Conduct biosafety testing to collect data necessary for regulatory approvals.

Categorical Exclusion. Certain activities justify a Categorical Exclusion from further environmental review, pursuant to 22 CFR §216.2(c)(1) and (2). General research investigations, technical assistance, capacity building, and communications activities all fall into one of the following classes of actions listed below for which a Categorical Exclusion is appropriate:

a) 22 CFR 216.2(c)(1)(iii), Research activities which may have an effect on the physical and natural environment but will not have a significant effect as a result of limited scope, carefully controlled nature and effective monitoring;
b) 22 CFR 216.2(c)(2)(i), activities limited to education, technical assistance or training programs except to the extent such programs include activities directly affecting the environment;
c) 22 CFR 216.2(c)(2)(ii), controlled experimentation exclusively for the purpose of research and field evaluation which are confined to small areas and carefully monitored;
d) 22 CFR 216.2(c)(2)(iii), activities limited to the performance of analyses, studies, academic or research workshops and meetings;
e) 22 CFR 216.2(c)(2)(v), activities limited to document and information transfers.

Many of the activities proposed involve meetings, training or are research activities that will take place in a contained greenhouse. As such, and if properly conducted, those activities would not be expected to have any environmental impact and would normally fit into one or more categories for which a Categorical Exclusion is appropriate.

Confined field trials and any future dissemination of transgenic varieties, however, require a USAID biosafety review to be completed before they can proceed. Successful conclusion of the review and approval by the USAID Biosafety Officer and an amended IEE, approved by the
Bureau Environmental Officer, will be required before any confined field trials or environmental release of bioengineered crops can proceed.

Apart from those activities qualifying for exception to the Pesticide Procedures, as provided below, this IEE does not cover the procurement, use, transport, storage or disposal of pesticides. Activities involving pesticides in controlled experimentation exclusively for the purpose of research and field evaluation which are confined to small areas (< 4 ha) and carefully monitored, shall be within the parameters of 22 CFR 216.3(b)(2)(iii) (Exceptions to Pesticide Procedures). In such cases, the following conditions apply, per the requirements of 22 CFR 216.3(b)(2)(iii):

- the manufacturers of the pesticides must provide toxicological and environmental data necessary to safeguard the health of research personnel and the quality of the local environment in which the pesticides will be used;
- treated crops will not be used for human or animal consumption unless appropriate tolerances have been established by EPA or recommended by FAO/WHO;
- treated crops will not be used for human or animal consumption unless appropriate tolerances have been established by EPA or recommended by FAO/WHO, and the rates and frequency of application, together with the prescribed pre-harvest intervals, do not result in residues exceeding such tolerances. (This prohibition does not apply to the feeding of such crops to animals for research purposes.)

All activities that fall outside of the category of controlled experimentation exclusively for the purpose of research and field evaluation, and entail the procurement or use, or both, of pesticides shall be analyzed in accordance with USAID Pesticide Procedures (22 CFR 216.3(b)) and no funds shall be obligated or expended for the procurement or use of pesticides unless they are specifically approved through an amendment to this IEE in accordance with 22 CFR 216.3(b).

THRESHOLD DECISION(S)

A Negative Determination with Conditions is recommended for activities involving confined field trials (CFT), specifically on transgenic rice and wheat lines under controlled experimentation exclusively for the purpose of research and field evaluation, which are carefully monitored (22 CFR 216.2(c)(2)(ii)). The following conditions are recommended:

- A Biosafety Review must be conducted and approved by the USAID Biosafety Officer and an amended IEE must be prepared and approved by the BFS Bureau Environmental Officer before any confined field trials or dissemination of transgenic cereals may proceed. The grantee will be responsible for completing and submitting the required information needed for the Biosafety Review. The detailed information requirements are found in the USAID Biosafety Proposal and Reporting Requirements and are attached in (Tab I). The USAID AOR will be responsible for ensuring the review is completed and an amended IEE is prepared and submitted to the BFS Bureau Environmental Officer. No confined field trials will be allowed until the biosafety review and amended IEE have been completed.
- No pesticides may be procured or used for efforts that are not confined to a small area (<4 ha), or recommended for procurement or use without first completing an amendment to this IEE that addresses the requirements of 22 CFR 216.3(b) including a Pesticide Evaluation Report/Safe Use Action Plan (PERSUAP) which must be approved in writing by the BFS Bureau Environmental Officer.
- If, during implementation, activities are considered other than those described, an amended Request for a Categorical Exclusion or IEE shall be submitted.

