Functional Series 200 - USAID Program Assistance
ADS 211 - Biosafety Procedures for Genetic Engineering Research

***This is a new ADS Chapter**

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211.6 DEFINITIONS

ADS 211 - Biosafety Procedures for Genetic Engineering Research

211.1 OVERVIEW

Biotechnology offers a new tool for improving crop and animal productivity, enhancing human health, and improving the environment. USAID requires that the biosafety procedures outlined in this chapter be followed to promote the safe and effective development, transfer, and use of organisms or products modified by genetic engineering (GE products).

Activities covered by these procedures include, but are not limited to,

- Transferring GE products to a developing country for release outside of a contained facility,
- Field testing livestock vaccines in a developing country,
- Field testing crop varieties in a developing country, and
- Testing or releasing genetically engineered bioremediation products in developing countries.

These procedures do not apply to

- Genetically engineered human pharmaceuticals (including vaccines), which undergo FDA approval and thus have already been reviewed for potential environmental impact; or
- The use of GE products in contained facilities such as laboratories, which are subject to existing NIH guidelines available on the NIH website at http://www.niehs.nih.gov/odhsb/biosafe/nih/rdna-apr98.pdf.

These procedures are designed to reduce and manage potential risks of biotechnology to the environment and to human health; ensure that international biotechnology applications funded by USAID meet standards of safety equivalent to domestic regulations; take into consideration the local environmental conditions and biosafety capabilities in developing countries; and meet relevant international standards. In essence, these procedures add a preliminary step to existing environmental procedures outlined in 22 CFR 216, Agency Environmental Procedures. **(See Mandatory Reference, 22 CFR 216)** This additional step is designed to specifically address biotechnology-related issues.

This chapter covers the following:

- Responsibilities of USAID Bureaus, Environmental Officers, and Cognizant Technical Officers (CTOs) or SO Teams;

- Procedures for the first transfer, testing, or use of genetically engineered products;
- Streamlined procedures for subsequent transfers, testing, or use; and
- Information required of grantees/contractors for biosafety reviews.

211.2 PRIMARY RESPONSIBILITIES

a. The Global Bureau is responsible for appointing a Biosafety Officer and providing a mechanism for conducting external biosafety reviews.

b. The Agency Biosafety Officer is responsible for assisting CTOs or Strategic Objective (SO) Teams in implementing these biosafety procedures and supporting Mission, Regional, or Bureau Environment Officers in incorporating external biosafety reviews into Agency environmental procedures.

The Biosafety Officer serves as a technical coordinator between CTOs or SO Teams and the corresponding Mission, Regional, or Bureau Environment Officers. As such, the Biosafety Officer is responsible for coordinating the external biosafety review for CTOs as a step prior to the preparation of the Initial Environmental Assessment.

c. CTOs or SO Teams are responsible for ensuring full compliance with these Agency biosafety procedures in the design and implementation of all programs involving GE products outside of contained facilities. CTOs and SO Teams are responsible for ensuring that all contractors and grantees are aware of these procedures and allow for adequate time and resources necessary to comply with them. Finally, CTOs and SO Teams are responsible for working with both the Biosafety Officer and the relevant Mission, Regional, or Bureau Environment Officer to execute these procedures.

d. Mission, Regional, or Bureau Environmental Officers from the funding Bureau are responsible for ensuring that these biosafety procedures are incorporated into environmental reviews and procedures for GE products. The Agency Biosafety Officer is responsible for assisting Environment Officers in achieving this.

211.3 POLICY AND PROCEDURES

This chapter outlines mandatory procedures for the transfer to, testing of, or use outside of contained facilities in developing countries of all GE products (e.g., plants, microorganisms, livestock vaccines, animals, or insects). Laboratory research involving GE products in both the U.S. and developing countries is covered under current USAID provisions referencing National Institutes of Health (NIH) guidelines. The NIH guidelines are available at the following website: http://www.niehs.nih.gov/odhsb/biosafe/nih/rdna-apr98.pdf.

The mandatory procedures in this ADS chapter apply to

- All USAID-funded transfers of GE products from the U.S. to developing countries for testing or use outside a contained facility;
- The testing of GE products in the developing country in which they were developed; and
- The transfer of GE products from one developing country to another.

