USAID Biosafety Proposal and Reporting Requirements

Part I - Required Proposal Information

1. Summary of Proposal - a one-page summary, including

a. A description of the bioengineered organism;

b. The aim of the application of this organism in terms of addressing a specific developmental constraint in the host country, including the intended use of the bioengineered organism;

c. A brief description of the nature of the testing (location (preferably, the latitude/longitude such that the site could be located using a Global Positioning System), scale, facilities, etc.).

d. Dates of proposed trial, including estimated planting date and estimated harvest.

2. Activity Information and Contacts

a. USAID activity title, number, and grant/cooperative agreement number from which the funding originated.

b. Names and contact information of those who developed and will test the bioengineered organism, including U.S. and developing country collaborators.

3. Host Country Biosafety Authority

a. Does the target developing country have in place a national biosafety committee, regulations, laws, or procedures?

b. From what entities/agencies will approval for transfer/testing/or use be sought? What is the legal or regulatory authority or these entities for biotechnology?

4. Species to Be Released

a. What is the taxonomy (species, strain, cultivar, etc.) of the organism to be released?

b. What is the origin of the inserted recombinant DNA? Does the donor organism cause disease or ill health to humans, plants, or animals?

c. Is the parent organism or the bioengineered organism capable of causing disease or other ill-health (such as toxicity) in humans, plants, or animals? If so, what is the nature of the harm?

d. Has the same bioengineered organism been approved for release in the U.S. or other countries? If so, specify where.

5. Genetics of the Bioengineered Organism

a. Describe the genetic modifications made and the extent to which the modifications have been characterized (location of insert, number of copies, presence of laboratory and field markers in the construct, level of expression, etc.).

b. Is the genotype of the bioengineered organism potentially unstable? Is there evidence of the stability of the genetic change or frequency of reversion of the genetic change?

c. What was the means of introducing the recombinant DNA? If a vector was used, can the vector transfer to other hosts? Is the vector present in the final construct, and if so, in what form (integrated or extra-chromosomal)?

6. Phenotype of the Bioengineered Organism

a. How does the genetic modification change the following phenotypic characteristics of the organism to be released? Present data to demonstrate the effect of the modification, including level of expression and regulation of the genetic insert:

i) morphological or structural characteristics
ii) physiological or biochemical processes
iii) growth and survival
iv) reproductive and dispersal processes

b. What secondary phenotypic effects may be anticipated as a result of the modification?

c. Does the modified trait confer a selective advantage over the parent organism under certain conditions?

7. Ecological Considerations

a. What is the natural range of the parent organism? Is it exotic to the country in which the bioengineered organism will be tested?

b. What is the distribution of the parent organism in the country in which the bioengineered organism will be tested and is the parent organism already present at or near the site?

c. Are there any known predators or parasites of the organism in the country of testing?

d. Describe the method of reproduction and dispersal of the parent organism, including parameters of the range of dispersal and potential for interbreeding with other species or wild relatives.

e. Could the release of the bioengineered organism affect the function of the parent organism in the environment (positive or negative functions of the organism)?

f. Is there any experimental or predictive evidence that the genetic modification affects or may affect the reproduction, growth rate, survival time, or range of the bioengineered organism compared to the parent organism?

g. Is the bioengineered organism likely to be able to establish in the open environment outside the release site?

h. What are the potential interactions and resulting impacts of the bioengineered organism with endemic flora and fauna?

i. What is the capability of the bioengineered organism to disperse from the release area and what is the dispersal mechanism? Can the parent organism form long-term survival structures such as seeds or spores?

8. Containment Procedures

a. Describe the destination of the release (greenhouse, growth chambers, laboratory, or field) and the size of the trial (area of land, number of plants or animals in the trial).

b. Describe the features of the test site physical environmental that may minimize any undesirable effects (contamination, escape, accidental release, or dissemination of the bioengineered organism). This would include the size of the site versus size of area planted with bioengineered crop, any border rows (number and depth), any fencing or other physical containment, or any natural features related to containment.

c. Describe the site supervision procedures and any safety procedures undertaken by the staff.

d. How close is the site to population centers, centers of agricultural activity, or wildlife areas that might affect, or be affected by, the release?

e. Describe the techniques for monitoring the presence of bioengineered organisms or transferred genetic material beyond the primary test site.

f. Will the bioengineered organism remain in the environment after the release? If so, for what expected period of time? What are the potential consequences or its persistence?

g. Describe the proposed method of final disposition of the bioengineered organism.

9. Pesticide Procedures

a. Is the use of any type of pesticide being considered (including fungicides, fumigants, herbicides or insecticides).

b. If yes, 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)). The following information must be provided:

i. The USEPA registration status of the requested pesticide;
ii. The basis for selection of the requested pesticide;
iii. The extent to which the proposed pesticide use is part of an integrated pest management program;
iv. The proposed method or methods of application and application rate, including availability of appropriate application and safety equipment;
v. Any acute and long-term toxicological hazards, either human or environmental, associated with the proposed use and measures available to minimize such hazards;
vi. The effectiveness of the requested pesticide for the proposed use;
vii. Compatibility of the proposed pesticide with target and nontarget ecosystems;
viii. The conditions under which the pesticide is to be used, including climate, flora, fauna, geography, hydrology, and soils;
ix. The availability and effectiveness of other pesticides or nonchemical control methods;
x. The requesting country's ability to regulate or control the distribution, storage, use and disposal of the requested pesticide;
xi. The provisions made for training of users and applicators; and
xii. The provisions made for monitoring the use and effectiveness of the pesticide.

Part II - End of Trial Report

1. Activity Information and Contacts

a. USAID activity title, number, and grant/cooperative agreement number from which the funding originated.

b. Names and contact information on those who will develop and test or use the bioengineered organism, including U.S. and developing country collaborators.

2. Location of Trials or Use

3. Dates of Completed Activities (date of commencement and completion)

4. Summary Report - including the following information:

a. What monitoring procedures were undertaken?

b. Were the aims of the testing achieved? Describe.

c. Were there any unexpected effects or incidents?

d. Are there any bioengineered organisms or organisms remaining at/within the test site/subject? If so, how many and what will be the fate of these products or organisms?

e. Do the results suggest that the project be continued? If so, what are the future plans?

Part III - Subsequent Release Notification

The following information must be provided on one page:

1. Summary - including the aims of follow-up testing, especially how the subsequent tests will further the previous research.

2. Reference to date of previous approval by USAID.

3. Species To Be Released - including the taxonomy (species, strain, cultivar, etc.) of the product or organism to be released and the nature of the inserted or naked recombinant DNA.

4. Location of Testing

5. Activity Information and Contacts - including USAID activity title, number, and grant/cooperative agreement number from which the funding originated; and names and contact information on those who developed and will test the bioengineered organism, including both the primary U.S. and developing country contacts for this specific activity.