**Monitoring.** As required by ADS 204.3.4, USAID/BFS/ARP will actively monitor and evaluate whether there are new or unforeseen consequences arising during implementation that were not identified and reviewed in accordance with 22 CFR 216. USAID/BFS shall also monitor the need for additional review. If additional activities not described in this document are added to this program, an amended environmental examination must be prepared and approved.
APPROVAL OF ENVIRONMENTAL ACTIONS RECOMMENDED:

Based on the attached description, USAID / BFS / ARP recommend that you concur with a Negative Determination with conditions for the Abiotic Stress Tolerant Bioengineered Cereals program led by the Australian Center for Plant Functional Genomics.

Approved:
Office Director, BFS/ARP: ___________________________ Date: Jan 10, 2013
Robert Bertram

Concurrence: ___________________________ Date: _______
Ron Greenberg, BFS Bureau Environmental Officer

Filename (USAID/BFS BEO):
BFS_IIE_ACPFG_Climate_Resilient_Cereals_Jan2013_Jan2018.docx

The scanned, signed versions of this document (both PDF and Word) will be posted to the Agency’s Environmental Compliance Database: http://gemini.info.usaid.gov/egat/envcomp/

Additional Clearances:
Agency Biosafety Officer, BFS: _________________/cleared/_________________ Date: 12/14/12
Saharah Moon Chapotin

Environmental Compliance Advisor to BFS: _________________/cleared/_________________ Date: 12/31/2012
Walter Knausenberger (AFR/SD)

Activity Manager (& drafter): ___________________________ Date: 12/13/12
S. Chapotin (BFS/ARP)
INITIAL ENVIRONMENTAL EXAMINATION (IEE)

Country/Region: Australia and India, South Asia

Project Title: Abiotic Stress Tolerant Bioengineered Cereals - ACPFG

Funding Begin: Jan 2013   Funding End: Jan 2018   LOP Amount: Approx. $4 million

Specific Activity: 1) Design DNA transformation vectors conferring traits for temporally sensitive and tissue specific responses to abiotic stress response. 2) Transform rice and wheat varieties with new constructs. 3) Test lines containing drought and salinity genes in the greenhouse. 4) Conduct confined field tests of transgenic varieties at multiple locations in Australia and India. 5) Transfer successful transgenic traits into local adapted varieties and elite lines through breeding. 6) Conduct biosafety testing to collect data necessary for regulatory approvals.

Activity Period: January 2013 to January 2018

1. PURPOSE

The Australian Centre for Plant Functional Genomics (ACPFG), in partnership with Vibha Agrotech Limited and DuPont Agricultural Biotechnology, is proposing to conduct research activities to develop and deploy transgenic rice and wheat varieties for improved tolerance to drought and salinity. This will be achieved through the design of various gene vectors that leverage different combinations of promoter and genes conferring temporal and tissue specific responses to stress. Sodium transporters will be employed as well as the introduction of transcriptional factors that confer improved tolerance to salinity and drought, respectively. Transgenic plants will be tested in greenhouses and confined field trials at multiple locations in Australia and India. Successful transgenic traits will also be crossed through breeding into local adapted varieties as well as elite lines.

The proposal was received under the Climate Resilient Cereals Addendum to the Global Development Alliance FY11 APS. During the proposed grant period, the project is expected to begin confined field trial testing during the third year for transgenic rice and wheat at multiple locations in Australia and India. These trials will be conducted by ACPFG and Vibha to test the performance of new transgenic rice and wheat under local conditions in Australia and India which will also be useful for comparison. Biosafety studies will also be concurrently executed.