Grantee/contractors are prohibited from transferring or releasing GE products prior to obtaining the required written approval as detailed in these procedures. In addition to these USAID procedures, grantee/contractors must obey applicable national laws (e.g., biosafety, shipping/packaging, sanitary, or phytosanitary standards).

211.3.1 Review of First Transfer, Testing, or Use

The procedures below detail the responsibilities of both the grantee/contractor and USAID in the biosafety review process. These responsibilities include the following:

- Documentation containing required information on the proposed transfer, testing, or use that the grantee/contractor must provide to the USAID Cognizant Technical Officer (CTO, formerly termed Project Officer) or Strategic Objective (SO) Team;
- Documentation demonstrating approval by the host country authorities of the proposed transfer, testing, or use that the grantee/contractor must provide to the USAID CTO or SO Team;
- How USAID will review that documentation;
- How the grantee/contractor will be notified of USAID's approval; and
- Final grantee/contractor reporting responsibilities.

The procedures in this section apply to the **first** transfer, testing, or use of a particular GE product under a particular set of conditions. Streamlined procedures for the **subsequent** transfer, testing, or use of the same GE product under the same set of conditions are stated in 211.3.2. **(See 211.3.2)**

211.3.1.1 Proposal

Before transferring GE products to a developing country for testing or use, the grantee/contractor must submit a proposal for approval by USAID. The information

required in this proposal is detailed in the reference document, USAID Biosafety Proposal and Reporting Requirements. **(See Mandatory Reference, USAID Biosafety Proposal and Reporting Requirements)** U.S and developing country researchers are encouraged to work collaboratively in developing the proposal to ensure that local environmental conditions and management capabilities are adequately considered. The proposal must be submitted to the USAID CTO or SO Team sufficiently in advance of the proposed transfer and/or testing to allow for the completion of an external review. **(See 211.3.1.2)**

211.3.1.2 External Review

The CTO must forward the proposal to the USAID Biosafety Officer for external review. The Biosafety Officer will arrange for an external biosafety review of the proposal. The external review is conducted by three to five experts in relevant technical fields. The scope of the external review is to assess any risks to the environment and human health associated with the proposed application and to determine how to manage those risks. The review will not examine the overall scientific quality or developmental potential of the proposal which are reviewed in the strategic objective and program planning process. USAID will base its approval of the application on the recommendations of the external reviewers.

211.3.1.3 Certification of Host Country Approval

The grantee/contractor or host country collaborator must submit to the USAID CTO or SO Team a letter or letters from the relevant authority in the host country approving the transfer and/or release of the GE product, including any specific conditions imposed by the host country. Grantees/contractors should note that **separate procedures** may be required in some countries to obtain (1) approval to import GE products and (2) approval to test or use the GE products, and that these may involve **separate authorities**. USAID will not grant approval of the transfer or testing in the absence of this letter or letters of approval.

If the country has a national biosafety authority or focal point (e.g., as required by Parties to the Cartagena Protocol on Biosafety), the letter of approval must come from this designated authority. If such a designated authority is not yet in place, the approval must come from the government authority or authorities in the area(s) with the closest corresponding responsibilities.

211.3.1.4 USAID Determination

The following steps must be taken to complete a USAID determination.

a. After the external biosafety review and receipt of the host country letter of approval, the USAID Biosafety Officer must submit to the CTO or SO Team a recommendation based on the results of the external biosafety review.

b. The CTO OR SO TEAM must submit this recommendation, along with an Initial Environmental Examination, to the Environmental Officer of the funding Bureau. **(See Mandatory Reference, 22 CFR 216)**

c. The Environmental Officer must draw up a USAID determination and provide it to the CTO OR SO TEAM.

d. The CTO OR SO TEAM must convey to the grantee/contractor in writing, with a copy to the USAID Biosafety Officer, the final results of the Environmental Examination in the form of a letter of approval, denial, or request for additional information.