Activities over the life of this activity will include the following:

- Isolation and characterization of newly identified genetic elements important for stress tolerance.
- Construction of vectors for transformation into rice and wheat.
- Initial transformation of rice and wheat with selected genes and promoters in the laboratory.
- Performance screen of transgenic lines under stress conditions in greenhouses.
Transgenic material evaluation with test-cross hybrids to determine efficacy and quality under multi-location trials in the field.
- Introgress transgenic traits to improve stress tolerance in local adapted varieties and elite lines through breeding.
- Compilation of relevant biosafety data with respect to target genes and events.

Many of the activities proposed will only take place in the laboratory. Therefore, if properly conducted, those activities would not be expected to have any environmental impact and would normally fit into one or more categories for which a categorical exclusion is appropriate. However, confined field trials of transgenic crops and any future dissemination of transgenic wheat and rice for use and/or commercialization may have potential for impact.

2. COUNTRY AND ENVIRONMENTAL INFORMATION

ACPFG is licensed to conduct field trials of genetically modified wheat in three locations in Australia and will expand their efforts to seven sites. The Australian government is set up to regulate confined GM crop field trials and applications for approvals are sent to the Office of the Gene Technology Regulator. New field sites for testing are established and approved by the Western Australian Department of Agriculture.

India has national biosafety policies in place to approve confined field trials on genetically engineering crops. In India, the Review Committee on Genetic Manipulation (RCGM) has the authority to review and approve applications for small-scale confined field trials (Biosafety Level I) and the Genetic Engineering Approval Committee (GEAC) has the authority to review and approve applications for larger scale confined field trials (Biosafety Level II). USAID has provided training and technical assistance to the Govt. of India to improve their standards for the conduct of confined field trials and to build the capacity of field inspectors and monitors to ensure that confined field trials are being conducted according to the guidelines. For this project, selected rice and wheat events will be assessed at seven sites over three seasons of testing under Biosafety Research Level-I (BRLI) based on the RCGM approvals and Biosafety Research Level II based on the approvals of GEAC.

3. EVALUATION OF PROJECT/PROGRAM ISSUES WITH RESPECT TO ENVIRONMENTAL IMPACT POTENTIAL

Many of the activities proposed are limited to basic laboratory research and analysis, or training and capacity building. Therefore, if properly conducted, these activities would not be expected to have any environmental impact and would fall into one or more categories for which a categorical exclusion is appropriate. Confined field trials, however, and any future dissemination of transgenic wheat and rice for use and/or commercialization may have potential for impact. A successful higher yielding, stress tolerant variety could lead to increases in productivity and improved food security for populations in India and possibly other South Asian countries as well as Africa. Improperly managed field trials or inappropriate dissemination of a transgenic variety could present hazards to the environment or other native rice and wheat varieties.
Further analysis of the specific lines proposed for field trial or dissemination will be required to evaluate the potential for impacts before those specific activities can go forward. Prior to approval of confined field trials of plants containing transgenic materials in any of the target countries, the grantee will be required to submit to USAID information describing the field site and proposed confinement procedures. USAID will conduct an external biosafety review to evaluate any risks posed by small scale field trials of rice or wheat having the traits proposed by ACPFG in their proposal to develop bioengineered cereals for drought and salinity.

3.1 Biotechnology, Biosafety, and GMOs

USAID ADS 201.3.11.b pre-obligation requirements states regarding biosafety procedures:

"If projects or activities will potentially involve the use of genetically modified organisms in research, field trials, or dissemination, they must be reviewed and approved for compliance with applicable U.S. requirements by the Agency biosafety staff in Washington before the obligation of funds and before the transfer, testing, or release of biotechnology products into the environment.

"The biosafety review that is reviewed and approved is limited to the safety aspects of the proposed activities and often involves external peer review or demonstration of comparable safety oversight by other expert U.S. Federal agencies. This biosafety determination is separate from, and should precede and inform, the 22 CFR 216 environmental impact assessment process. Because it precedes the 22 CFR 216 process, DO Teams should budget adequate time and funding in the design process for this review. It may be difficult to predict the amount of time needed, because reviews are highly dependent on the amount of analysis and information provided, whether other expert Federal agency biosafety reviews have been completed, whether additional information will be required, and whether external peer reviews will be undertaken. Therefore, it is important for a DO Team to contact USAID/Washington as early in a design process as possible to ensure timely handling.

"Biosafety review cannot be waived or delegated to the field. Please consult directly with Agency biosafety staff, such as the International Research and Biotechnology Team in the EGAT Bureau (now the Research Division in BFS), the Agency Environmental Coordinator, or the Senior Science Advisor for the Bureau for Global Health (GH) if there is a potential for the use of genetically modified organisms."

All USAID-funded interventions which involve biotechnologies are to be informed by the ADS 211 series governing "Biosafety Procedures for Genetic Engineering Research". In particular this guidance details the required written approval procedures needed before transferring or releasing GE products to the field.

The draft Agency ADS 211 Biosafety Procedures document details the steps that need to be taken prior to conducting the environmental review of a project with a biotechnology component (i.e. biosafety review, securing host country approval). Per the draft ADS 211, the following environmental designations under 22 CFR 216 are thought to apply:

<table>
<thead>
<tr>
<th>Environmental Determination</th>
<th>USAID-funded Activity</th>
<th>Mitigation and Monitoring Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Categorical Exclusion</td>
<td>Training or capacity building in the area of biotechnology research</td>
<td></td>
</tr>
</tbody>
</table>

IEE for Abiotic Stress Tolerant Bioengineered Cereals – ACPFG
### Environmental USAID-funded Activity Mitigation and Monitoring Conditions

<table>
<thead>
<tr>
<th>Environmental Determination</th>
<th>USAID-funded Activity</th>
<th>Mitigation and Monitoring Conditions</th>
</tr>
</thead>
</table>
| Farmer training related to bioengineered crop production | - Farmer training related to bioengineered crop production  
- Development and dissemination of biotechnology information  
- Technical assistance to support biotechnology policy and regulatory development | |

#### Negative Determination with Conditions

- Research on bioengineered crops, animal vaccines, microbes, or animals in physically contained buildings such as laboratories or barns

Grantees/contractors must follow the National Institute of Health Guidelines on Research Involving Recombinant DNA Molecules.


#### Streamlined biosafety review to precede any environmental determination

- Bioengineered products already fully approved in the host country, i.e. no longer subject to specific regulatory procedures

#### Biosafety review to precede any environmental determination

- Field testing of bioengineered crops  
- Testing of bioengineered animal vaccines in pens  
- Field tests of bioengineered microorganisms for bioremediation, biopesticides, biofertilizer, or other uses  
- Commercial or wide-spread promotion or dissemination of bioengineered crops or animal vaccines  
- Trials of bioengineered human vaccines if they have not been reviewed by the US Food and Drug Administration (FDA)  
- Research on bioengineered crops, animal vaccines, microbes, or animals which is not conducted in physically contained buildings such as laboratories or barns.

- A proposal for release will most often also require public notice as part of the environmental review process (See 216.6(e)(2)).

- Grantee/contractor must submit documentation demonstrating approval by the host country authorities of the proposed confined field trial or open release

---

When biotechnology, biosafety, and GMO/LMO activities are included in the scope of activities under review:

- USAID must assure that its grantees and contractors comply with national and international laws applicable to biotechnology research and testing.

- No biotechnology interventions of any kind are to begin until the host countries and regional institutions involved have drafted and approved a regulatory instrument dealing with the specific intervention.