211.3.1.5 Report on Completion of Testing or Use

Within six months of the completion of the approved activities, the grantee/contractor must submit to the CTO OR SO TEAM a report on the conduct and monitoring of the trial/use of the GE product to ensure compliance with the terms outlined in the approved proposal and to determine any unexpected outcomes. **(See Mandatory Reference, USAID Biosafety Proposal and Reporting Requirements, for the required informational content of the report.)**

211.3.2 Subsequent Transfer, Testing, or Use

In the event of subsequent proposed applications of the same GE product to/in the same country for testing or use under similar noncontained conditions, the grantee/contractor must submit to the CTO OR SO TEAM a one-page notification and a letter of approval from the host country authority in place of a full proposal. **(See Mandatory Reference, USAID Biosafety Proposal and Reporting Requirements)** A letter from the host country authority will only be waived if such a provision is stated in the first letter of approval submitted with the original proposal for transfer/testing/use. Given environmental variability, grantees/contractors must undertake a full proposal for the transfer, testing, or use of the same genetically modified organism or GE product to a different country.

211.3.3 Shipment of Genetically Engineered (GE) Products

GE products must be packaged, handled, transported, and shipped under conditions of safety. GE products must be clearly identified, specify any requirements for the safe handling, storage, transport, and use, and list a contact point, preferably the developing country partner, for further information. Grantees/contractors must obey any additional international or national regulations that may apply.

211.3.4 Accidents

In the event of an accident during the transfer or testing of GE products that may cause environmental or human health concerns, grantees/contractors or their developing

country partner(s) must notify the relevant national authority as soon as possible and subsequently notify USAID.

211.4 MANDATORY REFERENCES

211.4.1 External Mandatory References

a. 22 CFR 216, Agency Environmental Procedures

b. Foreign Assistance Act of 1961, as amended, Section 117

c. National Institutes of Health Guidelines for Research Involving Recombinant DNA, covering laboratory and other physically contained research involving GE products, available at the following website: http://www.niehs.nih.gov/odhsb/biosafe/nih/rdna-apr98.pdf

211.4.2 Internal Mandatory References

a. USAID Biosafety Proposal and Reporting Requirements

211.5 ADDITIONAL HELP

The Agency Biosafety Officer, located in the Global Bureau, can provide further assistance in the implementation of this chapter's policy and procedures.

211.6 DEFINITIONS

The terms and definitions listed below have been included in the ADS Glossary. See the ADS Glossary for all ADS terms and definitions. (See ADS Glossary)

biosafety procedures
Procedures for assessing and managing the potential risks of genetically engineered products to the environment or human health associated with the transfer, testing, or use outside of contained facilities. (Chapter 211)

Biosafety Officer
The Biosafety Officer, located in the Global Bureau, is appointed by the Agency to provide assistance in the implementation of USAID biosafety policy and procedures. (Chapter 211)

contained use
Contained use refers to the use of genetically engineered products in a physically contained facility such as a laboratory, hospital, greenhouse, or enclosed animal barn. (Chapter 211)

genetically engineered (GE)
The use of the modern biotechnology tools of *in vitro* recombinant DNA manipulation. (Chapter 211)

GE products
For the purposes of USAID, genetically engineered (GE) products are defined as organisms or products modified by genetic engineering, including viruses and naked DNA used as or vaccines. GE products do not include DNA fragments for use in the laboratory or diagnostic use. (Chapter 211)

transfer, testing, or use
These are activities in noncontained facilities that may involve the intentional introduction of genetically engineered (GE) products into the environment. Such activities include shipping GE products from the U.S. to developing countries; shipping from one developing country to another; and testing or use of GE products in an open environment such as field testing crops, vaccinating open livestock or animals, or testing or use of bioremediation products. (Chapter 211)

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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 genetically engineered (GE) product;

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 GE product;

c. A brief description of the nature of the testing (location, scale, facilities, etc.).

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 on those who developed and will test the GE product, 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 GE product 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 GE product been approved for release in the U.S. or other countries? If so, specify where.

5. Genetics of the GE Product

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 GE product 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 GE Product

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 GE product will be tested?

b. What is the distribution of the parent organism in the country in which the GE product 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.

d. Could the release of the GE product affect the function of the parent organism in the environment (positive or negative functions of the organism)?

e. 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 GE product compared to the parent organism?

f. Is the GE product likely to be able to establish in the open environment outside the release site?

g. What is the capability of the GE product 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 GE product).

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 GE products or transferred genetic material beyond the primary test site.

f. Will the GE product 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 GE product.

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 GE product, 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 GE products 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 GE product, including U.S. and developing country collaborators.

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