#### 3.2 Pesticides (Insecticides/Fungicides/Herbicides, etc.)

**Exceptions to Pesticide Procedures.** Apart from those activities qualifying for Exception to the Pesticide Procedures, as provided below, **this IEE does not cover the procurement, use, transport, storage or disposal of pesticides.** Activities involving pesticides in controlled experimentation exclusively for the purpose of research and field evaluation which are confined to small areas (< 4 ha) and carefully monitored, shall be within the parameters of 22 CFR 216.3(b)(2)(iii) (Exceptions to Pesticide Procedures). In such cases, the following conditions apply, per the requirements of 22 CFR 216.3(b)(2)(iii):

- the manufacturers of the pesticides must provide toxicological and environmental data necessary to safeguard the health of research personnel and the quality of the local environment in which the pesticides will be used;
- treated crops will not be used for human or animal consumption

All activities that fall outside of the category of controlled experimentation exclusively for the purpose of research and field evaluation and entail the procurement or use, or both, of pesticides shall be analyzed in accordance with USAID Pesticide Procedures (22 CFR 216.3(b)) and no funds shall be obligated or expended for the procurement or use of pesticides unless they are specifically approved through an amendment to this IEE in accordance with 22 CFR 216.3(b).

4.0 RECOMMENDED THRESHOLD DECISIONS & MITIGATION ACTIONS

4.1 Recommended Threshold Decisions and Conditions

A Negative Determination with Conditions is recommended for activities involving confined field trials (CFT), specifically on transgenic rice and wheat involving controlled experimentation exclusively for the purpose of research and field evaluation, which are carefully monitored (22 CFR 216.2(c)(2)(ii)). The following conditions are recommended:

- A Biosafety review must be conducted and approved by the USAID Biosafety Officer and an amended IEE must be prepared and approved by the BFS Bureau Environmental Officer before any confined field trials or dissemination of transgenic rice and wheat may proceed. The grantee will be responsible for completing and submitting the required information needed for the Biosafety Review. The detailed information requirements are found in the USAID Biosafety Proposal and Reporting Requirements and are attached in (Tab 1). The USAID AOR will be responsible for ensuring the review is completed and an amended IEE is prepared and submitted to the BFS Bureau Environmental Officer. No confined field trials will be allowed until the biosafety review and amended IEE have been completed.

- No pesticides may be procured or used for efforts that are not confined to a small area (<4 ha), or recommended for procurement or use without first completing an amendment to this IEE that addresses the requirements of 22 CFR 216.3(b) including a Pesticide Evaluation Report/Safe Use Action Plan (PERSUAP) which must be approved in writing by the BFS Bureau Environmental Officer.

- If, during implementation, activities are considered other than those described, an amended Request for a Categorical Exclusion or IEE shall be submitted.

4.2 Mitigation, Monitoring and Evaluation

As required by ADS 204.3.4, USAID/BFS/ARP will actively monitor and evaluate whether there are new or unforeseen consequences arising during implementation that were not identified and reviewed in accordance with 22 CFR 216. USAID/BFS shall also monitor the need for additional review. If additional activities not described in this document are added to this program, an amended environmental examination must be prepared and approved.
Application Guidelines for USAID Funded Confined Field Trials of GE plants

United States Agency for International Development

Washington D.C.
I Introduction
This document is intended to provide guidance for the developers of genetically engineered (GE) plants working in cooperation with USAID who wish to conduct confined field trials outside of the United States. USAID requires the information described in this guidance in order to meet its obligations to comply with U.S. law, all applicable laws in the jurisdiction where the trials will be carried out, and USAID’s internal policy of oversight, which may include independent biosafety review. The following sections discuss what information is needed by USAID, and describes how it will be used. Cooperators should have an understanding of these requirements prior to proposing or conducting confined field trials with USAID support.

What is a Confined Field Trial?
A confined field trial is an experimental release of a GE plant into the environment where the plant material and the engineered genes are confined within a prescribed area. This should not be confused with “containment” such as in a laboratory, growth chamber or greenhouse. Confined field trials are necessary in order to carry out agronomic evaluations in a realistic environment, generate information for risk assessment and regulatory approvals, and to conduct experiments involving GE plant interaction with endemic pests and diseases. Confinement can involve reproductive confinement as well as physical confinement, but ultimately the goal is to prevent persistence of the GE plant or the transgene outside of the control of the trial managers.

II Description of Information Requirements and Rationale
The following categories of information are required by USAID for two reasons. First, USAID must comply with U.S. law and USAID policy for conducting its activities outside of the United States, which specifically requires an initial environmental examination (IEE) to be prepared and reviewed by USAID staff. Second, USAID may use the information to conduct an external biosafety review, based on the uniqueness of the plant, capacity of those conducting the trial, and strength of the national regulatory system. The reviewers will need access to sufficient information on the design and implementation of the field trial to determine if it is adequate to meet the biosafety requirements of USAID and the jurisdiction where the trial is being conducted.

Description of the Proposed Trial
A short summary of the proposed trial, where and when it will be conducted and any special biosafety considerations should be provided.

Description of the Regulatory Requirements of the Local Jurisdiction
All USAID activities must comply with local legal and regulatory requirements. Further, considering local regulatory requirements during biosafety reviews allows reviewers to consider specific confinement
objectives that may be important to local authorities when reviewing the trial. Local requirements may also provide reviewers with insights into local conditions or practices that are important for biosafety.

Description of the Trial Location
Some basic information is required to establish the context for an evaluation of the confined field trial. This includes a description of the proposed location, time, and size of the field trial. A detailed map including reference to nearby agricultural production and the presence of sexually compatible relatives is the best tool for conveying this information to potential biosafety reviewers, but is not absolutely necessary and may be replaced by a explicit description of relevant trial location characteristics along with trial site GPS coordinates. Other potentially important characteristics include topography, the presence of flowing water and drainage patterns as well as prevailing winds or other local geography that might impact the dispersal of plants, pollen, or seeds. Many regulatory authorities request GPS coordinates for a field, however GPS coordinates alone are not a substitute for a description of the surrounding area.

Information on the Biology of the Plant
The biology of the plant will determine potential routes for the GE plant or the transgene to be exposed to the environment and persist outside of the control of the trial managers. Taxonomic information on the identity of the plant allows reviewers to find additional information on the species and important common names should be provided if they are relevant. Information on sexually compatible relatives and the potential for hybridization must also be included. Other life history characteristics and ecological interactions that may impact the ability of the plant to disperse or persist in the environment should also be included.

Information on the Inserted Gene(s) and Phenotype of the GE Plant
Although it is understood that a complete molecular and physiological characterization is not necessary to conduct a confined field trial, some information concerning the nature of the inserted gene or genes and the phenotype of the GE plant is useful when conducting biosafety reviews. In particular, any information on the origin of the inserted sequences and any novel phenotypes that might affect the ability of the GE plant to survive and persist outside of the field trial should be provided.

Management Plan for the Field Trial
A detailed description of the management plan for conducting the field trial, including sowing, growth, harvest and post-harvest procedures should be provided. This should include information on how seeds or propagative material will be distributed and labeled or marked in order to prevent mixture with non-trial material. A detailed description of the management of the field during the trial including information describing how access to the site will be controlled, measures to prevent animal incursion, plans to inspect the field, and any other practices that might impact the survival and persistence of the
plant or the dispersal of the transgene into the environment should also be provided. A description of training provided to workers who will be involved in all aspects of field trial should also be on record.

**Adverse Event Management Plan**
A variety of adverse events can occur during a confined field trial, and it is important to have a mechanism in place to document and correct any events that violate the conditions of confinement. Common adverse events include incursion from animals or people unauthorized at the trial site, weather events such as flooding or high winds which can disperse trial materials outside of the confinement area, and human error which causes material to be dispersed outside of the confinement area. It is not required that the field trial manager addresses every imaginable adverse event, but some consideration should be given to the most likely rational possibilities. A description of the procedures that will be implemented if an adverse event occurs should be provided and kept on file.

**Identification and Training of Personnel**
One of the most common reasons for a failure of confinement during a confined field trial is the failure to adequately train all of the personnel who come into contact with the trial material in the proper procedures for handling, storing, moving and otherwise working in the field. Although the names and personal identification of the individuals involved are unimportant, a description of the number of people who will be working on the site and with the material, as well as a description of their roles in conducting the trial should be provided. Information on how these personnel will be instructed in normal operation procedures as well as adverse event management procedures should also be provided.

In addition, the identity of a responsible party (i.e. the individual who is accountable for ensuring the activity proceeds in accordance with the field trial management plan) for each activity should be provided, most desirably with a backup individual also identified. Ordinarily for small trials, a single field site manager will be responsible for most or all of the activities of the field trial; however, in some circumstances including for larger, multi-site trials, there may be multiple individuals who are responsible for different activities. For example, one person may be in charge of shipping or receiving the trial material, while another is responsible for sowing and harvesting and another is responsible for monitoring the trial sight to ensure containment. The responsible party may be assisted in actually conducting the activity, but it is important to identify an individual who is accountable and ensure they are adequately informed of the field trial requirements related to their activities.

**Use of Pesticides**
In the event that any pesticide (insecticide, herbicide, fungicide) is used in the conduct of this confined field trial, a Pesticide Evaluation Report and Safe Use Action Plan (PERSUAP) must also be prepared in accordance with USAID Pesticide Procedures found at 22 CFR 216.3(b)). In accordance with these procedures, a listing of the information required on pesticide use (personnel training, toxicity, effect on non-target organisms, etc) can be found in section 9 below. If no pesticides will be used, please indicate
accordingly. In the event that a pesticide application is added to field trial procedures after environmental clearance is given by USAID, a separate amendment must be submitted and approved by USAID with the additional pesticide.

**End of Trial Report**

At the completion of each season of planting of the GE plant, a brief end of trial report should be submitted to USAID Bureau for Food Security, Office of Agricultural Research and Policy, as per guidelines in “USAID Post-trial Reporting Form” under separate cover.

**III Outline of Specific Information Requirements**

The following information should be included in the material provided to USAID for conducting biosafety reviews. *Not all of the information may be relevant in all cases, and some biosafety reviews may require additional information.* If the information is not available or is not relevant, a rationale should be provided explaining why this is the case. Please direct specific questions on requirements to biotechnology@usaid.gov

1. **Summary Description of the Proposed Trial**
   a. USAID activity title, number, and grant/cooperative agreement number from which funding originates
   b. Names and contact information for USAID applicants and developing country collaborators who are responsible for the trial
   c. Identity of the Country/Region where the trial takes place
   d. Brief description of the GE plant
      i. Any prior experience or regulatory approvals with the plant/trait combination

2. **Description of the Regulatory Requirements of the Local Jurisdiction**
   a. A copy of the regulatory requirements/regulations under which the trial will be conducted (in English), or a summary describing the local regulatory conditions
   b. Copies of any permits or official documents obtained pursuant to the field trial or plans for obtaining them in the future

3. **Description of the Trial Location**
   a. The size of the field trial
b. A detailed map or detailed description of the trial location including, for example:
   
   i. GPS coordinates
   
   ii. Physical field borders
   
   iii. Roads
   
   iv. Moving water
   
   v. Any other details that might affect confinement

c. Distance to other agricultural production
   
   i. Distance to agricultural production of sexually compatible species

d. Distance to wild or naturalized populations of sexually compatible species

e. Distance to any protected species or habitats

4. Information on the Biology of the Plant (note: an existing biology document such as those produced by the OECD may suffice for this information)

   a. Taxonomic identification

   b. Morphological description

   c. Distribution in natural and managed systems

      i. Distribution in the Country/Region where the trial will take place

   d. Cultivation and management practices

   e. Ability of the plant to disperse and persist outside of the field trial

   f. Centers of origin and biodiversity

   g. Reproductive biology

      i. Generation time

      ii. Mode(s) of reproduction (e.g. flowers, cones, fruits, seeds, vegetative propagules etc.)

      iii. Any relevant differences between populations (e.g. managed and unmanaged populations)
h. Hybridization and introgression
   i. Identity of any sexually compatible relatives
   ii. Extent of hybridization

i. Important ecological interactions
   i. Herbivores
   ii. Pollinators
   iii. Relevant pests or pathogens

5. Information on the inserted gene and phenotype
   a. Identity of the inserted gene
      i. Donor organism
      ii. Intended function
      iii. History of use (if any)
      iv. Any important modifications to the gene
   b. Phenotype of the GE plant
      i. Observations of the intended phenotype (if available)
      ii. Any information confirming the GE plant behaves as expected
      iii. Identification of any novel phenotypes that might affect confinement (both positive and negative)
         1. Changes in growth habit/vigor
         2. Significant intended or observed physiological changes
         3. Reproductive changes

6. Management Plan for the Field Trial
   a. Identity of the Field Trial Supervisor (i.e. person directly in charge of the site) and their backup
b. Timeline for the field trial
   i. Expected dates for planting
   ii. Expected dates for harvesting

c. Description of the Reproductive Isolation Methods
   i. Identification of relevant isolation distances from sexually compatible species
   ii. Additional reproductive isolation methods (i.e. mowing, deflowering, bagging etc.)

d. Description of Physical Isolation Methods
   i. Identification of required methods to safeguard and prevent movement of trial material by people
   ii. Identification of required methods to safeguard and prevent movement of trial material by animals
   iii. Identification of required methods to safeguard and prevent movement of trial material by wind, water etc.

e. Description of required procedures for moving material to and from the trial site

f. Description of agricultural management practices to be used
   i. Method of sowing
   ii. Method of irrigation, weed management, and pest management
   iii. Method of harvesting
   iv. Equipment to be used (if any)
      1. Procedures to clean equipment and safeguard against the movement of controlled trial material on equipment

g. Monitoring during the course of the trial
   i. Methods for monitoring the field and surrounding area
   ii. Frequency/timing of monitoring
h. Final Disposition of plant material following the trial
   i. Harvested material (saved or destroyed)
   ii. Field material or other GE plant detritus

i. Description of Post-trial Monitoring
   i. Period of time when monitoring will occur, along with monitoring frequency
   ii. Use of the field during post-trial monitoring
   iii. Method of monitoring

7. Adverse event management plan
   a. Plans to document and report any breach of confinement
   b. Plans to correct any breach of confinement by recovering trial material
   c. Plans to maintain records of any adverse events and documentation of corrective measures

8. Identification and training of personnel
   a. Identification of responsible party for the field trial (normally the Field Trial Supervisor)
   b. Identification of responsible party for any major activity (One individual may be responsible for several or all of the major activities)
      i. Receiving field trial material at the trial site
      ii. Sowing
      iii. Agricultural monitoring and management of the field
      iv. Surveillance to ensure confinement
      v. Harvesting
      vi. Final disposition of trial materials
      vii. Post trial monitoring of the trial site
      viii. Adverse event management and reporting
c. Enumeration of additional individuals who will contact trial material or provide labor for any aspect of the trial (e.g. field labor)

   i. Description of their role in conducting the trial

d. Plan for training all individuals participating in any aspect of the trial with regards to the proper procedures and requirements for confinement.

e. Plans for documentation establishing that the training has occurred.

9. Pesticide Procedures

   a. The USEPA registration status of the requested pesticide;

   b. The basis for selection of the requested pesticide;

   c. The extent to which the proposed pesticide use is part of an integrated pest management program;

   d. The proposed method or methods of application and application rate, including availability of appropriate application and safety equipment;

   e. Any acute and long-term toxicological hazards, either human or environmental, associated with the proposed use and measures available to minimize such hazards;

   f. The effectiveness of the requested pesticide for the proposed use;

   g. Compatibility of the proposed pesticide with target and non-target ecosystems;

   h. The conditions under which the pesticide is to be used, including climate, flora, fauna, geography, hydrology, and soils;

   i. The availability and effectiveness of other pesticides or nonchemical control methods;

   j. The requesting country’s ability to regulate or control the distribution, storage, use and disposal of the requested pesticide;

   k. The provisions made for training of users and applicators; and

   l. The provisions made for monitoring the use and effectiveness of the pesticide.